RULE 17, EXHIBIT 9

Chronic Pain Disorder

Medical Treatment Guideline

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Presented by:

COLORADO
Department of
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DIVISION OF WORKERS' COMPENSATION

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DEPARTMENT OF LABOR AND EMPLOYMENT

Division of Workers' Compensation
CCR 1101-3

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CHRONIC PAIN DISORDER MEDICAL TREATMENT GUIDELINE

A. INTRODUCTION

This document has been prepared by the Colorado Department of Labor and Employment, Division of Workers' Compensation (Division) and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Colorado's Workers' Compensation Act as injured workers with chronic pain.

Although the primary purpose of this document is advisory and educational, these guidelines are enforceable under the Workers' Compensation Rules of Procedure, 7 CCR 1101-3. The Division recognizes that acceptable medical practice may include deviations from these guidelines, as individual cases dictate. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care.

To properly utilize this document, the reader should not skip nor overlook any sections.

B. GENERAL GUIDELINE PRINCIPLES

The principles summarized in this section are key to the intended implementation of all Division of Workers' Compensation medical treatment guidelines and critical to the reader's application of the guidelines in this document.

1. **APPLICATION OF THE GUIDELINES** The Division provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Workers' Compensation Rules of Procedure. In lieu of more costly litigation, parties may wish to seek administrative dispute resolution services through the Division or the office of administrative courts.

2. **EDUCATION** Education of the patient and family, as well as the employer, insurer, policy makers, and the community, should be the primary emphasis in the treatment of chronic pain and disability. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must implement strategies to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring and evidence-based information to the patient. More in-depth patient education is currently a component of treatment regimens which employ functional, restorative, preventive, and rehabilitative programs. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention. Facilitation through language interpretation, when necessary, is a priority and part of the medical care treatment protocol.

3. **INFORMED DECISION MAKING** Providers should implement informed decision making as a crucial element of a successful treatment plan. Patients, with the assistance of their health care practitioner, should identify their personal and professional functional goals of treatment at the first visit. Progress towards the individual's identified functional goals should be addressed by all members of the health care team at subsequent visits and throughout the established treatment plan. Nurse case managers, physical therapists, and other members of the health care team play an integral role in informed decision making and achievement of functional goals. Patient education and informed decision making should facilitate self-management of symptoms and prevention of further injury.

4. **TREATMENT PARAMETER DURATION** Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient adherence, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document.

5. **ACTIVE INTERVENTIONS** Active interventions emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.

6. **ACTIVE THERAPEUTIC EXERCISE PROGRAM** Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.

7. **POSITIVE PATIENT RESPONSE** Positive results are defined primarily as functional gains that can be objectively measured. Objective functional gains include, but are not limited to: positional tolerances, range-of-motion (ROM), strength, endurance, activities of daily living, ability to function at work, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings. Patient completed functional questionnaires such as those recommended by the Division as part of Quality Performance and Outcomes Payments (QPOP, see Rule 18-8) and/or the Patient Specific Functional Scale can provide useful additional confirmation.

8. **RE-EVALUATION OF TREATMENT NO LESS THAN EVERY 3 TO 4 WEEKS** If a given treatment or modality is not producing positive results within 3 to 4 weeks or within the time to produce effect in the guidelines, the treatment should be either modified or discontinued. Before discontinuing the treatment, the provider should have a detailed discussion with the patient to determine the reason for failure to produce positive results. Reconsideration of diagnosis should also occur in the event of a poor response to a seemingly rational intervention.

9. **SURGICAL INTERVENTIONS** Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.

10. **SIX-MONTH TIME FRAME** The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than six months. The emphasis within these guidelines is to move patients along a continuum of care and return to work within a six-month time frame, whenever possible. It is important to note that time frames may be less pertinent for injuries that do not involve work-time loss or are not occupationally related.

11. **RETURN-TO-WORK** A return-to-work is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific physical limitations, and the patient should never be released to non-specific and vague descriptions such as "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage, and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated. The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should request clarification of the patient's job duties. Clarification should be obtained from the employer or, if necessary, from including, but not limited to, an occupational health nurse, occupational therapist, vocational rehabilitation specialist, an industrial hygienist, or another professional.

12. **DELAYED RECOVERY** Strongly consider a psychological evaluation, if not previously provided, as well as initiating interdisciplinary rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after initiation of treatment of an injury. Therefore, all chronic pain patients should have a documented psychological evaluation and psychological treatment as appropriate to address issues of chronic pain. It is also appropriate to clinically reassess the patient, function goals, and differential diagnosis. The Division recognizes that 3 to 10% of all

industrially injured patients will not recover within the timelines outlined in this document, despite optimal care. Such individuals may require treatments beyond the timelines discussed within this document, but such treatment requires clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

13. **GUIDELINE RECOMMENDATIONS AND INCLUSION OF MEDICAL EVIDENCE** All recommendations are based on available evidence and/or consensus judgment. When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. It is generally recognized that early reports of a positive treatment effect are frequently weakened or overturned by subsequent research. When interpreting medical evidence statements in the guideline, the following apply:

- Consensus means the judgment of experienced professionals based on general medical principles. Consensus recommendations are designated in the guidelines as "generally well-accepted," "generally accepted," "acceptable/accepted," or "well-established."

- "Some evidence" means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective. The Division recognizes that further research is likely to have an impact on the intervention's effect.

- "Good evidence" means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective. The Division recognizes that further research may have an impact on the intervention's effect.

- "Strong evidence" means the recommendation considered the availability of multiple relevant and high-quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment. The Division recognizes that further research is unlikely to have an important impact on the intervention's effect.

All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, irrespective of the level of evidence or consensus statement attached to them. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as "***not recommended***."

Please refer to the Colorado Department of Labor and Employment's website for evidence tables and study critiques which provide details on the studies used to develop the evidence statements.

14. **TREATMENT OF PRE-EXISTING CONDITIONS** The conditions that preexisted the work injury/disease will need to be managed under two circumstances: (a) A pre-existing condition exacerbated by a work injury/disease should be treated until the patient has returned to their objectively verified prior level of functioning or Maximum Medical Improvement (MMI); and (b) A pre-existing condition not directly caused by a work injury/disease but which may prevent recovery from that injury should be treated until its objectively verified negative impact has been controlled. The focus of treatment should remain on the work injury/disease.

The remainder of this document should be interpreted within the parameters of these guideline principles that may lead to more optimal medical and functional outcomes for injured workers.

C. OVERVIEW OF CHRONIC PAIN MANAGEMENT

It is estimated by the Institute of Medicine that approximately 100 million adults suffer from chronic pain in the United States. The World Health Organization's survey found that 37% of adults in 10 developed countries have chronic pain conditions. This overview covers the biopsychosocial nature of chronic pain and a comprehensive plan of care including: functional assessment and goal setting, psychological assessment, medication management, sleep considerations, and active therapy.

Chronic pain may develop from persistent acute pain due to neuroplastic changes occurring in the central nervous system. All chronic pain appears to involve a central sensitization which changes the perception of pain. Thus, treatment patterns are aimed at a number of mechanisms contributing to chronic pain.

Chronic pain is recognized as a biopsychosocial disease process. Each treatment plan should be individualized with a patient-centered approach addressing the many available treatment combinations. Therefore, all areas of the chronic pain guideline should be considered when developing a treatment plan. This includes: the mandatory psychological evaluation; an active therapy plan; medications specific to the pain process for that patient; continuing functional assessment; complementary medication alternatives, when appropriate; and continued return to work/regular daily activity.

Once a patient has been identified as a chronic pain patient, usually 3 months after an injury when pain persists or when pain persists beyond a reasonable post-operative period, the physician should perform a complete re-evaluation. This will assist both the patient and the provider in developing an appropriate treatment plan. Although it is unusual to identify an unknown pathology at this point in the treatment, it is recommended that the provider acknowledge the full complement of patient symptoms and concerns. Repeating or ordering new imaging may be necessary; however, it is not usually recommended as the findings may add to the patient's confusion regarding the work-related injury.

It is essential that the patient and provider understand the type of pain the patient is experiencing and how the pain affects day-to-day activities. Identifying the presence of neuropathic pain, as well as any sources of nocioceptive pain, will assist the patient and provider when choosing medication and other forms of treatment recommended in the guideline.

During the chronic pain assessment, it is suggested that all physicians review with the patient their usual activities over several different typical 24-hour periods. This will assist both parties in understanding what functions are not able to be performed by the patient, how significantly sleep is impacted, and whether pain is affecting social and family relationships. This information is also essential for establishing agreed upon functional goals.

All chronic pain patients should have psychological evaluations. Patients may merely need assistance with coping mechanisms, and/or anxiety or depression may be caused or exacerbated by chronic pain. Treatment in this area is essential for the chronic pain patient. A limited number of cognitive behavioral sessions are frequently effective for these conditions.

Review of the current prescribed and over-the-counter medications is an important part of this initial chronic pain evaluation. If the patient has been chronically on opioids, it is very likely that the full required opioid trial and review has not been performed. Thus, the physician will need to ensure that the proper steps have been taken if opioids are to be continued. It is also reasonable to taper opioids in order to determine the patient's baseline and how other medications are actually affecting the pain.

Refer to Section G.10.g, Opioids, in this guideline for more details. The following is a general summary of the required elements. A number of other guidelines, including the Center for Disease Control and Prevent (CDC) and Colorado's Board of Medical Examiners, have confirmed these steps.

1. An opioid trial shall be performed before chronic opioids are determined to be useful for patients. About 50% of patients will not be able to tolerate the side effects and/or not show a sufficient increase in function with opioid use. Patients should be aware that this is a trial and like any other medication trial, it will not be continued unless there is sufficient benefit. The average benefit is about a 30% decrease in pain. Thus, all other required treatment must be continued during the time period of the chronic opioid trial.

2. Long acting opioids should never be used for acute pain, post-operative pain, or before an opioid trial has been completed. There is no evidence they are more beneficial than short acting opioids, and the trial should began with short acting opioids.

3. A risk assessment tool, such as the Opioid Risk Tool (ORT) should be completed to assure the provider that there are no prior elements suggesting substance abuse or, when such elements are present, the physician may choose to refer to a provider with more expertise in substance abuse.

4. Urine drug testing should be done prior to the trial.

5. Check the Prescription Drug Monitoring Program (PDMP).

6. The psychological evaluation should have been completed and hopefully treatment as appropriate is being continued.

7. A functional history should be taken and functional goals should be set. This needs to be followed throughout all chronic pain treatment to determine if the patient is increasing or decreasing in function.

8. A provider physician agreement must be completed. This is extremely helpful as it reviews for the patient the expectations regarding his/her behavior as well as the expectations regarding when a physician would choose to taper or remove the patient from opioids and what other treatment is expected to continue during an opioid trial.

If the opioid trial is successful, the physician should continue to monitor with random drug testing and PDMP checks. In addition, the Current Opioid Misuse Measure (COMM) is a tool that can be used for patients on opioids to screen for possible abuse. It should be noted that current estimates suggest approximately 14 to 19 percent of chronic opioid users may become addicted to opioids.

The patient will need to be monitored for side effects. Constipation is anticipated. There may also be problems with sexual dysfunction. Opioids may increase or cause sleep apnea problems, and this should be monitored. At all visits, the functional status of the patient should be recorded. This can be accomplished with reliable, patient-reported functional status tools. Function is preferably validated by physical exam or by other objective measures from the provider.

Lack of sleep is a significant problem for patients with uncontrolled chronic pain. Taking a good

history in this area and promoting an appropriate sleep regime is essential for patients, if they are to establish a productive life-style.

Active therapy is one of the most important components. Regular exercise is shown to decrease depression as well as decrease chronic pain. Helping the patient choose appropriate physical activities and cognitive activities will be important for recovery.

Although treating chronic pain patients is challenging due to the many disciplines and treatment patterns available, the rewards are great when a patient with chronic pain is able to resume work and engage in satisfying life activities.

D. INTRODUCTION TO CHRONIC PAIN

The International Association for the Study of Pain (IASP) defines pain as "an unpleasant sensory and emotional experience with actual or potential tissue damage." Pain is a complex experience embracing physical, mental, social, and behavioral processes that often compromises the quality of life of many individuals.

Pain is an unpleasant subjective perception usually in the context of tissue damage. Pain is subjective and cannot be measured or indicated objectively. Pain evokes negative emotional reactions such as fear, anxiety, anger, and depression. People usually regard pain as an indicator of physical harm, despite the fact that pain can exist without tissue damage and tissue damage can exist without pain. Many people report pain in the absence of tissue damage or any likely pathophysiologic cause. There is no way to distinguish their experience from pain due to actual tissue damage. If they regard their experience as pain and they report it the same way as pain caused by tissue damage, it should be accepted as pain.

Pain can generally be classified as:

- Nociceptive, which includes pain from visceral origins or damage to other tissues. Myofascial pain is a nociceptive type of pain characterized by myofascial trigger points limited to a specific muscle or muscles;

- Neuropathic, including pain originating from the brain, peripheral nerves, or both; and

- Psychogenic, which originates in mood, characterological, social, or psychophysiological processes.

Recent advances in the neurosciences reveal additional mechanisms involved in chronic pain. In the past, pain was seen as a sensation arising from the stimulation of pain receptors by damaged tissue, initiating a sequence of nerve signals ending in the brain and there recognized as pain. A consequence of this model was that ongoing pain following resolution of tissue damage was seen as less physiological and more psychological than acute pain with identifiable tissue injury. Current research indicates that chronic pain involves additional mechanisms that cause: 1) neural remodeling at the level of the spinal cord and higher levels of the central nervous system; 2) changes in membrane responsiveness and connectivity leading to activation of larger pain pathways; and 3) recruitment of distinct neurotransmitters.

Changes in gene function and expression may occur, with lasting functional consequences. These physiologic functional changes cause chronic pain to be experienced in body regions beyond the original injury and to be exacerbated by little or no stimulation. The chronic pain experience clearly represents both psychologic and complex physiologic mechanisms, many of which are just beginning to be understood.

Chronic pain is defined as "pain that persists for at least 30 days beyond the usual course of an acute disease or a reasonable time for an injury to heal or that is associated with a chronic pathological process that causes continuous pain (e.g., Complex Regional Pain Syndrome)." The very definition of chronic pain describes a delay or outright failure to increase function and relieve pain associated with some specific illness or accident. Delayed recovery should prompt a clinical review of the case and a psychological evaluation by the health care provider. Consideration may be given to new diagnostic testing or a change in treatment plan. Referral to a specialist with experience in chronic pain management is recommended.

The term “chronic pain syndrome” has been incorrectly used and defined in a variety of ways that generally indicate a belief on the part of the health care provider that the patient's pain is inappropriate or out of proportion to existing problems or illness. Use of the term “chronic pain syndrome” should be discontinued because the term ceases to have meaning due to the many different physical and psychosocial issues associated with it. The IASP offers a taxonomy of pain, which underscores the wide variety of pathological conditions associated with chronic pain. This classification system may not address the psychological and psychosocial issues that occur in the perception of pain, suffering, and disability and may require referral to psychiatric or psychological clinicians. Practitioners should use the nationally accepted terminology indicated in the most current ICD system. Chronic pain can be diagnosed as F45.42 “Pain disorder with related psychological factors” when the associated body part code is also provided. Alternately, chronic pain can also be diagnosed as F54 “Psychological factors affecting physical conditions,” and this code should also be accompanied by the associated body part.

Injured patients generally initiate treatment with complaints of pain, which is generally attributable to a specific injurious event, but occasionally to an ostensible injury. Thus, the physician should not automatically assume that complaints of acute pain are directly attributable to pathophysiology at the tissue level. Pain is known to be associated with sensory, affective, cognitive, social, and other processes. The pain sensory system itself is organized into two parts, often called first and second pain. A-∂ nerve fibers conduct first pain via the neospinalthalamic tract to the somatosensory cortex and provide information about pain location and quality. In contrast, unmyelinated C fibers conduct second pain via the paleospinalthalamic tract and provide information about pain intensity. Second pain is more closely associated with emotion and memory neural systems than it is with sensory systems.

As a patient’s condition transitions through the acute, subacute, and chronic phases, the central nervous system (CNS) is reorganized. The temporal summation of second pain produces a sensitization or “windup” of the spinal cord, and the connections between the brain regions involved in pain perception, emotion, arousal, and judgment are changed by persistent pain. These changes cause the CNS’s “pain neuromatrix” to become sensitized to pain. This CNS reorganization is also associated with changes in the volume of brain areas, decreased grey matter in the prefrontal cortex, and the brain appearing to age more rapidly. As pain continues over time, the CNS remodels itself so that pain becomes less closely associated with sensation, and more closely associated with arousal, emotion, memory, and beliefs. Because of these CNS processes, all clinicians should be aware that as the patient enters the subacute phase, it becomes increasingly important to consider the psychosocial context of the disorder being treated, including the patient’s social circumstances, arousal level, emotional state, and beliefs about the disorder. However, behavioral complications and physiological changes associated with chronicity and central sensitization may also be present in the acute phase, and within hours of the initial injury. It is the intent of many of the treatments in this guideline to assist in remodeling these CNS changes.

Chronic pain is a phenomenon not specifically relegated to anatomical or physiologic parameters. The prevailing biomedical model (which focuses on identified disease pathology as the sole cause of pain) cannot capture all of the important variables in pain behavior. While diagnostic labels may pinpoint contributory physical and/or psychological factors and lead to specific treatment interventions that are helpful, a large number of patients defy precise taxonomic classification. Furthermore, such diagnostic labeling often overlooks important social contributions to the chronic pain experience. Failure to address these operational parameters of the chronic pain experience may lead to incomplete or faulty treatment plans. The concept of a "pain disorder" is perhaps the most useful term, in that it captures the multi-factorial nature of the chronic pain experience.

It is recognized that some health care practitioners have much greater expertise in the area of chronic pain evaluation and treatment than others by virtue of their experience, additional training,

and/or accreditation by pain specialty organizations. Referrals for the treatment of chronic pain should be to such recognized specialists. Chronic pain treatment plans should be monitored and coordinated by physicians with expertise in pain management including specialty training and/or certification.

Most acute and some chronic pain problems are adequately addressed in other Division Medical Treatment Guidelines and are generally not within the scope of this guideline. However, because chronic pain is more often than not multi-factorial, involving more than one pathophysiologic or mental disorder, some overlap with other guidelines is inevitable. This guideline is meant to apply to any patient who fits the operational definition of chronic pain discussed at the beginning of this section.

E. DEFINITIONS

1. **AFTER SENSATION**: refers to the abnormal persistence of a sensory perception provoked by a stimulus even though the stimulus has ceased.

2. **ALLODYNIA**: pain due to a non-noxious stimulus that does not normally provoke pain.

Mechanical Allodynia: refers to the abnormal perception of pain from usually non-painful mechanical stimulation.

Static Mechanical Allodynia: refers to pain obtained by applying a single stimulus such as light pressure to a defined area.

Dynamic Mechanical Allodynia: obtained by moving the stimulus such as a brush or cotton tip across the abnormal hypersensitive area.

Thermal Allodynia: refers to the abnormal sensation of pain from usually non-painful thermal stimulation such as cold or warmth.

3. **ANALGESIA**: absence of pain in response to stimulation that would normally be painful.

4. **BIOPSYCHOSOCIAL**: a term that reflects the multiple facets of any clinical situation; namely, the biological, psychological, and social situation of the patient.

5. **CENTRAL PAIN**: pain initiated or caused by a primary lesion or dysfunction in the central nervous system.

6. **CENTRAL SENSITIZATION**: the experience of pain evoked by the excitation of non-nociceptive neurons or of nerve fibers that normally relay non-painful sensations to the spinal cord. This results when non-nociceptive afferent neurons act on a sensitized central nervous system (CNS). Experimental data suggest that pathways normally carrying pain signals themselves become overstimulated and/or fail to respond to inhibitory influences causing increased pain**.** An example is 'wind-up' which occurs when cells in the dorsal horn of the spinal cord increase their rate of action potential discharge in response to repeated stimulation by nociceptors.

7. **DYSESTHESIA**: an abnormal sensation described by the patient as unpleasant. As with paresthesia, dysesthesia may be spontaneous or evoked by maneuvers on physical examination.

8. **HYPERALGESIA**: refers to an exaggerated pain response from a usually painful stimulation.

9. **HYPERESTHESIA (POSITIVE SENSORY PHENOMENA)**: includes allodynia, hyperalgesia, and hyperpathia. Elicited by light touch, pin prick, cold, warm, vibration, joint position sensation or two-point discrimination, which is perceived as increased or more.

10. **HYPERPATHIA**: a condition of altered perception such that stimuli which would normally be innocuous, if repeated or prolonged, result in severe explosive persistent pain.

11. **HYPOALGESIA**: diminished pain perception in response to a normally painful stimulus.

12. **HYPOESTHESIA/HYPESTHESIA (NEGATIVE SENSORY PHENOMENA)**: diminished sensitivity to stimulation.

13. **MALINGERING**: intentional feigning of illness or disability in order to achieve external incentives such as recreational drugs or money.

14. **MYOFASCIAL PAIN**: a regional pain characterized by tender points in taut bands of muscle that produce pain in a characteristic reference zone.

15. **MYOFASCIAL TRIGGER POINT**: a physical sign in a muscle which includes a) exquisite tenderness in a taut muscle band; and b) referred pain elicited by mechanical stimulation of the trigger point. The following findings may be associated with myofascial trigger points: 1) Local twitch or contraction of the taut band when the trigger point is mechanically stimulated; 2) Reproduction of the patient's spontaneous pain pattern when the trigger point is mechanically stimulated; 3) Weakness without muscle atrophy; 4) Restricted range-of-motion of the affected muscle; and 5) Autonomic dysfunction associated with the trigger point such as changes in skin or limb temperature.

16. **NEURALGIA**: pain in the distribution of a nerve or nerves.

17. **NEURITIS**: inflammation of a nerve or nerves.

18. **NEUROGENIC PAIN**: pain initiated or caused by a primary lesion, dysfunction, or transitory perturbation in the peripheral or central nervous system.

19. **NEUROPATHIC PAIN**: pain due to an injured or dysfunctional central or peripheral nervous system.

20. **NEUROPATHY**: a disturbance of function or pathological change in a nerve: in one nerve (mononeuropathy), in several nerves (mononeuropathy multiplex), **OR** diffuse and bilateral (polyneuropathy). Neuropathy should be associated with objective findings such as consistent sensory abnormalities, consistent motor findings (e.g., weakness, atrophy, fasciculations, muscle cramping), and/or neuropathic abnormalities on EMG/nerve conduction testing.

21. **NOCICEPTOR**: a receptor preferentially sensitive to a noxious stimulus or to a stimulus which would become noxious if prolonged.

22. **PAIN BEHAVIOR**: the non-verbal actions (such as grimacing, groaning, limping, using visible pain relieving or support devices, and requisition of pain medications, among others) that are outward manifestations of pain and through which a person may communicate that pain is being experienced.

23. **PAIN THRESHOLD**: the smallest stimulus perceived by a subject as painful during laboratory testing. The term also loosely applies to the biological variation among human beings in sensing and coping with pain.

24. **PARESTHESIA**: an abnormal sensation that is not described as pain. It can be either a spontaneous sensation (such as pins and needles) or a sensation evoked from non-painful or painful stimulation, such as light touch, thermal, or pinprick stimulus on physical examination.

25. **PERIPHERAL NEUROPATHIC PAIN**: pain initiated or caused by a primary lesion or dysfunction in the peripheral nervous system.

26. **SOMATIC DYSFUNCTION**: somatic dysfunction is impaired or altered function of related components of the somatic (body framework) system which includes skeletal, arthrodial, and myofascial structures.

27. **SUMMATION**: refers to abnormally painful sensation to a repeated stimulus although the actual stimulus remains constant. The patient describes the pain as growing and growing as the same intensity stimulus continues.

28. **SYMPATHETICALLY MAINTAINED PAIN (SMP)**: a pain that is maintained by sympathetic efferent pathways and is eliminated by blockade of these pathways. It is intensified by circulating catecholamines.

29. **TENDER POINTS**: tenderness on palpation at a tendon insertion, muscle belly, or over bone. Palpation should be done with the thumb or forefinger, applying pressure approximately equal to a force of 4 kilograms (blanching of the entire nail bed).

F. INITIAL EVALUATION & DIAGNOSTIC PROCEDURES

The Division recommends the following diagnostic procedures be considered, at least initially. It is the responsibility of the workers' compensation carrier to ensure that an accurate diagnosis and treatment plan can be established. Standard procedures that should be utilized when initially diagnosing a work-related chronic pain complaint are listed below.

1. **HISTORY TAKING AND PHYSICAL EXAMINATION (HX & PE)**: These are generally accepted, well-established, and widely used procedures that establish the foundation/basis for and dictate subsequent stages of diagnostic and therapeutic procedures. When findings of clinical evaluations and those of other diagnostic procedures are not complementing each other, the objective clinical findings should have preference. The medical records should reasonably document the following:

a. **Medical History**: As in other fields of medicine, a thorough patient history is an important part of the evaluation of chronic pain. In taking such a history, factors influencing a patient's current status can be made clear and taken into account when planning diagnostic evaluation and treatment. It may be necessary to acquire previous medical records. One efficient manner in which to obtain historical information and patient reported functional status is by using a questionnaire. The questionnaire may be sent to the patient prior to the initial visit or administered at the time of the office visit. History should ascertain the following elements.

i. General Information: General items requested are name, sex, age, birth date, etc.

ii. Level of Education: The level of the patient's education may influence response to treatment.

iii. Work History/Occupation: to include both impact of injury on job duties and impact on ability to perform job duties, work history, job description, mechanical requirements of the job, duration of employment, and job satisfaction.

iv. Current employment status.

v. Marital status.

vi. Family Environment: Is the patient living in a nuclear family or with friends? Is there, or were there, any family members with chronic illness or pain problems? Responses to such questions reveal the nature of the support system or the possibility of conditioning toward chronicity.

vii. Ethnic Origin: Ethnicity of the patient, including any existing language barriers, may influence the patient's perception of and response to pain. Literature indicates that providers may under-treat patients of certain ethnic backgrounds due to underestimation of their pain.

viii. Belief System: Patients should be asked about their value systems, including spiritual and cultural beliefs, in order to determine how these

may influence the patient's and family's response to illness and treatment recommendations.

ix. Functional Assessment: Functional ability should be assessed and documented at the beginning of treatment. Periodic assessment should be recorded throughout the course of care to follow the trajectory of recovery. Functional measures are likely to be more reliable over time than pain measures.

Patient-reported outcomes, whether of pain or function, are susceptible to a phenomenon called response shift. This refers to changes in self-evaluation, which may accompany changes in health status. Patient self-reports may not coincide with objective measures of outcome, due to reconceptualization of the impact of pain on daily function and internal recalibration of pain scales. Response shift may obscure treatment effects in clinical trials and clinical practice, and it may lead to apparent discrepancies in patient-reported outcomes following treatment interventions. While methods of measuring and accounting for response shift are not yet fully developed, understanding that the phenomenon exists can help clinicians understand what is happening when some measures of patient progress appear inconsistent with other measures of progress.

x. Activities of Daily Living (ADLs) and Instrumental Activities of Daily Living (IADLs): Pain has a multidimensional effect on the patient that is reflected in changes in the ability to perform self-care tasks and usual daily vocational, social, recreational, and sexual activities.

xi. Past and present psychological problems.

xii. History of abuse: physical, emotional, sexual.

xiii. History of disability in the family.

xiv. Sleep disturbances: Poor sleep has been shown to increase patient's self-perceived pain scores. Pre-injury and post-injury sleep should be recorded.

xv. Causality: How did this injury occur? Was the problem initiated by a work-related injury or exposure? Patient's perception of causality (e.g., was it their fault or the fault of another).

b. **Pain History**: Characterization of the patient's pain and of the patient's response to pain is one of the key elements in treatment.

i. Site of Pain: Localization and distribution of the pain help determine the type of pain the patient has (i.e., central versus peripheral).

ii. Pain diagram drawings to document the distribution of pain.

iii. Visual Analog Scale (VAS): Current pain, highest pain level, and usual pain level may be recorded. Include a discussion of the range of pain during the day and how activities, use of modalities, and other actions affect the intensity of pain.

iv. Duration: including intermittent pain, activity related pain.

v. Place of onset: circumstances during which the pain began (e.g., an accident, an illness, a stressful incident, or spontaneous onset).

vi. Pain Characteristics: such as burning, shooting, stabbing, and aching. Time of pain occurrence, as well as intensity, quality, and radiation, give clues to the diagnosis and potential treatment. Quality of pain can be helpful in identifying neuropathic pain which is normally present most of the day, at night, and is often described as burning.

vii. List of activities which aggravate or exacerbate, ameliorate, decrease, or have no effect on the level of pain.

viii. Associated Symptoms: Does the patient have numbness or paresthesia, dysesthesia, weakness, bowel or bladder dysfunction, altered temperature, increased sweating, cyanosis, or edema? Is there local tenderness, allodynia, hyperesthesia, or hyperalgesia? Does the patient have constitutional symptoms such as fevers, chills, night sweats, unexplained weight loss, or pain that awakes them from a deep sleep at night?

c. Medical Management History:

i. Diagnostic Tests: All previous radiological and laboratory investigations should be reviewed.

ii. Prior Treatment: chronological review of medical records including previous medical evaluations and response to treatment interventions. In other words, what has been tried and which treatments have helped?

iii. Prior Surgery: If the patient has had prior surgery specifically for the pain, he/she may be less likely to have a positive outcome.

iv. Medications: history of and current use of medications, including opioids, over-the-counter medications, cannabis products, and herbal/dietary supplements, to determine drug usage (or abuse) interactions and efficacy of treatment. Drug allergies and other side effects experienced with previous or current medication therapy and adherence to currently prescribed medications should be documented. Ideally, this includes dosing schedules as reported by the patient or patient representative. Information should be checked against the Colorado Prescription Drug Monitoring Program (PDMP), offered by the Colorado Pharmacy Board.

v. Review of Systems Check List: Determine if there is any interplay between the pain complaint and other medical conditions.

vi. Psychosocial Functioning: Determine if any of the following are present: current symptoms of depression or anxiety; evidence of stressors in the workplace or at home; and past history of psychological problems. Other confounding psychosocial issues may be present, including the presence of psychiatric disease. Due to the high incidence of co-morbid problems in populations that develop chronic pain, it is recommended that all

patients diagnosed with chronic pain should be referred for a full psychosocial evaluation.

vii. Pre-existing Conditions: Treatment of these conditions is appropriate when the pre-existing condition affects recovery from chronic pain.

viii. Family history pertaining to similar disorders.

d. Substance Use/Abuse:

i. Alcohol use.

ii. Smoking History and use of nicotine replacements.

iii. History of current and prior prescription and recreational drug use or abuse.

iv. The use of caffeine or caffeine containing beverages.

v. Substance abuse information may be only fully obtainable from multiple sources over time. Patient self-reports may be unreliable. Patient self-reports should always be checked against medical records.

e. Other Factors Affecting Treatment Outcome:

i. Compensation/Disability/Litigation.

ii. Treatment Expectations: What does the patient expect from treatment: complete relief of pain or reduction to a more tolerable level?

iii. Other scales may be used to identify cases which are likely to require more complex care. Examples include:

A) Fear Avoidance Beliefs Questionnaire

B) Tampa Scale of Kinesiophobia

C) Pain Catastrophizing Scale

f. Physical Examination:

i. Neurologic Evaluation: includes cranial nerves survey, muscle tone and strength, atrophy, detailed sensory examination (see ii-below), motor evaluation (station, gait, coordination), reflexes (normal tendon reflexes and presence or absence of abnormal reflexes such as frontal lobe release signs or upper motor neuron signs), cerebellar testing, signs suggestive of a sensory ataxia (positive Romberg, impaired proprioception, etc.), and provocative neurological maneuvers.

ii. Sensory Evaluation: A detailed sensory examination is crucial in evaluating a patient with chronic pain complaints. Quantitative sensory testing, such as Semmes-Weinstein, may be useful tools in determining sensory abnormalities. Ideally, the examination should determine if the

following sensory signs are present and consistent on repeated examination.

A) Hyperalgesia.

B) Hyperpathia.

C) Paresthesia.

D) Dysesthesia.

E) Mechanical Allodynia – static versus dynamic.

F) Thermal Allodynia.

G) Hypoesthesia.

H) Hyperesthesia.

I) Summation.

iii. Musculoskeletal Evaluation: range-of-motion, segmental mobility, musculoskeletal provocative maneuvers, palpation, observation, and functional activities. All joints, muscles, ligaments, and tendons should be examined for asymmetry, swelling, laxity, and tenderness. A portion of the musculoskeletal evaluation is the myofascial examination. The myofascial examination includes palpating soft tissues for evidence of tightness, tenderness, and trigger points.

iv. Evaluation of non-physiologic findings:

A) Waddell's Signs cannot be used to predict or diagnose malingering. It is not an appropriate test for assessing non-physiologic causes of low back pain. The sole purpose of the Waddell's signs is to identify low back pain patients who may need further psychosocial assessment prior to surgery. Refer to Section F.2, Personality/Psychological/Psychosocial Evaluation.

B) Variability on formal exam including variable sensory exam, inconsistent tenderness, and/or swelling secondary to extrinsic sources.

C) Inconsistencies between formal exam and observed abilities of range-of-motion, motor strength, gait, and cognitive/emotional state should be noted in the assessment.

2. PERSONALITY/ PSYCHOLOGICAL/PSYCHOSOCIAL EVALUATIONS FOR PAIN MANAGEMENT: These are generally accepted, well-established, and widely used diagnostic procedures not only with selected use in acute pain problems but also with more widespread use in subacute and chronic pain populations. Diagnostic evaluations should distinguish between conditions that are pre-existing, aggravated by the current injury, or work related.

Psychosocial evaluations should determine if further psychosocial or behavioral

interventions are indicated for patients diagnosed with chronic pain. The interpretations of the evaluation should provide clinicians with a better understanding of the patient in his or her social environment, thus allowing for more effective rehabilitation. Psychosocial assessment requires consideration of variations in pain experience and expression resulting from affective, cognitive, motivational and coping processes, and other influences such as gender, age, race, ethnicity, national origin, religion, sexual orientation, disability, language, or socioeconomic status.

While there is some agreement about which psychological factors need to be assessed in patients with chronic pain, a comprehensive psychological evaluation should attempt to identify both primary psychiatric risk factors or "red flags" (e.g., psychosis, active suicidality) as well as secondary risk factors or "yellow flags" (e.g., moderate depression, job dissatisfaction). Significant personality disorders must be taken into account when considering a patient for spinal cord stimulation and other major procedures.

Psychometric Testing is a valuable component of a consultation to assist the physician in making a more effective treatment plan. There is good evidence that psychometric testing can have significant ability to predict medical treatment outcome. For example, one study found that psychometric testing exceeded the ability of discography to predict disability in patients with low back pain. Pre-procedure psychiatric/psychological evaluation must be done prior to diagnostic confirmatory testing for a number of procedures. Examples include discography for fusion, spinal cord stimulation, or intrathecal drug delivery systems, and they should not be done by a psychologist employed by the physician planning to perform the procedure.

In many instances, psychological testing has validity comparable to that of commonly used medical tests; for example, the correlation between high trait anger and blood pressure is equal to the correlation between reduced blood flow and the failure of a synthetic hemodialysis graft. Thus, psychometric testing may be of comparable validity to medical tests and may provide unique and useful diagnostic information.

All patients who are diagnosed as having chronic pain should be referred for a psychosocial evaluation, as well as concomitant interdisciplinary rehabilitation treatment. This referral should be performed in a way so as to not imply that the patient's claims are invalid or that the patient is malingering or mentally ill. Even in cases where no diagnosable mental condition is present, these evaluations can identify social, cultural, coping, and other variables that may be influencing the patient's recovery process and may be amenable to various treatments including behavioral therapy. As pain is understood to be a biopsychosocial phenomenon, these evaluations should be regarded as an integral part of the assessment of chronic pain conditions.

a. **Qualifications**:

i. A psychologist with a PhD, PsyD, or EdD credentials or a physician with Psychiatric MD/DO credentials may perform the initial comprehensive evaluations. It is preferable that these professionals have experience in diagnosing and treating chronic pain disorders and/or working with patients with physical impairments.

ii. Psychometric tests should be administered by psychologists with a PhD, PsyD, or EdD or health professionals working under the supervision of a doctorate level psychologist. Physicians with appropriate training may also administer such testing, but interpretation of the tests should be done by properly credentialed mental health professionals.

b. **Clinical Evaluation**:

Special note to health care providers: most providers are required to adhere to the federal regulations under the Health Insurance Portability and Accountability Act (HIPAA). Unlike general health insurers, workers' compensation insurers are not required to adhere to HIPAA standards. Thus, providers should assume that sensitive information included in a report sent to the insurer could be forwarded to the employer. The Colorado statute provides a limited waiver of medical information regarding the work-related injury or disease to the extent necessary to resolve the claim. It is recommended that the health care provider either 1) obtain a full release from the patient regarding information that may go to the employer or 2) not include sensitive health information not directly related to the work related conditions in reports sent to the insurer.

All chronic pain patients should have a clinical evaluation that addresses the following areas recalling that not all details should be included in the report sent to the insurer due to the HIPAA issue noted above:

i. History of Injury: The history of the injury should be reported in the patient's words or using similar terminology. Caution must be exercised when using translators.

- Nature of injury.
- Psychosocial circumstances of the injury.
- Current symptomatic complaints.
- Extent of medical corroboration.
- Treatment received and results.
- Adherence with treatment.
- Coping strategies used, including perceived locus of control, catastrophizing, and risk aversion.
- Perception of medical system and employer.
- History of response to prescription medications.

ii. Health History:

- Nature of injury.
- Medical history.
- Psychiatric history: to include past diagnoses, counseling, medications, and response to treatment.
- Past, recent, and concurrent stressors.
- History of substance related and addictive disorders to include:

- Alcohol
- Cannabis products
- Opioids
- Sedative, hypnotic, and anxiolytic medications
- Stimulants
- Prescription drug abuse
- Nicotine use
- Other substances of abuse / dependence

- Activities of daily living.
- Previous injuries, including disability, impairment, and compensation.

iii. Psychosocial History:

- Childhood history, including abuse/neglect.
- Educational history.
- Family history, including disability.
- Current living situation including roommates, family, intimate partners, and financial support.
- Marital history and other significant adulthood activities and events.
- Legal history, including but not limited to substance use related, domestic violence, criminal, and civil litigation.
- Employment history.
- Military duty: Because post-traumatic stress disorder (PTSD) might be an unacceptable condition for many military personnel to acknowledge, it may be prudent to screen initially for signs of depression or anxiety – both of which may be present in PTSD.
- Signs of pre-injury psychological dysfunction.
- Financial history.
- Prior level of function including self-care, community, recreational, and employment activities.

iv. Mental status exam including orientation, cognition, activity, speech, thinking, affect, mood, and perception. May include screening tests such as the mini mental status exam or frontal assessment battery if appropriate.

v. Assessment of any danger posed to self or others.

vi. Psychological test results, if performed.

vii. Current psychiatric diagnosis consistent with the standards of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders.

viii. Pre-existing psychiatric conditions: Treatment of these conditions is appropriate when the pre-existing condition affects recovery from chronic pain.

ix. Causality: to address medically probable cause and effect and to distinguish pre-existing psychological symptoms, traits, and vulnerabilities from current symptoms.

x. Treatment recommendations with respect to specific goals, frequency, time frames, and expected outcomes.

c. **Tests of Psychological Functioning**: Psychometric testing is a valuable component of a consultation to assist the physician in making a more effective treatment plan. Psychometric testing is useful in the assessment of mental conditions, pain conditions, cognitive functioning, treatment planning, vocational planning, and evaluation of treatment effectiveness. While there is no general agreement as to which psychometric tests should be specifically recommended for psychological evaluations of chronic pain conditions, standardized tests are preferred over those which are not for assessing diagnosis. Generally, it is helpful if tests consider the following issues: validity, physical symptoms, affective disorders, character disorders and traits, and psychosocial history. Character strengths that support the healing/rehabilitative process should also be evaluated and considered with any dysfunctional behavior patterns or pathology to more accurately assess the patient's prognosis and likely response to a proposed intervention.

In contrast, non-standardized tests can be useful for "ipsative" outcome assessment, in which a test is administered more than once and a patient's current and past reports are compared.

It is appropriate for the mental health providers to use their discretion and administer selective psychometric tests within their expertise and within standards of care in the community. Use of screening psychometrics by non-mental health providers is encouraged, but mental health provider consultation should always be utilized for chronic pain patients in which invasive palliative pain procedures or chronic opiate treatment is being contemplated. Some of these tests are available in Spanish and other languages, and many are written at a 6th grade reading level. Examples of frequently used psychometric tests performed include, but are not limited to, the tests identified below. (For a description of the psychometric tests listed in this section, refer to the Appendix, Description of Tests of Psychological Functioning.)

i. Comprehensive Inventories for Medical Patients:

A) Battery for Health Improvement, 2nd Edition (BHI™ -2).

B) Millon™ Behavioral Medical Diagnostic (MBMD™).

ii. Comprehensive Psychological Inventories:

These tests are designed for detecting various psychiatric syndromes but in general are more prone to false positive findings when administered to medical patients.

A) Millon® Clinical Multiaxial Inventory® (MCMI®-IV).

B) Minnesota Multiphasic Personality Inventory®, 2nd Edition (MMPI®-2).

C) Minnesota Multiphasic Personality Inventory®, 2nd Edition Revised Form (MMPI®-2).

D) Personality Assessment Inventory™ (PAI®).

iii. Brief Multidimensional Screens for Medical Patients:

Treating providers may use brief instruments to assess a variety of psychological and medical conditions, including depression, pain, disability, and others. These instruments may also be employed as repeated measures to track progress in treatment or as one test in a more comprehensive evaluation. Brief instruments are valuable in that the test may be administered in the office setting and hand scored by the physician. Results of these tests should help providers distinguish which patients should be referred for a specific type of comprehensive evaluation.

A) Brief Battery for Health Improvement, 2nd Edition (BBHI™-2).

B) Pain Patient Profile (P-3®).

C) SF-36®.

D) Sickness Impact Profile (SIP).

E) McGill Pain Questionnaire (MPQ).

F) McGill Pain Questionnaire – Short Form (MPQ-SF).

G) Oswestry Disability Questionnaire (ODQ).

H) Visual Analog Scales (VAS).

I) Numerical Rating Scales (NRS).

J) Chronic Pain Grade Scale (CPGS).

K) Pain Catastrophizing Scale (PCS).

iv. Brief Multidimensional Screens for Psychiatric Patients:

These tests are designed for detecting various psychiatric syndromes but in general are more prone to false positive findings when administered to medical patients.

A) Brief Symptom Inventory (BSI®).

B) Brief Symptom Inventory–18 (BSI®-18).

C) Symptom Check List - 90 Revised (SCL-90 R®).

v. Brief Specialized Psychiatric Screening Measures:

A) Beck Depression Inventory® (BDI®).

B) Center of Epidemiologic Studies – Depression Questionnaire (CES-D).

Note: Designed for assessment of psychiatric patients, not pain patients, which can bias results, and this should be a consideration when using.

C) Brief Patient Health Questionnaire from PRIME - MD®. (The PHQ-9 may also be used as a depression screen.)

D) Zung Depression Questionnaire.

Note: The Zung Depression Scale must be distinguished from the Modified Zung Depression scale used by the DRAM (a QPOP measure). The Zung Depression Scale has different items and a different scoring system than the Modified Zung Depression scale, making the cutoff scores markedly different. The cutoff scores for one measure cannot be used for the other.

E) Generalized Anxiety Disorder 7-item scale (GAD-7).

Evidence Statements Regarding Psychometric Testing		
Good Evidence	Evidence Statement	Design
	Psychometric testing can have significant ability to predict medical treatment outcome.	Prospective cohort study, Observational cohort study

3. **DIAGNOSTIC STUDIES** Imaging of the spine and/or extremities is a generally accepted, well-established, and widely used diagnostic procedure when specific indications, based on history and physical examination, are present. Practitioners should be aware of the radiation doses associated with various procedures and provide appropriate warnings to patients. Coloradans have a substantial background exposure to radiation, and

unnecessary CT scans or X-rays increase the lifetime risk of cancer death. Physicians should refer to the Division's Medical Treatment Guidelines on specific acute care for detailed information about specific testing procedures. Tests should be performed to rule in or out specific diagnoses.

a. Radiographic Imaging, MRI, CT, bone scan, radiography, and other special imaging studies may provide useful information for many musculoskeletal disorders causing chronic pain. It is probably most helpful in ruling out rare, significant diagnoses that may present with pain, such as metastatic cancer. Most imaging is likely to demonstrate aging changes which are usually not pathologic. Refer to specific Division Medical Treatment Guidelines for details. Before the test is performed, patients should be informed of the purpose of the exam (e.g., to rule out unsuspected cancer) and the likelihood of finding non-pathologic changes that are part of the normal aging process.

b. Electrodiagnostic studies may be useful in the evaluation of patients with suspected myopathic or neuropathic disease and may include Nerve Conduction Studies (NCS), Standard Needle Electromyography, or Somatosensory Evoked Potential (SSEP). The evaluation of electrical studies is complex and should be performed by specialists who are well trained in the use of this diagnostic procedure.

c. Special testing procedures may be considered when attempting to confirm the current diagnosis or reveal alternative diagnosis. Additional special tests may be performed at the discretion of the physician.

d. Testing for Complex Regional Pain Syndrome (CRPS I) or Sympathetically Maintained Pain (SMP) is described in the Division's Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy Medical Treatment Guidelines.

4. **LABORATORY TESTING** Laboratory tests are generally accepted, well-established, and widely used procedures. Patients should be carefully screened at the initial exam for signs or symptoms of diabetes, hypothyroidism, arthritis, and related inflammatory diseases. For patients at risk for sleep apnea, testing may be appropriate depending on medication use and issues with insomnia. The presence of concurrent disease does not refute work-relatedness of any specific case. This frequently requires laboratory testing. When a patient's history and physical examination suggest infection, metabolic or endocrinologic disorders, tumorous conditions, systemic musculoskeletal disorders (e.g., rheumatoid arthritis or ankylosing spondylitis), or problems potentially related to medication (e.g., renal disease and non-steroidal anti-inflammatory medications), then laboratory tests, including, but not limited to the following can provide useful diagnostic information:

a. Thyroid stimulating hormone (TSH) for hypothyroidism;

b. Diabetic screening: recommended for men and women with a BMI over 30, patients with a family history of diabetes, those from high risk ethnic groups, and patients with a previous history of impaired glucose tolerance. There is some evidence that diabetic patients with upper extremity disorders have sub-optimal control of their diabetes;

c. Serum protein electrophoresis;

d. Sedimentation rate and C-reactive protein (CRP) are nonspecific but elevated in infection, neoplastic conditions, and rheumatoid arthritis. Other screening tests to rule out inflammatory or autoimmune disease may be added when appropriate;

e. Serum calcium, phosphorus, uric acid, alkaline, and acid phosphatase for metabolic, endocrine and neo-plastic conditions;

f. Complete blood count (CBC), liver, and kidney function profiles for metabolic or endocrine disorders or for adverse effects of various medications;

g. Bacteriological (microorganism) work-up for wound, blood, and tissue;

h. Vitamin B12 levels may be appropriate for some patients.

The Division recommends that the workers' compensation carrier cover initial lab diagnostic procedures to ensure that an accurate diagnosis and treatment plan is established. When an authorized treating provider has justification for the test, insurers should cover the costs. Laboratory testing may be required periodically to monitor patients on chronic medications.

5. INJECTIONS–DIAGNOSTIC

a. Spinal Diagnostic Injections:

Diagnostic spinal injections are not commonly used in chronic pain patients as usually they have been performed previously in the acute or subacute stage. They may rarely be necessary for aggravations of low back pain. Refer to the Division's Low Back Pain Medical Treatment Guideline for indications.

i. Steroid Associated Issues:

If steroids are injected, only non-particulate steroids should be used to avoid the risk of spinal infection.

The majority of diabetic patients will experience an increase in glucose following steroid injections. Average increases in one study were 125mg/dL and returned to normal in 48 hours, whereas in other studies, the increased glucose levels remained elevated up to 7 days, especially after multiple injections. All diabetic patients should be told to follow their glucose levels carefully over the 7 days after a steroid injection. For patients who have not been diagnosed with diabetes, one can expect some increase in glucose due to insulin depression for a few days after a steroid injection. Clinicians may consider diabetic screening tests for those who appear to be at risk for type 2 diabetes.

Intra-articular or epidural injections cause rapid drops in plasma cortisol levels which usually resolve in 1 to 4 weeks. There is some evidence that an intra-articular injection of 80 mg of methylprednisolone acetate into the knee has about a 25% probability of suppressing the adrenal gland response to exogenous adrenocortocotrophic hormone ACTH for four or more weeks after injection, but complete recovery of the adrenal response is seen by week 8 after injection. This adrenal suppression could require treatment if surgery or other physiologically stressful events occur.

There is good evidence that there are no significant differences between

epidural injections with corticosteroid plus local anesthetic versus local anesthetic alone in patients with symptomatic spinal stenosis; however, there are measureable differences with respect to morning cortisol levels at 3 and 6 weeks after the injection, suggesting that the corticosteroid injection is capable of inducing suppression of the hypothalamic-pituitary-adrenal axis.

Case reports of Cushing's syndrome, hypopituitarism and growth hormone deficiency have been reported uncommonly and have been tied to systemic absorption of intra-articular and epidural steroid injections. Cushing's syndrome has also been reported from serial occipital nerve injections and paraspinal injections.

Morning cortisol measurements may be ordered prior to repeating steroid injections or prior to the initial steroid injection when the patient has received multiple previous steroid injections.

The effect of steroid injections on bone mineral density (BMD) and any contribution to osteoporotic fractures is less clear. Patients on long-term steroids are clearly more likely to suffer from fractures than those who do not take steroids. However, the contribution from steroid injections to this phenomenon does not appear to be large. A well-controlled, large retrospective cohort study found that individuals with the same risk factors for osteoporotic fractures were 20% more likely to suffer a lumbar fracture if they had an epidural steroid injection. The risk increased with multiple injections. Other studies have shown inconsistent findings regarding BMD changes.

Thus the risk of epidural injections must be carefully discussed with the patient, particularly for patients over 60, and repeat injections should generally be avoided unless the functional goals to be reached outweigh the risk for future fracture. Patients with existing osteoporosis or other risk factors for osteoporosis should rarely receive epidural steroid injections.

Time Frame for Spinal Diagnostic Injections	
Maximum	Given this information regarding increase in blood glucose levels, effects on the endocrine system, and possible osteoporotic influence, it is suggested that intra-articular and epidural injections be limited to a total of 3 to 4 per year [***all joints combined***].

ii. Specific Diagnostic Injections: In general, relief should last for at least the duration of the local anesthetic used and should significantly result in functional improvement and relief of pain. Refer to Section G.7, Injections – Spinal Therapeutic, for information on specific therapeutic injections.

A) Epidural injections: Diagnostic epidural injections are usually not necessary in chronic pain as herniated discs have already been treated. They may be used for spinal stenosis. Refer to the Division's Low Back Pain Medical Treatment Guideline for indications.

B) Medial Branch Blocks: Diagnostic medical branch blocks are usually not necessary in chronic pain. Refer to the Division's Low Back Pain Medical Treatment Guideline for indications.

C) Sacroiliac Joint Injection: Diagnostic sacroiliac joint injections are usually not necessary in chronic pain. Refer to the Division's Low Back Pain Medical Treatment Guideline for indications.

D) Zygapophyseal (Facet) Blocks: Diagnostic zygapophyseal blocks are usually not necessary in chronic pain. Refer to the Division's Low Back Pain Medical Treatment Guideline for indications.

E) Peripheral Nerve Blocks: These are diagnostic injections that may be used for specific nerve injury or entrapment syndromes. Not all peripheral nerve blocks require fluoroscopy. On occasion, they are used for treatment in chronic pain or CRPS. Repeat injection for treatment should be based on functional changes. These injections are usually limited to 3 injections per site per year.

Evidence Statements Regarding Diagnostic Spinal Injections and Steroid Associated Issues		
Strong Evidence	Evidence Statement	Design
	Epidural steroid injections (ESIs) have a small average short-term benefit for leg pain and disability for those with sciatica.	Meta-analysis of randomized clinical trials
	ESIs do not, on average, provide clinically meaningful long-term improvements in leg pain, back pain, or disability in patients with sciatica (lumbar radicular pain or radiculopathy).	
	ESIs have no short-term or long-term benefit for low back pain.	
Good Evidence	Evidence Statement	Design
	The addition of steroids to a transforaminal bupivacaine injection has a small effect on patient reported pain and disability.	Randomized clinical trials
	There are no significant differences between epidural injections with corticosteroid plus local anesthetic versus local anesthetic alone in patients with symptomatic spinal stenosis. However, there are measureable differences with respect to morning cortisol levels at 3 and 6 weeks after the injection, suggesting that the corticosteroid injection is capable of inducing suppression of the hypothalamic-pituitary-adrenal axis.	Randomized clinical trial

Evidence Statements Regarding Diagnostic Spinal Injections and Steroid Associated Issues		
Some Evidence	Evidence Statement	Design
	The addition of steroids to a transforaminal bupivacaine injection may reduce the frequency of surgery in the first year after treatment in patients with neurologic compression and corresponding imaging findings who also are strong candidates for surgery and have completed 6 weeks of therapy without adequate benefit. The benefits for the non-surgical group persisted for at least 5 years in most patients, regardless of the type of block given.	Randomized clinical trial
	After 6 weeks of conservative therapy for large herniated discs, an epidural injection may be attempted, as it does not compromise the results of a discectomy at a later date. One half of the patients in this study who were randomized to ESIs did not have surgery and this benefit persisted. Because this study did not have a control group that received neither treatment nor a group which received injections without steroids, one cannot make definite conclusions regarding the efficacy of ESI injections in this setting.	Randomized clinical trial
	An intra-articular injection of 80 mg of methylprednisolone acetate into the knee has about a 25% probability of suppressing the adrenal gland response to exogenous adrenocortocotrophic hormone ACTH for four or more weeks after injection, but complete recovery of the adrenal response is seen by week 8 after injection.	Randomized clinical trial

Evidence Against		
Good Evidence	Evidence Statement	Design
	There is good evidence against the use of lumbar facet or epidural injections for relief of non-radicular low back pain.	Systematic review of randomized clinical trials

6. **SPECIAL TESTS** are generally well-accepted tests and are performed as part of a skilled assessment of the patient's capacity to return to work, his/her strength capacities, and/or physical work demand classifications and tolerance. The procedures in this subsection are listed in alphabetical order.

a. **Computer-Enhanced Evaluations**: These may include isotonic, isometric, isokinetic, and/or isoinertial measurements of movement; ROM; endurance; or strength. Values obtained can include degrees of motion, torque forces, pressures, or resistance. Indications include determining validity of effort, effectiveness of treatment, and demonstrated motivation. These evaluations should not be used alone to determine return-to-work restrictions.

Time Frames for Computer-Enhanced Evaluations	
Frequency	One time for evaluation, one for mid-treatment assessment, and one at final evaluation.

b. **Functional Capacity Evaluation (FCE)**: This is a comprehensive or modified evaluation of the various aspects of function as they relate to the worker's ability to return to work. Areas such as endurance, lifting (dynamic and static), postural tolerance, specific ROM, coordination and strength, worker habits, employability, as well as psychosocial aspects of competitive employment may be evaluated. Reliability of patient reports and overall effort during testing is also reported. Components of this evaluation may include: (a) musculoskeletal screen; (b) cardiovascular profile/aerobic capacity; (c) coordination; (d) lift/carrying analysis; (e) job-specific activity tolerance; (f) maximum voluntary effort; (g) pain assessment/psychological screening; and (h) non-material and material handling activities. Standardized national guidelines (such as National Institute for Occupational Safety and Health (NIOSH)) should be used as the basis for FCE recommendations.

Most studies of FCEs were performed on chronic low back cases. There is some evidence that an FCE fails to predict which injured workers with chronic low back pain will have sustained return to work. Another cohort study concluded that there was a significant relation between FCE information and return to work, but the predictive efficiency was poor. There is some evidence that time off work and gender are important predictors for return to work, and floor-to-waist lifting may also help predict return to work; however, the strength of that relationship has not been determined.

A full review of the literature reveals no evidence to support the use of FCEs to prevent future injuries. There is some evidence in chronic low back pain patients that (1) FCE task performance is weakly related to time on disability and time for claim closure, and (2) even claimants who fail on numerous physical performance FCE tasks may be able to return to work. These same issues may exist for lower extremity issues.

Full FCEs are rarely necessary. In many cases, a work tolerance screening or return to work performance will identify the ability to perform the necessary job tasks. There is some evidence that a short form FCE reduced to a few tests produces a similar predictive quality compared to the longer 2-day version of the FCE regarding length of disability and recurrence of a claim after return to work.

When an FCE is being used to determine return to a specific jobsite, the provider is responsible for fully understanding the physical demands and the duties of the job that the worker is attempting to perform. A jobsite evaluation is usually necessary. A job description should be reviewed by the provider and FCE evaluator prior to this evaluation. FCEs cannot be used in isolation to determine work restrictions. It is expected that the FCE may differ from both self-report of abilities and pure clinical exam findings in chronic pain patients. The length of a return to work evaluation should be based on the judgment of the referring physician and the provider performing the evaluation. Since return to work is a complicated multidimensional issue, multiple factors beyond functional ability and work demands should be considered and measured when attempting

determination of readiness or fitness to return to work. FCEs should not be used as the sole criteria to diagnose malingering.

Evidence Statements Regarding Functional Capacity Evaluation		
Some Evidence	Evidence Statement	Design
	An FCE fails to predict which injured workers with chronic low back pain will have sustained return to work.	Observational prognostic study
	In chronic low back pain patients, (1) FCE task performance is weakly related to time on disability and time for claim closure and (2) even claimants who fail on numerous physical performance FCE tasks may be able to return to work.	
	Time off work and gender are important predictors for return to work, and floor-to-waist lifting may also help predict return to work; however, the strength of that relationship has not been determined.	Retrospective Study
	A short form FCE reduced to a few tests produces a similar predictive quality compared to the longer 2-day version of the FCE regarding length of disability and recurrence of a claim after return to work.	Randomized clinical trial

Time Frames for Functional Capacity Evaluation	
Frequency	Once when the patient is unable to return to the pre-injury position and further information is desired to determine permanent work restrictions. Prior authorization is required for repeat FCEs.

c. **Jobsite Evaluation and Alterations**: A comprehensive analysis of the physical, mental, and sensory components of a specific job. The goal of the jobsite evaluation is to identify any job modification needed to ensure the safety of the employee upon return to work. These components may include but are not limited to: (a) postural tolerance (static and dynamic); (b) aerobic requirements; (c) range-of-motion; (d) torque/force; (e) lifting/carrying; (f) cognitive demands; (g) social interactions; (h) visual perceptual; (i) environmental requirements of a job; (j) repetitiveness; (k) essential functions of a job; and (l) ergonomic set up. Job descriptions provided by the employer are helpful but should not be used as a substitute for direct observation.

Jobsite evaluation and alteration should include input from a health care professional with experience in ergonomics or a certified ergonomist, the employee, and the employer. The employee must be observed performing all job functions in order for the jobsite evaluation to be a valid representation of a typical workday. If the employee is unable to perform the job function for observation, a co-worker in an identical job position may be observed instead. Periodic follow-up is recommended to assess the effectiveness of the

intervention and need for additional ergonomic changes.

A jobsite evaluation may include observation and instruction of how work is done, what material changes (desk, chair) should be made, and determination of readiness to return to work.

Requests for a jobsite evaluation should describe the expected goals for the evaluation. Goals may include but are not limited to the following:

i. To determine if there are potential contributing factors to the person's condition and/or for the physician to assess causality;

ii. To make recommendations for and to assess the potential for ergonomic changes;

iii. To provide a detailed description of the physical and cognitive job requirements;

iv. To assist patients in their return to work by educating them on how they may be able to do their job more safely in a bio-mechanically appropriate manner;

v. To give detailed work/activity restrictions.

Time Frames for Jobsite Evaluation and Alterations	
Frequency	One time with additional visits as needed for follow-up per jobsite.

d. **Vocational Assessment**: Once an authorized practitioner has reasonably determined and objectively documented that a patient will not be able to return to his/her former employment and can reasonably prognosticate final restrictions, implementation of a timely vocational assessment can be performed. The vocational assessment should provide valuable guidance in the determination of future rehabilitation program goals. It should clarify rehabilitation goals which optimize both patient motivation and utilization of rehabilitation resources. If prognosis for return to former occupation is determined to be poor, except in the most extenuating circumstances, vocational assessment should be implemented within 3 to 12 months post-injury. Declaration of Maximum Medical Improvement (MMI) should not be delayed solely due to lack of attainment of a vocational assessment.

Time Frames for Vocational Assessment	
Frequency	One time with additional visits as needed for follow-up.

e. **Work Tolerance Screening (Fitness for Duty)**: is a determination of an individual's tolerance for performing a specific job based on a job activity or task. It may include a test or procedure to specifically identify and quantify work-relevant cardiovascular, physical fitness, and postural tolerance. It may also

address ergonomic issues affecting the patient's return-to-work potential. May be used when a full FCE is not indicated.

Time Frames for Work Tolerance Screening	
Frequency	One time for initial screen. May monitor improvements in strength every 3 to 4 weeks up to a total of 6 visits.

G. THERAPEUTIC PROCEDURES – NON-OPERATIVE

Non-operative therapeutic rehabilitation is applied to patients with chronic and complex problems of de-conditioning and functional disability. Treatment modalities may be utilized sequentially or concomitantly depending on chronicity, complexity of the problem, and anticipated therapeutic effect. Treatment plans should always be based on a diagnosis utilizing appropriate diagnostic procedures.

All treatment plans begin with shared decision making with the patient. Before initiation of any therapeutic procedure, an authorized treating physician, employer, and insurer must consider these important issues in the care of the injured worker:

- Patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to Section G.17, Return-to-Work, in this section for detailed information.

- Reassessment of the patient's status in terms of functional improvement should be documented after each treatment. If patients are not responding within the recommended time periods, alternative treatment interventions, further diagnostic studies, or consultations should be pursued. Continued treatment should be monitored using objective measures such as:

    - Return-to-work or maintaining work status;

    - Fewer restrictions at work or performing activities of daily living (ADL);

    - Decrease in usage of medications related to the work injury; and

    - Measurable functional gains, such as increased range-of-motion, documented increase in strength, increased ability to stand, sit or lift, or patient completed functional evaluations.

- Clinicians should provide and document education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms.

- Psychological or psychosocial screening should be performed on all chronic pain patients.

The following procedures are listed in alphabetical order.

1. ACUPUNCTURE

a. **Overview**: When acupuncture has been studied in randomized clinical trials, it is often compared with sham acupuncture and/or no acupuncture (usual care). The differences between true acupuncture and usual care have been moderate but clinically important. These differences can be partitioned into two components: non-specific effects and specific effects. Non-specific effects include patient beliefs and expectations, attention from the acupuncturist, administration of acupuncture in a relaxing setting, and other components of what is often called the placebo effect. Specific effects refer to any additional effects which occur in

the same setting of expectations and attention, but they are attributable to the penetration of the skin in the specific, classic acupuncture points on the surface of the body by the needles themselves.

A sham procedure is intended as a non-therapeutic procedure that appears similar to the patient as the purported therapeutic procedure being tested. In most controlled studies, sham and classic acupuncture have produced similar effects. However, the sham controlled studies have shown consistent advantages of both true and sham acupuncture over no acupuncture when the studies have included a third comparison group that was randomized to usual medical care. Having this third comparison group has been advantageous in the interpretation of the non-specific effects of acupuncture since the third comparison group controls for some influences on study outcome. These influences include: more frequent contact with providers; the natural history of the condition; regression to the mean; the effect of being observed in a clinical trial; and for biased reporting of outcomes if the follow-up observations are done consistently in all three treatment groups. Controlling for these factors enables researchers to more closely estimate the contextual and personal interactive effects of acupuncture as it is generally practiced.

There is some evidence that in the setting of chronic joint pain arising from aromatase inhibitor treatment of non-metastatic breast cancer, the symptomatic relief from acupuncture is strongly influenced by the expectations with which patients approach treatment, and a patient who expects significant benefits from acupuncture is more likely to derive benefits from sham acupuncture than a patient with low expectations is to derive benefits from real acupuncture. On average, real and sham acupuncture do not lead to significantly different symptom responses, but different treatment expectations do lead to different symptom responses.

Clinical trials of acupuncture typically enroll participants who are interested in acupuncture and who may respond to some of the non-specific aspects of the intervention more than patients who have no interest in or desire for acupuncture. The non-specific effects of acupuncture may not be produced in patients who have no wish to be referred for it.

There is a high quality study which does not support good evidence that true acupuncture is meaningfully superior to sham acupuncture with blunt needles in relieving the bothersomeness of nonspecific low back pain. The overall evidence from similar high quality studies does not support evidence of a treatment difference between true and sham acupuncture. In these studies, 5–15 treatments were provided. Comparisons of acupuncture and sham acupuncture have been inconsistent, and the advantage of true over sham acupuncture has been small in relation to the advantage of sham over no acupuncture.

Acupuncture is recommended for subacute or chronic pain patients who are trying to increase function and/or decrease medication usage and have an expressed interest in this modality. It is also recommended for subacute or acute pain for patients who cannot tolerate NSAIDs or other medications.

Acupuncture is not the same procedure as dry needling for coding purposes; however, some acupuncturists may use acupuncture treatment for myofascial trigger points. Dry needling is performed specifically on myofascial trigger points. Refer to Section G.8.i, Trigger Point Injections, and Section G.19.n, Trigger Point Dry Needling Treatment.

Acupuncture should generally be used in conjunction with manipulative and physical therapy/rehabilitation.

Credentialed practitioners with experience in evaluation and treatment of chronic pain patients must perform evaluations prior to acupuncture treatments. The exact mode of action is only partially understood. Western medicine studies suggest that acupuncture stimulates the nervous system at the level of the brain, promotes deep relaxation, and affects the release of neurotransmitters. Acupuncture is commonly used as an alternative or in addition to traditional Western pharmaceuticals. It may be used when pain medication is reduced or not tolerated; as an adjunct to physical rehabilitation and surgical intervention; and/or as part of multidisciplinary treatment to hasten the return of functional activity. Acupuncture must be performed by practitioners with the appropriate credentials in accordance with state and other applicable regulations. Therefore, if not otherwise within their professional scope of practice and licensure, those performing acupuncture must have the appropriate credentials, such as L.A.c. R.A.c, or Dipl. Ac.

There is good evidence that the small therapeutic effects of needle acupuncture, active laser acupuncture, and sham acupuncture for reducing pain or improving function among patients older than 50 years with moderate to severe chronic knee pain from symptoms of osteoarthritis are due to non-specific effects similar to placebo.

The Agency for Healthcare Research and Quality (AHRQ) supports acupuncture as effective for chronic low back pain. There is good evidence that acupuncture is effective in the treatment of low back pain in patients with positive expectations of acupuncture. There is good evidence that acupuncture, true or sham, is superior to usual care for the reduction of disability and pain in patients with chronic nonspecific low back pain, but true and sham acupuncture are likely to be equally effective. There is some evidence that acupuncture is better than no acupuncture for axial chronic low back pain. In summary, there is strong evidence that true or sham acupuncture may be useful for chronic low back pain in patients with high expectations, and it should be used accordingly.

Indications: All patients being considered for acupuncture treatment should have subacute or chronic pain (lasting approximately 3-4 weeks depending on the condition) and meet the following criteria:

- they should have participated in an initial active therapy program; and
- they should show a preference for this type of care or previously have benefited from acupuncture; and
- they must continue to be actively engaged in physical rehabilitation therapy and return to work.

It is less likely to be successful in patients who are more focused on pain than return to function. Time to produce effect should clearly be adhered to.

b. **Acupuncture**: is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated, and retained for a period of time. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range-of-motion, decrease the side

effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm.

Indications include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain.

c. **Acupuncture with Electrical Stimulation**: is the use of electrical current (micro-amperage or milli-amperage) on the needles at the acupuncture site. It is used to increase effectiveness of the needles by continuous stimulation of the acupoint. Physiological effects (depending on location and settings) can include endorphin release for pain relief, reduction of inflammation, increased blood circulation, analgesia through interruption of pain stimulus, and muscle relaxation.

It is indicated to treat chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites.

d. **Other Acupuncture Modalities**: may include a combination of procedures to enhance treatment effect. Other procedures may include the use of heat, soft tissue manipulation/massage, and exercise. Refer to Section G.18, Active Therapy (Therapeutic Exercise), and Section G.19, Passive Therapy (Massage and Superficial Heat and Cold Therapy), for a description of these adjunctive acupuncture modalities and time frames.

Evidence Statements Regarding Acupuncture		
Good Evidence	Evidence Statement	Design
	The small therapeutic effects of needle acupuncture, active laser acupuncture, and sham acupuncture for reducing pain or improving function among patients older than 50 years with moderate to severe chronic knee pain from symptoms of osteoarthritis are due to non-specific effects similar to placebo.	Negative randomized clinical trial
	Acupuncture is effective in the treatment of low back pain in patients with positive expectations of acupuncture.	Randomized clinical trial
	Acupuncture, true or sham, is superior to usual care for the reduction of disability and pain in patients with chronic nonspecific low back pain, but true and sham acupuncture are likely to be equally effective.	Randomized clinical trial

Evidence Statements Regarding Acupuncture		
Some Evidence	Evidence Statement	Design
	In the setting of chronic joint pain arising from aromatase inhibitor treatment of non-metastatic breast cancer, the symptomatic relief from acupuncture is strongly influenced by the expectations with which patients approach treatment, and a patient who expects significant benefits from acupuncture is more likely to derive benefits from sham acupuncture than a patient with low expectations is to derive benefits from real acupuncture. On average, real and sham acupuncture do not lead to significantly different symptom responses, but different treatment expectations do lead to different symptom responses.	Randomized clinical trial
	Acupuncture is better than no acupuncture for axial chronic low back pain.	Randomized clinical trial
Summary of Evidence Regarding Acupuncture		
Based on the multiple studies with good and some evidence listed above, there is strong evidence that true or sham acupuncture may be useful for chronic low back pain in patients with high expectations, and it should be used accordingly.		

e. **Total Time Frames for Acupuncture and Acupuncture with Electrical Stimulation**: are not meant to be applied to acupuncture and acupuncture with electrical stimulation separately. The time frames are to be applied to all acupuncture treatments regardless of the type or combination of therapies being provided.

Time Frames for Acupuncture and Acupuncture with Electrical Stimulation	
Time to Produce Effect	3 to 6 treatments.
Frequency	1 to 3 times per week.
Optimum Duration	1 to 2 months.
Maximum Duration	14 treatments within 6 months.

Any of the above acupuncture treatments may extend longer if objective functional gains can be documented and when symptomatic benefits facilitate progression in the patient's treatment program. Treatment beyond 14 treatments must be documented with respect to need and ability to facilitate positive symptomatic or functional gains. Such care should be re-evaluated and documented with each series of treatments.

2. BIOFEEDBACK

a. **Overview**: Biofeedback is a form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology, such as muscle activity, brain waves, and measures of autonomic nervous system activity. Stress-related psycho-physiological reactions may arise as a reaction to organic pain and in some cases may cause pain. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorily, or tactilely, with coaching by a biofeedback specialist. There is good evidence that biofeedback or relaxation therapy is equal in effect to cognitive behavioral therapy for chronic low back pain. There is good evidence that cognitive behavioral therapy, but not behavioral therapy (e.g., biofeedback), shows weak to small effects in reducing pain and small effects on improving disability, mood, and catastrophizing in patients with chronic pain.

Indications for biofeedback include cases of musculoskeletal injury in which muscle dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of pain, anxiety, panic, anger or emotional distress, opioid withdrawal, insomnia/sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often utilized for relaxation training. Mental health professionals may also utilize it as a component of psychotherapy, where biofeedback and other behavioral techniques are integrated with psychotherapeutic interventions. Biofeedback is often used in conjunction with physical therapy or medical treatment.

Recognized types of biofeedback include the following:

b. **EMG/Electromyogram (EMG)**: used for self-management of pain and stress reactions involving muscle tension.

c. **Skin Temperature**: used for self-management of pain and stress reactions, especially vascular headaches.

d. **Respiration Feedback (RFB)**: used for self-management of pain and stress reactions via breathing control.

e. **Respiratory Sinus Arrhythmia (RSA)**: used for self-management of pain and stress reactions via synchronous control of heart rate and respiration. Respiratory sinus arrhythmia is a benign phenomenon which consists of a small rise in heart rate during inhalation and a corresponding decrease during exhalation. This phenomenon has been observed in meditators and athletes and is thought to be a psycho-physiological indicator of health.

f. **Heart Rate Variability (HRV)**: used for self-management of stress via managing cardiac reactivity.

g. **Electrodermal Response (EDR)**: used for self-management of stress involving palmar sweating or galvanic skin response.

h. **Electroencephalograph (EEG, QEEG)**: used for self-management of various psychological states by controlling brainwaves.

The goal in biofeedback treatment is normalizing the physiology to the pre-injury

status to the extent possible and involves transfer of learned skills to the workplace and daily life. Candidates for biofeedback therapy or training should be motivated to learn and practice biofeedback and self-regulation techniques. In the course of biofeedback treatment, patient stressors are discussed and self-management strategies are devised. If the patient has not been previously evaluated, a psychological evaluation should be performed prior to beginning biofeedback treatment for chronic pain. The psychological evaluation may reveal cognitive difficulties, belief system conflicts, somatic delusions, secondary gain issues, hypochondriasis, and possible biases in patient self-reports, which can affect biofeedback. Home practice of skills is often helpful for mastery and may be facilitated by the use of home training tapes.

Psychologists or psychiatrists, who provide psycho-physiological therapy which integrates biofeedback with psychotherapy, should be either Biofeedback Certification International Alliance (BCIA) certified or practicing within the scope of their training. All non-licensed health care providers of biofeedback for chronic pain patients must be BCIA certified and shall have their biofeedback treatment plan approved by an authorized treating psychologist or psychiatrist. Biofeedback treatment must be done in conjunction with the patient's psychosocial intervention. Biofeedback may also be provided by licensed health care providers who follow a set treatment and educational protocol. Such treatment may utilize standardized material, relaxation tapes, or smart phone apps.

Evidence Statements Regarding Biofeedback		
Good Evidence	Evidence Statement	Design
	Biofeedback or relaxation therapy is equal in effect to cognitive behavioral therapy for chronic low back pain.	Meta-analysis of controlled clinical trials
	Cognitive behavioral therapy, but not behavioral therapy e.g., biofeedback, shows weak to small effects in reducing pain and small effects on improving disability, mood, and catastrophizing in patients with chronic pain.	Meta-analysis of randomized clinical trials favoring cognitive behavioral therapy over biofeedback

Time Frames for Biofeedback	
Time to Produce Effect	3 to 4 sessions.
Frequency	1 to 2 times per week.
Optimum Duration	5 to 6 sessions.
Maximum Duration	10 to 12 sessions. Treatment beyond 12 sessions must be documented with respect need, expectation, and ability to facilitate functional gains.

3. COMPLEMENTARY MEDICINE

a. **Overview**: Complementary Medicine, termed Complementary Alternative Medicine (CAM) in some systems, is a term used to describe a broad range of treatment modalities, a number of which are generally accepted and supported by some scientific literature and others which still remain outside the generally accepted practice of conventional Western Medicine. In many of these approaches, there is attention given to the relationship between physical, emotional, and spiritual well-being. While CAM may be performed by a myriad of both licensed and non-licensed health practitioners with training in one or more forms of therapy, credentialed practitioners should be used when available or applicable.

Although CAM practices are diverse and too numerous to list, they can be generally classified into five domains:

b. **Alternative Medical Systems**: These are defined as medical practices that have developed their own systems of theory, diagnosis, and treatment and have evolved independent of and usually prior to conventional Western Medicine. Some examples are Traditional Chinese Medicine, Ayurvedic Medicine, Homeopathy, and Naturopathy.

c. **Mind-body Interventions**: These include practices such as hypnosis, meditation, bioenergetics, and prayer. Reflexology does not appear to relieve low back pain.

d. **Biological-based Practices**: These include herbal and dietary therapy as well as the use of nutritional supplements. To avoid potential drug interactions, supplements should be used in consultation with an authorized treating physician.

e. **Body-based Therapy**: This category includes Rolfing bodywork. For information on yoga, please refer to Section G.18.g, Therapeutic Exercise.

f. **Energy-based Practices**: Energy-based practices include a wide range of modalities that support physical as well as spiritual and/or emotional healing. Some of the more well-known energy practices include Qi Gong, Tai Chi, Healing Touch, and Reiki. Practices such as Qi Gong and Tai Chi are taught to the patient and are based on exercises the patient can practice independently at home. Other energy-based practices such as Healing Touch and Reiki that involve a practitioner/patient relationship may provide some pain relief. Tai Chi may improve range-of-motion in those with rheumatoid arthritis. There is some evidence that a 10-week tai chi program was effective for improving pain symptoms and disability compared with usual care controls for those who have chronic low back pain symptoms. There is insufficient evidence that the results from Qi Gong are equivalent to exercise therapy.

Methods used to evaluate chronic pain patients for participation in CAM will differ with various approaches and with the training and experience of individual practitioners. A patient may be referred for CAM therapy when the patient's cultural background, religious beliefs, or personal concepts of health suggest that an unconventional medical approach might assist in the patient's recovery or when the physician's experience and clinical judgment support a CAM approach. The patient must demonstrate a high degree of motivation to return to work and improve his or her functional activity level while participating in therapy. Other

more traditional conservative treatments should generally be attempted before referral to CAM. Treatment with CAM requires prior authorization.

All CAM treatments require prior authorization and must include agreed upon number of visits for time to produce functional effects.

Evidence Statements Regarding Complementary Medicine		
Some Evidence	Evidence Statement	Design
	A 10-week tai chi program was effective for improving pain symptoms and disability compared with usual care controls for those who have chronic low back pain symptoms.	Assessor single-blind randomized controlled trial

Time Frames for Complementary Medicine	
Time to Produce Effect	Functional treatment goals and number of treatments for time to produce effect should be set with the practitioner and the patient before the beginning of treatment.
Frequency	Per CAM therapy selected.
Optimum Duration	Should be based upon the physician's clinical judgment and demonstration by the patient of positive symptomatic and functional gains. Practitioner provided CAM therapy is ***not recommended*** on a maintenance basis.

4. DIRECT CORTICAL STIMULATION

There are several types of cortical stimulation to relieve pain. All of these are undergoing further investigation and are considered experimental at this time. The limited studies available do not allow translation to the workers' compensation chronic pain population. An invasive option is implantation in the epidural motor cortex. Given the invasive nature and lack of evidence applying to the working population, direct cortical stimulation is ***not recommended***.

5. DISTURBANCES OF SLEEP

a. **Overview**: Disturbances of sleep are common in chronic pain. An essential element of chronic pain treatment is restoration of normal sleep cycles. Although primary insomnia may accompany pain as an independent co-morbid condition, it more commonly occurs secondary to the pain condition itself. Exacerbations of pain often are accompanied by exacerbations of insomnia; the reverse can also occur. Sleep laboratory studies have shown disturbances of sleep architecture in pain patients. Loss of deep slow-wave sleep and an increase in light sleep occur. Sleep efficiency, the proportion of time in bed spent asleep, is also decreased. These changes are associated with patient reports of non-restorative sleep.

Sleep apnea may also occur as a primary diagnosis or be caused or exacerbated by opioid and hypnotic use. This should be investigated diagnostically. (Refer to Section G.10.g, Medications and Medical Management, Opioids).

A recent systematic review explored the relationship between sleep and pain. It noted that studies of healthy individuals and those in pain from medical conditions both showed decreased pain thresholds after sleep deprivation. In this report some studies focusing on sleep continuity disruption showed a disruption of the natural pain inhibitory function. Sleep continuity disruption may be one of the most common sleep problems associated with pain. Thus, clinicians should strongly focus on assuring functional sleep for patients.

Many chronic pain patients develop behavioral habits that exacerbate and maintain sleep disturbances. Excessive time in bed, irregular sleep routine, napping, low activity, and worrying in bed are all maladaptive responses that can arise in the absence of any psychopathology. Relaxation training such as progressive relaxation, biofeedback, mindfulness meditation, or imagery training, and other forms of cognitive therapy can reduce dysfunctional beliefs and attitudes about sleep.

There is some evidence that behavioral modification, such as patient education and group or individual counseling with cognitive behavioral therapy, can be effective in reversing the effects of insomnia. Cognitive and behavioral interventions should be undertaken before prescribing medication solely for insomnia. Behavioral modifications are easily implemented and can include:

- Maintaining a regular sleep schedule; retiring and rising at approximately the same time on weekdays and weekends, regardless of the number of hours slept.
- Limiting naps to 30 minutes twice per day or less.
- Avoiding caffeinated beverages after lunchtime.
- Making the bedroom quiet and comfortable, eliminating disruptive lights, sounds, television sets, pets, and keeping a bedroom temperature of about 65 degrees Fahrenheit.
- Avoiding alcohol or nicotine within 2 hours of bedtime.
- Avoiding large meals within 2 hours of bedtime.
- Avoiding exposure to TV screens or computers within 2 hours of bedtime.
- Exercising vigorously during the day but not within 2 hours of bedtime since this may raise core temperature and activate the nervous system.
- Associating the bed with sleep and sexual activity only; using other parts of the home for television, reading, and talking on the telephone.
- Leaving the bedroom when unable to sleep for more than 20 minutes and returning to the bedroom when ready to sleep again.

- Reducing time in bed to estimated typical sleeping time.
- Engaging in relaxing activities until drowsy.

Behavioral modifications should be trialed before the use of hypnotics. Reinforcing these behaviors may also decrease hypnotic use and overall medication costs. Some patients may use other medications to assist in sleep, such as: trazadone, amitriptyline, doxepin, or low doses of melatonin. There is some evidence that group cognitive behavioral therapy reduces the severity and daytime consequences of insomnia for at least six months. There is some evidence that ramelteon, while producing a small amount of reduction in sleep latency, does not appreciably increase total sleep time or daytime function. There is some evidence that a dietary supplement containing melatonin, magnesium, and zinc, conveyed in pear pulp, taken 1 hour before bedtime, results in significantly better quality of sleep and quality of life than a placebo treatment in long-term care facility residents aged 70 and older with primary insomnia.

Many medications used in chronic pain can affect the sleep cycle. There is some evidence that the following medications exert different effects with respect to sleep variables. Total sleep time and REM sleep duration are likely to be greater with pregabalin than with duloxetine or amitriptyline. However, pregabalin is likely to lead to dizziness and fatigue more frequently than the other drugs, and oxygen desaturation during sleep also appears to be greater with pregabalin.

Insomnia requires difficulty initiating or maintaining sleep, waking up early, or insufficient restorative sleep despite adequate opportunity for sleep, as well as, daytime symptoms of sleep deprivation. In general, recommendations for treatment of insomnia include Cognitive Behavioral Therapy.

Evidence Statements Regarding Disturbance of Sleep		
Some Evidence	Evidence Statement	Design
	Group cognitive behavioral therapy reduces the severity and daytime consequences of insomnia for at least six months.	Randomized clinical trial
	Behavioral modification, such as patient education and group or individual counseling with cognitive behavioral therapy, can be effective in reversing the effects of insomnia.	Randomized clinical trial
	Ramelteon, while producing a small amount of reduction in sleep latency, does not appreciably increase total sleep time or daytime function.	Randomized clinical trial
	A dietary supplement containing melatonin, magnesium, and zinc, conveyed in pear pulp, taken 1 hour before bedtime, results in significantly better quality of sleep and quality of life than a placebo treatment in long-term care facility residents aged 70 and older with primary insomnia.	Double-blind placebo controlled randomized clinical trial

Evidence Statements Regarding Disturbance of Sleep		
Some Evidence, Continued	The following medications exert different effects with respect to sleep variables. Total sleep time and REM sleep duration are likely to be greater with pregabalin than with duloxetine or amitriptyline. However, pregabalin is likely to lead to dizziness and fatigue more frequently than the other drugs, and oxygen desaturation during sleep also appears to be greater with pregabalin.	Randomized clinical trial
Summary of Evidence Regarding Disturbance of Sleep		
Based on the multiple studies with some evidence listed above, there is good evidence supporting the use of cognitive behavioral therapy for sleep disturbances.		

6. **EDUCATION/INFORMED/SHARED DECISION MAKING**: of the patient and family, as well as the employer, insurer, policy makers, and the community should be the primary emphasis to prevent disability. Unfortunately, practitioners often think of education and informed decision making last, after medications, manual therapy, and surgery.

Informed decision making is the hallmark of a successful treatment plan. In most cases, the continuum of treatment from the least invasive to the most invasive (e.g., surgery) should be discussed. The intention is to find the treatment along this continuum which most completely addresses the condition. Patients should identify their personal values and functional goals of treatment at the first visit. It is recommended that specific individual goals are articulated at the beginning of treatment as this is likely to lead to increased patient satisfaction above that achieved from improvement in pain or other physical function. Progress toward the individual functional goals identified should be addressed at follow-up visits and throughout treatment by other members of the health care team as well as an authorized physician.

Documentation of the informed decision process should occur whenever diagnostic tests or referrals from an authorized treating physician are contemplated. The informed decision making process asks the patients to set their personal functional goals of treatment and describe their current health status and any concerns they have regarding adhering to the diagnostic or treatment plan proposed. The provider should clearly describe the following:

- The expected functional outcomes from the proposed treatment or the expected results and plan of action if diagnostic tests are involved.
- Expected course of illness/injury without the proposed intervention.
- Any side effects and risks to the patient.
- Required post-treatment rehabilitation time and impact on work, if any.
- Alternative therapies or diagnostic testing.

Before diagnostic tests or referrals for invasive treatment take place, the patient should be able to clearly articulate the goals of the intervention, the general side effects and risks associated with it, and his/her decision regarding compliance with the suggested plan. There is some evidence that information provided only by video is not sufficient

education.

Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with providing reassuring information to the patient and informed decision making. More in-depth education currently exists within a treatment regimen employing functional restoration, prevention, and cognitive behavioral techniques. Patient education and informed decision making should facilitate self-management of symptoms and prevention.

Evidence Statements Regarding Education / Informed Decision Making		
Some Evidence	Evidence Statement	Design
	Information provided only by video is not sufficient education.	Prospective randomized controlled trial

Time Frames for Education / Informed Decision Making	
Time to Produce Effect	Varies with individual patient
Frequency	Should occur at every visit.

7. INJECTIONS–SPINAL THERAPEUTIC:

The following injections are considered reasonable treatment for chronic pain exacerbations when therapy is continuing and specific indications are met. Refer to the Division's appropriate Medical Treatment Guideline for indications. For post-MMI care, refer to Section I.8, Injection Therapy Maintenance Management, in this guideline.

a. Steroid Associated Issues: If steroids are injected, only non-particulate steroids should be used to avoid the risk of spinal infarction.

The majority of diabetic patients will experience an increase in glucose following steroid injections. Average increases in one study were 125mg/dL and returned to normal in 48 hours, whereas in other studies, the increased glucose levels remained elevated up to 7 days, especially after multiple injections. All diabetic patients should be told to follow their glucose levels carefully over the 7 days after a steroid injection. For patients who have not been diagnosed with diabetes, one can expect some increase in glucose due to insulin depression for a few days after a steroid injection. Clinicians may consider diabetic screening tests for those who appear to be at risk for type 2 diabetes.

Intra-articular or epidural injections cause rapid drops in plasma cortisol levels which usually resolve in 1 to 4 weeks. There is some evidence that an intra-articular injection of 80 mg of methylprednisolone acetate into the knee has about a 25% probability of suppressing the adrenal gland response to exogenous adrenocortocotrophic hormone (ACTH) for 4 or more weeks after injection, but complete recovery of the adrenal response is seen by week 8 after injection. This adrenal suppression could require treatment if surgery or other physiologically

stressful events occur.

There is good evidence that there are no significant differences between epidural injections with corticosteroid plus local anesthetic versus local anesthetic alone in patients with symptomatic spinal stenosis; however, there are measureable differences with respect to morning cortisol levels at 3 and 6 weeks after the injection, suggesting that the corticosteroid injection is capable of inducing suppression of the hypothalamic-pituitary-adrenal axis.

Case reports of Cushing's syndrome, hypopituitarism, and growth hormone deficiency have been reported uncommonly and have been tied to systemic absorption of intra-articular and epidural steroid injections. Cushing's syndrome has also been reported from serial occipital nerve injections and paraspinal injections.

Morning cortisol measurements may be ordered prior to repeating steroid injections or prior to the initial steroid injection when the patient has received multiple previous steroid injections.

The effect of steroid injections on bone mineral density (BMD) and any contribution to osteoporotic fractures is less clear. Patients on long-term steroids are clearly more likely to suffer from fractures than those who do not take steroids. However, the contribution from steroid injections to this phenomenon does not appear to be large. A well-controlled, large retrospective cohort study found that individuals with the same risk factors for osteoporotic fractures were 20% more likely to suffer a lumbar fracture if they had an epidural steroid injection. The risk increased with multiple injections. Other studies have shown inconsistent findings regarding BMD changes. Thus, the risk of epidural injections must be carefully discussed with the patient, particularly for patients over 60, and repeat injections should generally be avoided unless the functional goals to be reached outweigh the risk for future fracture. Patients with existing osteoporosis or other risk factors for osteoporosis should rarely receive epidural steroid injections.

Time Frames for Intra-Articular and Epidural Injections	
Maximum Duration	Given this information regarding increase in blood glucose levels, effects on the endocrine system, and possible osteoporotic influence, it is suggested that intra-articular and epidural injections be limited to a total of 3 to 4 per year [***all joints combined***].

b. **Epidural Steroid Injection (ESI)**: may include caudal, transforaminal, or interlaminar injections. Epidural injections are usually not necessary in chronic pain as herniated discs have already been treated. They may be used for spinal stenosis. Refer to the Division's Low Back Pain Medical Treatment Guideline for indications of herniated disc.

For radicular pain due to disc herniation, refer to the Division's Low Back Pain Medical Treatment Guideline as this condition is not usually treated in chronic pain.

Spinal Stenosis Patients: Refer to the Division's Low Back Pain Medical Treatment Guideline for patients with radicular findings and claudication for

indications.

For chronic radiculopathy, injections may be repeated only if a functional documented response lasts for 3 months. Patients should be reassessed after each injection session for an 80% improvement in pain (as measured by accepted pain scales) and evidence of functional improvement. A positive result would include a return to baseline function, return to increased work duties, and a measurable improvement in physical activity goals including return to baseline after an exacerbation.

c. Intradiscal Steroid Injections:

There is some evidence that intradiscal steroid injection is unlikely to relieve pain or provide functional benefit in patients with non-radicular back pain; therefore, they are ***not recommended***.

Intradiscal injections of other substances such as bone marrow, stem cells, are ***not recommended*** at this time due to lack of evidence and possible complications.

d. Sacroiliac Joint Injection:

A generally accepted injection of local anesthetic in an intra-articular fashion into the sacroiliac joint under fluoroscopic guidance. May include the use of corticosteroids. Long-term therapeutic effect has not yet been established. Refer to the Division's Low Back Pain Medical Treatment Guideline for indications.

e. Transforaminal Injection with Etanercept:

Transforaminal injection with a tumor necrosis factor alpha inhibitor is thought to decrease the inflammatory agents which may be associated with the pathophysiology of lumbar radicular pain from a herniated disc.

It is ***not recommended*** due to the results of a study which showed no advantage over steroids or saline injections.

f. Zygapophyseal (Facet) Injection:

This is an accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid with very limited uses. There is no justification for a combined facet and medial branch block.

A high quality meta-analysis provides good evidence against the use of lumbar facet or epidural injections for relief of non-radicular low back pain. Facet injections have very limited use. Refer to the Division's Low Back Pain Medical Treatment Guideline for indications.

Evidence Statements Regarding Therapeutic Spinal Injections and Steroid Associated Issues		
Strong Evidence	Evidence Statement	Design
	Epidural steroid injections (ESIs) have a small average short-term benefit for leg pain and disability for those with sciatica.	Meta-analysis of randomized clinical trials
	ESIs do not, on average, provide clinically meaningful long-term improvements in leg pain, back pain, or disability in patients with sciatica (lumbar radicular pain or radiculopathy).	
	ESIs have no short-term or long-term benefit for low back pain.	
Good Evidence	Evidence Statement	Design
	The additional of steroids to a transforaminal bupivacaine injection has a small effect on patient reported pain and disability.	Randomized clinical trials
	There are no significant differences between epidural injections with corticosteroid plus local anesthetic versus local anesthetic alone in patients with symptomatic spinal stenosis. However, there are measureable differences with respect to morning cortisol levels at 3 and 6 weeks after the injection, suggesting that the corticosteroid injection is capable of inducing suppression of the hypothalamic-pituitary-adrenal axis.	Randomized clinical trial
Some Evidence	Evidence Statement	Design
	The addition of steroids to a transforaminal bupivacaine injection may reduce the frequency of surgery in the first year after treatment in patients with neurologic compression and corresponding imaging findings who also are strong candidates for surgery and have completed 6 weeks of therapy without adequate benefit. The benefits for the non-surgical group persisted for at least 5 years in most patients, regardless of the type of block given.	Randomized clinical trial
	After 6 weeks of conservative therapy for large herniated discs, an epidural injection may be attempted, as it does not compromise the results of a discectomy at a later date. One half of the patients in this study who were randomized to ESIs did not have surgery and this benefit persisted. Because this study did not have a control group that received neither treatment nor a group which received injections without steroids, one cannot make definite conclusions regarding the efficacy of ESI injections in this setting.	Randomized clinical trial

Evidence Statements Regarding Therapeutic Spinal Injections and Steroid Associated Issues		
Some Evidence, Continued	An intra-articular injection of 80 mg of methylprednisolone acetate into the knee has about a 25% probability of suppressing the adrenal gland response to exogenous adrenocortocotrophic hormone ACTH for 4 or more weeks after injection, but complete recovery of the adrenal response is seen by week 8 after injection.	Randomized clinical trial
	Patients who smoke respond less well to non-operative spine care, and quitting smoking results in greater improvement.	Prospective cohort study
	Translaminar steroid injections do not increase walking tolerance for those with spinal stenosis compared to local anesthetic.	Randomized clinical trial
	Intradiscal steroid injection is unlikely to relieve pain or provide functional benefit in patients with non-radicular back pain.	Randomized clinical trial

Evidence Against		
Good Evidence	Evidence Statement	Design
	There is good evidence against the use of lumbar facet or epidural injections for relief of non-radicular low back pain.	Systematic review of randomized clinical trials

8. **INJECTIONS – OTHER (INCLUDING RADIO FREQUENCY)**: The following are in alphabetical order:

a. **Botulinum Toxin Injections**:

Description: Used to temporarily weaken or paralyze muscles. These injections may reduce muscle pain in conditions associated with spasticity or dystonia. Neutralizing antibodies develop in at least 4% of patients treated with botulinum toxin type A, rendering it ineffective. Several antigenic types of botulinum toxin have been described. Botulinum toxin type B, first approved by the Food and Drug Administration (FDA) in 2001, is similar pharmacologically to botulinum toxin type A. It appears to be effective in patients who have become resistant to the type A toxin. The immune responses to botulinum toxins type A and B are not cross-reactive, allowing type B toxin to be used when type A action is blocked by antibody. Experimental work with healthy human volunteers suggests that muscle paralysis from type B toxin is not as complete or as long lasting as that resulting from type A. The duration of treatment effect of botulinum toxin type B for cervical dystonia has been estimated to be 12 to 16 weeks. Electromyography (EMG) needle guidance may permit more precise delivery of botulinum toxin to the target area.

There is strong evidence that botulinum toxin A has objective and asymptomatic benefits over placebo for cervical dystonia. There is good evidence that a single

injection of botulinum toxin type B is more effective than placebo in alleviating the severity and pain of idiopathic cervical dystonia. The duration of effect of botulinum toxin type B is not certain but appears to be approximately 12 to 18 weeks.

There is a lack of adequate evidence supporting the use of these injections to lumbar musculature for the relief of isolated low back pain. There is insufficient evidence to support its use for longer-term pain relief of other myofascial trigger points and it is likely to cause muscle weakness or atrophy if used repeatedly. Examples of such consequences include subacromial impingement, as the stabilizers of the shoulder are weakened by repeated injections of trigger points in the upper trapezii. Therefore, it is ***not recommended*** for use for low back pain or other myofascial trigger points.

They may be used for chronic piriformis syndrome. There is some evidence to support injections for electromyographically proven piriformis syndrome. Prior to consideration of botulinum toxin injection for piriformis syndrome, patients should have had marked (80% or better) but temporary improvement, verified with demonstrated improvement in functional activities, from three separate trigger point injections. To be a candidate for botulinum toxin injection for piriformis syndrome, patients should have had symptoms return to baseline or near baseline despite an appropriate stretching program after trigger point injections. Botulinum toxin injections of the piriformis muscle should be performed by a physician experienced in this procedure and utilize either ultrasound, fluoroscopy, or EMG needle guidance. Botulinum toxin should be followed by limb strengthening and reactivation.

Indications: for conditions which produce dystonia or piriformis syndrome. It is important to note that dystonia, torticollis, and spasticity are centrally mediated processes that are distinct from spasm, tightness, or myofascial pain. True dystonia is uncommon and consists of a severe involuntary contraction which results in abnormal postures or movements. Cervical dystonia or torticollis is the most common dystonia seen in the work related population. There should be evidence of limited range-of-motion prior to the injection. Refer to the Division's Traumatic Brain Injury (TBI) Medical Treatment Guideline for indications regarding headache.

There is insufficient evidence to support its use in myofascial trigger points for longer-term pain relief, and it is likely to cause muscle weakness or atrophy if used repeatedly. Examples of such consequences include subacromial impingement, as the stabilizers of the shoulder are weakened by repeated injections of trigger points in the upper trapezii. Therefore, it is ***not recommended*** for use for other myofascial trigger points.

Complications: There is good evidence that cervical botulinum toxin A injections cause transient dysphagia and neck weakness. Allergic reaction to medications, dry mouth, and vocal hoarseness may also occur. Dry mouth and dysphagia occur 15% of the time after one injection. Rare systemic effects include flu-like syndrome and weakening of distant muscle. There is an increased risk of systemic effects in patients with motor neuropathy or disorders of the neuromuscular junction.

Evidence Statements Regarding Botulinum Toxin Injections for Cervical Dystonia		
Strong Evidence	Evidence Statement	Design
	Botulinum toxin A has objective and asymptomatic benefits over placebo for cervical dystonia.	Meta-analysis of randomized clinical trials
Good Evidence	Evidence Statement	Design
	A single injection of botulinum toxin type B is more effective than placebo in alleviating the severity and pain of idiopathic cervical dystonia. The duration of effect of botulinum toxin type B is not certain but appears to be approximately 12 to 18 weeks.	Meta-analysis of randomized clinical trials

Evidence Statements Regarding Botulinum Toxin Injections for Piriformis Syndrome		
Some Evidence	Evidence Statement	Design
	There is some evidence to support injections for electromyographically proven piriformis syndrome.	Randomized clinical trial

Time Frames for Botulinum Toxin Injections	
Time to Produce Effect	24 to 72 hours post injection with peak effect by 4 to 6 weeks.
Frequency	No less than 3 months between re-administration. Patients should be reassessed after each injection session for approximately an 80% improvement in pain (as measured by accepted pain scales) and evidence of functional improvement for 3 months. A positive result would include a return to baseline function, return to increased work duties, and measurable improvement in physical activity goals including return to baseline after an exacerbation.
Optimum Duration	3 to 4 months.
Maximum Duration	Currently unknown. Repeat injections should be based upon functional improvement and therefore used sparingly in order to avoid development of antibodies that might render future injections ineffective. In most cases, not more than 4 injections are appropriate due accompanying muscle atrophy.

b. **Epiduroscopy and Epidural Lysis of Adhesions**: is a controversial and investigational treatment of low back pain. It involves the introduction of a fiberoptic endoscope into the epidural space via the sacral hiatus. With cephalad advancement of the endoscope under direct visualization, the epidural space is irrigated with saline. Adhesiolysis may be done mechanically with a fiberoptic endoscope. The saline irrigation is performed with or without epiduroscopy and is intended to distend the epidural space in order to obtain an adequate visual field.

It is designed to produce lysis of adhesions, which are conjectured to produce symptoms due to traction on painful nerve roots. Saline irrigation is associated with risks of elevated pressures which may impede blood flow and venous return, possibly causing ischemia of the cauda equina and retinal hemorrhage. Other complications associated with instrumented lysis include catheter shearing, need for catheter surgical removal, infection (including meningitis), hematoma, and possible severe hemodynamic instability during application. Although epidural adhesions have been postulated to cause chronic low back pain, studies have failed to find a significant correlation between the level of fibrosis and pain or difficulty functioning. Studies of epidural lysis demonstrate no transient pain relief from the procedure. Given the low likelihood of a positive response, the additional costs and time requirement, and the possible complications from the procedure, epiduroscopy, or mechanical lysis, is ***not recommended***.

Epiduroscopy-directed steroid injections are also ***not recommended*** because there is no evidence to support an advantage in using an epiduroscope with steroid injections.

c. **Prolotherapy**: Also known as sclerotherapy, prolotherapy consists of a series of injections of hypertonic dextrose, with or without glycerine and phenol, into the ligamentous structures of the low back. Its proponents claim that the inflammatory response to the injections will recruit cytokine growth factors involved in the proliferation of connective tissue, stabilizing the ligaments of the low back when these structures have been damaged by mechanical insults.

There is good evidence that prolotherapy alone is not an effective treatment for chronic low back pain. There is some evidence that prolotherapy of the sacroiliac (SI) joint is longer lasting, up to 15 months, than intra-articular steroid injections. The study was relatively small and long-term blinding was unclear; however, all injections were done under fluoroscopic guidance. Indications included an 80% reduction in pain from an SI joint injection with local anesthetic, as well as physical findings of SI joint dysfunction. Lasting functional improvement has not been shown and approximately 3 injections were required. The injections are invasive, and may be painful to the patient. The use of prolotherapy for low back pain is generally ***not recommended,*** as the majority of patients with SI joint dysfunction will do well with a combination of active therapy and manipulation and not require prolotherapy. However, it may be used in select patients. Prolotherapy is ***not recommended*** for other non-specific back pain.

Indications: insufficient functional progress after 6 months of an appropriate program that includes a combination of active therapy, manual therapy and psychological evaluation and treatment. There should be documented relief from previously painful maneuvers (e.g., Patrick's or Faber's test, Gaenslen, distraction or gapping, and compression test). A positive result from SI joint diagnostic block including improvement in at least 3 previously identified physical functions. Standards of evaluation should follow those noted in the diagnostic section. Refer to Section F.5, Injections-Diagnostic.

At the minimum, manual therapy, performed on a weekly basis per guideline limits by a professional specializing in manual therapy (such as a doctor of osteopathy or chiropractor) would address any musculoskeletal imbalance causing sacroiliac joint pain such as lumbosacral or sacroiliac dysfunction, pelvic imbalance, or sacral base unleveling. This thorough evaluation would include identification and treatment to resolution of all causal conditions such as iliopsoas, piriformis, gluteal or hamstring tonal imbalance, leg length inequality,

loss of motion of the sacrum, lumbar spine or pelvic bones, and ligamentous, visceral or fascial restrictions.

An active therapy program would consist of a functionally appropriate rehabilitation program which is advanced in a customized fashion as appropriate commensurate with the patient's level of strength and core spinal stability. Such a program would include stretching and strengthening to address areas of muscular imbalance as noted above and neuromuscular re-education to address maintenance of neutral spine via core stabilization with concomitant inhibition of lumbar paravertebral muscles. Patients who demonstrate a directional preference are usually not candidates for this procedure and should receive a trial of directional preference therapy.

Informed decision making must be documented including a discussion of possible complications and the likelihood of success. It is suggested that the individual be evaluated by a non-injection specialist to determine whether all reasonable treatment has been attempted and to verify the physical findings. Procedures should not be performed in patients who are unwilling to engage in the active therapy and manual therapy necessary to recover.

Evidence Statements Regarding Prolotherapy		
Good Evidence	Evidence Statement	Design
	Prolotherapy alone is not an effective treatment for chronic low back pain.	Systematic reviews of controlled clinical trials
Some Evidence	Evidence Statement	Design
	Prolotherapy of the sacroiliac (SI) joint is longer lasting, up to 15 months, than intra-articular steroid injections. The study was relatively small and long-term blinding was unclear; however, all injections were done under fluoroscopic guidance.	Randomized clinical trial

d. **Radio Frequency Ablation – Dorsal Nerve Root Ganglion**: Due to the combination of possible adverse side effects, time limited effectiveness, and mixed study results, this treatment is ***not recommended***.

e. **Radio Frequency Ablation – Genicular Nerves**: Neurotomy – There is currently inadequate evidence to support radiofrequency neurotomy for knee osteoarthritis failing conservative therapy. The one randomized controlled study identified was inadequate to support this invasive procedure. No long-term follow up is available, and there is a risk of charcot's joint. If an independent medical review is considering recommending it for functionally debilitation pain after failed knee arthroplasty, all of the usual criteria must be meet, including significant pain reduction and demonstrated objective functional improvement after diagnostic genicular injections.

f. **Radio Frequency (RF) Denervation - Medial Branch Neurotomy/Facet Rhizotomy**:

Description: a procedure designed to denervate the facet joint by ablating the corresponding sensory medial branches. Continuous percutaneous radiofrequency is the method generally used. Pulsed radiofrequency should not be used as it may result in incomplete denervation. Cooled radiofrequency is generally ***not recommended*** due to current lack of evidence.

There is good evidence in the lumbar spine that carefully selected patients who had 80% relief with medial branch controlled blinded blocks and then had RF neurotomy will have improved pain relief over 6 months and decreased impairment compared to those who had sham procedures. Pain relief was defined as one hour of 80% relief from the lidocaine injection and 2 hours of 80% relief with bupivacaine. Generally, pain relief lasts 7-9 months and repeat radiofrequency neurotomy can be successful and last longer. RF neurotomy is the procedure of choice over alcohol, phenol, or cryoablation. Precise positioning of the probe using fluoroscopic guidance is required because the maximum effective diameter of the device is a 5x8 millimeter oval. Permanent images should be recorded to verify placement of the device.

Needle Placement: Multi-planar fluoroscopic imaging is required for all injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications: those patients with proven, significant, facetogenic pain. A minority of low back patients would be expected to qualify for this procedure. This procedure is ***not recommended*** for patients with multiple pain generators or involvement of more than 3 levels of medial branch nerves or 2 facet levels unilateral or bilateral.

Individuals should have met all of the following indications:

- Physical exam findings consistent with facet origin pain; and
- Positive response to controlled medial branch blocks; and
- At least 3 months of pain, unresponsive to 6-8 weeks of conservative therapies, including manual therapy; and
- A psychosocial screening (e.g., thorough psychosocial history, screening questionnaire) with treatment as appropriate has been undergone.

Since one study found 67% false positives with controlled medical branch blocks, it is reasonable to delay radiotherapy if a false positive is suspected or pain has not returned.

All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients will have had prior to the procedure, will frequently require a repeat of the sessions previously ordered (Refer to Section G.18, Therapy-Active).

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the value of the medial branch block is evident to other

reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. As recommended by the SIS guidelines, the examiner should identify 3 or 4 measurable physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range-of-motion or assessing activity performance. The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians. To be successful, the results should occur within the expected time frame and there should be pain relief of approximately 80% demonstrated by pre and post Visual Analog Scale (VAS) scores. Examples of functional changes may include sitting, walking, and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg). The practitioner must identify the local anesthetic used and the expected duration of response for assessment purposes.

In almost all cases, this will mean a reduction of pain to 1 or 2 on the 10-point Visual Analog Scale (VAS) correlated with functional improvement. The patient should also identify activities of daily living (ADLs) (which may include measurements of ROM) that are impeded by their pain and can be observed to document objective functional improvement in the clinical setting. Ideally, these activities should be assessed throughout the observation period for function. The observer should not be the physician who performed the procedure. It is suggested that this be recorded on a form similar to SIS recommendations.

A separate comparative block on a different date should be performed to confirm the level of involvement prior to the rhizotomy. A comparative block uses anesthetics with varying lengths of activity. Medial Branch blocks are probably not helpful to determine the likelihood of success for spinal fusion.

The success rate of RF neurotomy is likely to decrease with lower percentages of pain relief from a medial branch block.

Informed decision making should also be documented for injections and all invasive procedures. This must include a thorough discussion of the pros and cons of the procedure and the possible complications as well as the natural history of the identified diagnosis. The purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Patients should be encouraged to express their personal goals, outcome expectations and desires from treatment as well as any personal habits or traits that may be impacted by procedures or their possible side effects. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation usually beginning within 7 days, at the injectionist's discretion. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment. All injections must be accompanied by active therapy.

i. Complications: bleeding, infection, or neural injury. The clinician must be aware of the risk of developing a localized neuritis, or rarely, a deafferentation centralized pain syndrome as a complication of this and other neuroablative procedures. Spinal musculature atrophy is likely to occur especially with repeat procedures as a rhizotomy denervates the multifidus-muscle in patients. For this reason, repeated rhizotomies and multiple level rhizotomies can be harmful by decreasing supportive spinal musculature. This is especially problematic for younger patients who may engage in athletic activities or workers with strenuous job requirements as the atrophy could result in increased injuries or pain, although this has not been documented.

ii. Post-Procedure Therapy — Active therapy: implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-procedure week, barring complications. Instruction and participation in a long-term, home-based program of ROM, core strengthening, postural or neuromuscular re-education, endurance, and stability exercises should be accomplished over a period of 4 to 10 visits post-procedure. Patients who are unwilling to engage in this therapy should not receive this procedure.

iii. Requirements for Repeat Radiofrequency Medial Branch Neurotomy: In some cases, pain may recur. Successful RF neurotomy usually provides from 6 to 18 months of relief.

Before a repeat RF neurotomy is done, a confirmatory medial branch injection should be performed if the patient's pain pattern presents differently than the initial evaluation. In occasional patients, additional levels of RF neurotomy may be necessary. The same indications and limitations apply.

It is recommended the total number of RF neurotomy sessions not exceed 12 in a lifetime as continued degradation of muscle strength is likely to result in other painful conditions.

Evidence Statements Regarding Radio Frequency (RF) Denervation - Medial Branch Neurotomy/Facet Rhizotomy		
Good Evidence	Evidence Statement	Design
	For the lumbar spine, carefully selected patients who had 80% relief with medial branch controlled blinded blocks and then had RF neurotomy will have improved pain relief over 6 months and decreased impairment compared to those who had sham procedures. Pain relief was defined as one hour of 80% relief from the lidocaine injection and two hours of 80% relief with bupivacaine.	Randomized clinical trials

g. **Radio Frequency Denervation - Sacro-iliac (SI) Joint Cooled**: This procedure requires neurotomy of multiple nerves, L5 dorsal ramus, and lateral branches of S1-S3 under C-arm fluoroscopy. There is good evidence that cooled RF neurotomy performed in a highly selected population results in better pain relief

and functional gains than a sham procedure. The benefits persisted for 9 months. Approximate half of the patients had benefits initially, and approximately half of those reported the pain was completely relieved.

i. Needle Placement: Multi-planar fluoroscopic imaging is required for all steroid injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

ii. Indications: The following three requirements must be fulfilled:

A) The patient has physical exam findings of at least 3 positive physical exam maneuvers (e.g., Patrick's sign, Faber's test, Ganslen distraction or gapping, or compression test). Insufficient functional progress after 6 months of an appropriate program that includes a combination of active therapy, manual therapy, and psychological evaluation and treatment.

At the minimum, manual therapy, performed on a weekly basis per guideline limits by a professional specializing in manual therapy (such as a doctor of osteopathy or chiropractor) would address any musculoskeletal imbalance causing sacroiliac joint pain such as lumbosacral or sacroiliac dysfunction, pelvic imbalance, or sacral base unleveling. This thorough evaluation would include identification and treatment to resolution of all causal conditions such as iliopsoas, piriformis, gluteal or hamstring tonal imbalance, leg length inequality, loss of motion of the sacrum, lumbar spine or pelvic bones, and ligamentous, visceral or fascial restrictions.

An active therapy program would consist of a functionally appropriate rehabilitation program which is advanced in a customized fashion as appropriate commensurate with the patient's level of strength and stability. Such a program would include stretching and strengthening to address areas of muscular imbalance as noted above and neuromuscular re-education to address maintenance of neutral spine via core stabilization with concomitant inhibition of lumbar paravertebral muscles. Patients who demonstrate a directional preference are usually not candidates for this procedure and should receive a trial of directional preference therapy. Patients with confounding findings suggesting zygapophyseal joint or intervertebral disc pain generators should be excluded.

B) Two fluoroscopically guided comparative blocks of the appropriate branches with differing anesthetics, 80% relief of pain for the appropriate time periods, and functional improvement must be documented to meet standards for control blocks. Refer to Section F.5, Injections-Diagnostic.

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the value of the procedure is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. The examiner should

identify 3 or 4 measurable provocative physical exam maneuvers (e.g., Patrick's sign, Faber's test, Gaenslen, distraction or gapping, or compression test), and physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range-of-motion or assessing activity performance. The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians. To be successful the results should occur within the expected time frame and there should be pain relief of approximately 80% demonstrated by pre and post Visual Analog Scale (VAS) scores. Examples of functional changes may include sitting, walking, and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg). The practitioner must identify the local anesthetic used and the expected duration of response for assessment purposes.

C) Informed decision making must be documented including a discussion of possible complications and the likelihood of success. It is suggested that the individual be evaluated by a non-injection specialist to determine whether all reasonable treatment has been attempted and to verify the physical findings. Procedures should not be performed in patients who are unwilling to engage in the active therapy necessary to recover.

iii. Complications: damage to sacral nerve roots – issues with bladder dysfunction etc. Bleeding, infection, or neural injury. The clinician must be aware of the risk of developing a localized neuritis, or rarely, a deafferentation centralized pain syndrome as a complication of this and other neuroablative procedures.

iv. Post-Procedure Therapy — Active Therapy: implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-procedure week, barring complications. Instruction and participation in a long-term home-based program of ROM, core strengthening, postural or neuromuscular re-education, endurance, and stability exercises should be accomplished over a period of 4 to 10 visits post-procedure. Patients who are unwilling to engage in this therapy should not receive this procedure.

v. Requirements for Repeat Radiofrequency SI Joint Neurotomy: In some cases, pain may recur. Successful RF neurotomy usually provides from 6 to 18 months of relief. Repeat neurotomy should only be performed if the initial procedure resulted in improved function for 6 months.

Due to denervation of spinal musculature, repeated neurotomy should be limited.

Evidence Statements Regarding Radio Frequency Denervation - Sacro-iliac (SI) Joint Cooled		
Good Evidence	Evidence Statement	Design
	Cooled RF neurotomy performed in a highly selected population results in better pain relief and functional gains than a sham procedure. The benefits persisted for 9 months. Approximate half of the patients had benefits initially, and approximately half of those reported the pain was completely relieved.	Randomized clinical trial

h. **Transdiscal Biacuplasty**:

Description: cooled radiofrequency procedure intended to coagulate fissures in the disc and surrounding nerves which could be pain generators.

It is ***not recommended*** due to lack of published data demonstrating effectiveness.

i. **Trigger Point Injections**:

Description: Trigger point injections are generally accepted treatments. Trigger point treatments can consist of the injection of local anesthetic, with or without corticosteroid, into highly localized, extremely sensitive bands of skeletal muscle fibers. These muscle fibers produce local and referred pain when activated. Medication is injected in a four-quadrant manner in the area of maximum tenderness. Injection can be enhanced if treatments are immediately followed by myofascial therapeutic interventions, such as vapo-coolant spray and stretch, ischemic pressure massage (myotherapy), specific soft tissue mobilization and physical modalities. There is conflicting evidence regarding the benefit of trigger point injections. There is no evidence that injection of medications improves the results of trigger-point injections. Needling alone may account for some of the therapeutic response of injections. Needling must be performed by practitioners with the appropriate credentials in accordance with state and other applicable regulations.

There is no indication for conscious sedation for patients receiving trigger point injections. The patient must be alert to help identify the site of the injection.

Indications: Trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other treatment modalities such as active therapy programs. Trigger point injections should be utilized primarily for the purpose of facilitating functional progress. Patients should continue in an aggressive aerobic and stretching therapeutic exercise program, as tolerated, while undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problems. Any abnormalities need to be ruled out prior to injection.

Trigger point injections are indicated in patients with consistently observed, well-circumscribed trigger points. This demonstrates a local twitch response, characteristic radiation of pain pattern, and local autonomic reaction such as persistent hyperemia following palpation. Generally, trigger point injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a 6-week time frame. However, trigger point injections may be occasionally effective when utilized in the patient with immediate, acute onset of pain or in a post-operative patient with persistent muscle spasm or myofascial pain.

Complications: Potential but rare complications of trigger point injections include infection, pneumothorax, anaphylaxis, penetration of viscera, neurapraxia, and neuropathy. If corticosteroids are injected in addition to local anesthetic, there is a risk of local myopathy. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

Time Frames for Trigger Point Injections	
Time to Produce Effect	Local anesthetic 30 minutes; 24 to 48 hours for no anesthesia.
Frequency	No more than 4 injection sites per session per week for acute exacerbations only, to avoid significant post-injection soreness.
Optimum/Maximum Duration	4 sessions per year. Injections may only be repeated when the above functional and time goals are met.

9. INTERDISCIPLINARY REHABILITATION PROGRAMS

a. Overview:

Interdisciplinary Rehabilitation Programs are the gold standard of treatment for individuals who have not responded to less intensive modes of treatment. There is good evidence that interdisciplinary programs that include screening for psychological issues, identification of fear-avoidance beliefs and treatment barriers, and establishment of individual functional and work goals will improve function and decrease disability. There is good evidence that multidisciplinary rehabilitation (physical therapy and either psychological, social, or occupational therapy) shows small effects in reducing pain and improving disability compared to usual care and that multidisciplinary biopsychosocial rehabilitation is more effective than physical treatment for disability improvement after 12 months of treatment in patients with chronic low back pain. Patients with a significant psychosocial impact are most likely to benefit. The Agency for Healthcare Research and Quality (AHRQ) supports multidisciplinary rehabilitation as effective for chronic low back pain. These programs should assess the impact of pain and suffering on the patient's medical, physical, psychological, social, and/or vocational functioning.

The International Classification of Functioning, Disability and Health (ICF) model should be considered in patient program planning. The following factors should

be addressed: body function and structures, activity expectations, participation barriers, and environmental and personal factors. In general, interdisciplinary programs evaluate and treat multiple and sometimes irreversible conditions, including but not limited to: painful musculoskeletal, neurological, and other chronic pain conditions and psychological issues; drug dependence, abuse, or addiction; high levels of stress and anxiety; failed surgery; and pre-existing or latent psychopathology. The number of professions involved on the team in a chronic pain program may vary due to the complexity of the needs of the person served. The Division recommends consideration of referral to an interdisciplinary program within 6 months post-injury in patients with delayed recovery, unless successful surgical interventions or other medical and/or psychological treatment complications intervene.

Chronic pain patients need to be treated as outpatients within a continuum of treatment intensity. Outpatient chronic pain programs are available with services provided by a coordinated interdisciplinary team within the same facility (formal) or as coordinated among practices by an authorized treating physician (informal). Formal programs are able to provide a coordinated, high-intensity level of services and are recommended for most chronic pain patients who have received multiple therapies during acute management.

Patients with addiction problems, high-dose opioid use, or abuse of other drugs may require inpatient and/or outpatient chemical dependency treatment programs before or in conjunction with other interdisciplinary rehabilitation. Guidelines from the American Society of Addiction Medicine are available and may be consulted relating to the intensity of services required for different classes of patients in order to achieve successful treatment.

There is some evidence that a telephone-delivered collaborative care management intervention for primary care veteran patients produced clinically meaningful improvements in pain at 12-month follow-up compared with usual care by increasing non-opioid analgesic medications and without changing opioid usage for the management of chronic musculoskeletal pain. The management was directed by nurse case managers. Because the control group was usual care rather than an attention control, the non-specific effects of attention received in the intervention group could have contributed to the effectiveness of the intervention. If an attention control had been used as the control group, the effect size observed for improvement in pain in the intervention group may have been smaller. It is unknown how successful this would be with injured workers.

Informal interdisciplinary pain programs may be considered for patients who are currently employed, those who cannot attend all-day programs, those with language barriers, or those living in areas not offering formal programs. Before treatment has been initiated, the patient, physician, and insurer should agree on treatment approach, methods, and goals. Generally, the type of outpatient program needed will depend on the degree of impact the pain has had on the patient’s medical, physical, psychological, social, and/or vocational functioning.

When referring a patient for formal outpatient interdisciplinary pain rehabilitation, an occupational rehabilitation program, or an opioid treatment program, the Division recommends the program meets the criteria of the Commission on Accreditation of Rehabilitation Facilities (CARF).

Inpatient pain rehabilitation programs are rarely needed but may be necessary for patients with any of the following conditions: (a) high risk for medical

instability, (b) moderate-to-severe impairment of physical/functional status, (c) moderate-to-severe pain behaviors, (d) moderate impairment of cognitive and/or emotional status, (e) dependence on medications from which he/she needs to be withdrawn, and (f) the need for 24-hour supervised nursing. Whether formal or informal programs, they should be comprised of the following dimensions:

i. Communication: To ensure positive functional outcomes, communication between the patient, insurer, and all professionals involved must be coordinated and consistent. Any exchange of information must be provided to all parties, including the patient. Care decisions should be communicated to all parties and should include the family and/or support system.

ii. Documentation: Thorough documentation by all professionals involved and/or discussions with the patient. It should be clear that functional goals are being actively pursued and measured on a regular basis to determine their achievement or need for modification. It is advisable to have the patient undergo objective functional measures.

iii. Risk assessments: The following should be incorporated into the overall assessment process, individual program planning, and discharge planning: aberrant medication related behavior, addiction, suicide, and other maladaptive behavior.

iv. Treatment Modalities: Use of modalities may be necessary early in the process to facilitate compliance with and tolerance to therapeutic exercise, physical conditioning, and increasing functional activities. Active treatments should be emphasized over passive treatments. Active and self-monitored passive treatments should encourage self-coping skills and management of pain, which can be continued independently at home or at work. Treatments that can foster a sense of dependency by the patient on the caregiver should be avoided. Treatment length should be decided based upon observed functional improvement. For a complete list of active and passive therapies, refer to Section G.18, Therapy – Active, and Section G.19, Therapy – Passive. All treatment time frames may be extended based on the patient's positive functional improvement.

v. Therapeutic Exercise Programs: A therapeutic exercise program should be initiated at the start of any treatment rehabilitation. Such programs should emphasize education, independence, and the importance of an on-going exercise regimen. There is good evidence that exercise alone or as part of a multi-disciplinary program results in decreased disability for workers with non-acute low back pain. There is not sufficient evidence to support the recommendation of any particular exercise regimen over another exercise regimen.

vi. Return-to-Work: An authorized treating physician should continually evaluate the patients for their potential to return to work. For patients who are currently employed, efforts should be aimed at keeping them employed. Formal rehabilitation programs should provide assistance in creating work profiles. For more specific information regarding return to work, refer to Section G.17, Return-to-Work.

vii. Patient Education: Patients with pain need to re-establish a healthy balance in lifestyle. All providers should educate patients on how to overcome barriers to resuming daily activity, including pain management, decreased energy levels, financial constraints, decreased physical ability, and change in family dynamics.

viii. Psychosocial Evaluation and Treatment: Psychosocial evaluation should be initiated, if not previously done. Providers should have a thorough understanding of the patient's personality profile, especially if dependency issues are involved. Psychosocial treatment may enhance the patient's ability to participate in pain treatment rehabilitation, manage stress, and increase their problem-solving and self-management skills.

ix. Family/Support System Services as appropriate: The following should be considered in the initial assessment and program planning for the individual: ability and willingness to participate in the plan, coping, expectations, educational needs, insight, interpersonal dynamics, learning style, problem solving, responsibilities, and cultural and financial factors. Support would include counseling, education, assistive technology, and ongoing communication.

x. Vocational Assistance: Vocational assistance can define future employment opportunities or assist patients in obtaining future employment. Refer to Section G.17, Return-to-Work, for detailed information.

xi. Discharge Planning: Follow-up visits will be necessary to assure adherence to treatment plan. Programs should have community and/or patient support networks available to patients on discharge.

xii. Interdisciplinary Teams: Interdisciplinary programs are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of the treatment program. These programs are for patients with greater levels of perceived disability, dysfunction, de-conditioning, and psychological involvement. Programs should have sufficient personnel to work with the individual in the following areas: behavioral, functional, medical, cognitive, communication, pain management, physical, psychological, social, spiritual, recreation and leisure, and vocational. Services should address impairments, activity limitations, participation restrictions, environmental needs, and personal preferences of the worker.

b. Formal Interdisciplinary Rehabilitation Programs:

i. Interdisciplinary Pain Rehabilitation: An Interdisciplinary Pain Rehabilitation Program provides outcome-focused, coordinated, goal-oriented interdisciplinary team services to measure and improve the functioning of persons with pain and encourage their appropriate use of health care system and services. The program can benefit persons who have limitations that interfere with their physical, psychological, social, and/or vocational functioning. The program shares information about the scope of the services and the outcomes achieved with patients, authorized providers, and insurers.

The interdisciplinary team maintains consistent integration and

communication to ensure that all interdisciplinary team members are aware of the plan of care for the patient, are exchanging information, and are implementing the plan of care. The team members make interdisciplinary team decisions with the patient and then ensure that decisions are communicated to the entire care team.

Teams that assist in the accomplishment of functional, physical, psychological, social, and vocational goals must include: a medical director, pain team physician(s) who should preferably be board certified in an appropriate specialty, and a pain team psychologist. The Medical Director of the pain program and each pain team physician should be board certified in pain management or be board certified in his/her specialty area and have one of the following: 1) completed a one-year fellowship in interdisciplinary pain medicine or palliative care recognized by a national board, 2) two years of experience in an interdisciplinary pain rehabilitation program, or 3) if less than 2 years of experience, participate in a mentorship program with an experienced pain team physician. The pain team psychologist should have 1) one year's full-time experience in an interdisciplinary pain program, or 2) if less than 2 years of experience, participate in a mentorship program with an experienced pain team psychologist. Professionals from other disciplines on the team may include but are not limited to: a biofeedback therapist, an occupational therapist, a physical therapist, a registered nurse (RN), a case manager, an exercise physiologist, a psychologist, a psychiatrist, and/or a nutritionist. A recent French interdisciplinary functional spine restoration program demonstrated increased return to work at 12 months.

Time Frames for Interdisciplinary Pain Rehabilitation	
Time to Produce Effect	3 to 4 weeks.
Frequency	Full time programs – No less than 5 hours per day, 5 days per week; part-time programs – 4 hours per day, 2–3 days per week.
Optimum Duration	3 to 12 weeks at least 2–3 times a week. Follow-up visits weekly or every other week during the first 1 to 2 months after the initial program is completed.
Maximum Duration	4 months for full-time programs and up to 6 months for part-time programs. Periodic review and monitoring thereafter for 1 year, and additional follow-up based on the documented maintenance of functional gains.

ii. Occupational Rehabilitation: This is a formal interdisciplinary program addressing a patient's employability and return to work. It includes a progressive increase in the number of hours per day in which a patient completes work simulation tasks until the patient can tolerate a full work day. A full work day is case specific and is defined by the previous employment of the patient. Safe workplace practices and education of

the employer and family and/or social support system regarding the person's status should be included. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return to work.

The following are best practice recommendations for an occupational rehabilitation program:

A) Work assessments including a work-site evaluation when possible (Refer to Section G.17, Return-To-Work).

B) Practice of component tasks with modifications as needed.

C) Development of strength and endurance for work tasks.

D) Education on safe work practices.

E) Education of the employer regarding functional implications of the worker when possible.

F) Involvement of family members and/or support system for the worker.

G) Promotion of responsibility and self-management.

H) Assessment of the worker in relationship to productivity, safety, and worker behaviors.

I) Identification of transferable skills of the worker.

J) Development of behaviors to improve the ability of the worker to return to work or benefit from other rehabilitation.

K) Discharge includes functional/work status, functional abilities as related to available jobs in the community, and a progressive plan for return to work if needed.

There is some evidence that an integrated care program, consisting of workplace interventions and graded activity teaching that pain need not limit activity, is effective in returning patients with chronic low back pain to work, even with minimal reported reduction of pain. The occupational medicine rehabilitation interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation, team physicians having experience in occupational rehabilitation, an occupational therapist, and a physical therapist. As appropriate, the team may also include any of the following: a chiropractor, an RN, a case manager, a psychologist, a vocational specialist, or a certified biofeedback therapist.

Time Frames for Occupational Rehabilitation	
Time to Produce Effect	2 weeks.
Frequency	2 to 5 visits per week, up to 8 hours per day.
Optimum Duration	2 to 4 weeks.
Maximum Duration	6 weeks. Participation in a program beyond 6 weeks must be documented with respect to need and the ability to facilitate positive symptomatic and functional gains.

iii. Opioid/Chemical Treatment Programs: Refer to the Division's Chronic Pain Disorder Medical Treatment Guideline. Recent programs which incorporate both weaning from opioids and interdisciplinary therapy appear to demonstrate positive long-term results.

c. **Informal Interdisciplinary Rehabilitation Program**: A coordinated interdisciplinary pain rehabilitation program is one in which an authorized treating physician coordinates all aspects of care. This type of program is similar to the formal programs in that it is goal-oriented and provides interdisciplinary rehabilitation services to manage the needs of the patient in the following areas: (a) functional, (b) medical, (c) physical, (d) psychological, (e) social, and (f) vocational.

This program is different from a formal program in that it involves lower frequency and intensity of services/treatment. Informal rehabilitation is geared toward those patients who do not need the intensity of service offered in a formal program or who cannot attend an all-day program due to employment, daycare, language, or other barriers.

Patients should be referred to professionals experienced in outpatient treatment of chronic pain. The Division recommends an authorized treating physician consult with physicians experienced in the treatment of chronic pain to develop the plan of care. Communication among care providers regarding clear objective goals and progress toward the goals is essential. Employers should be involved in return to work and work restrictions, and the family and/or social support system should be included in the treatment plan. Professionals from other disciplines likely to be involved include: a biofeedback therapist, an occupational therapist, a physical therapist, an RN, a psychologist, a case manager, an exercise physiologist, a psychiatrist, and/or a nutritionist.

Time Frames for Informal Interdisciplinary Rehabilitation Program	
Time to Produce Effect	3 to 4 weeks.

Time Frames for Informal Interdisciplinary Rehabilitation Program	
Frequency	Full-time programs – No less than 5 hours per day, 5 days per week; Part-time programs – 4 hours per day for 2–3 days per week.
Optimum Duration	3 to 12 weeks at least 2–3 times a week. Follow-up visits weekly or every other week during the first 1 to 2 months after the initial program is completed.
Maximum Duration	4 months for full-time programs and up to 6 months for part-time programs. Periodic review and monitoring thereafter for 1 year, and additional follow-up based upon the documented maintenance of functional gains.

Evidence Statements Regarding Interdisciplinary Rehabilitation Programs		
Good Evidence	Evidence Statement	Design
	Interdisciplinary programs that include screening for psychological issues, identification of fear-avoidance beliefs and treatment barriers, and establishment of individual functional and work goals will improve function and decrease disability.	Cluster randomized trial, Randomized clinical trial
	Multidisciplinary rehabilitation (physical therapy and either psychological, social, or occupational therapy) shows small effects in reducing pain and improving disability compared to usual care, and multidisciplinary biopsychosocial rehabilitation is more effective than physical treatment for disability improvement after 12 months of treatment in patients with chronic low back pain. Patients with a significant psychosocial impact are most likely to benefit.	Meta-analyses of randomized clinical trials
	Exercise alone or as part of a multi-disciplinary program results in decreased disability for workers with non-acute low back pain.	Meta-analysis of randomized clinical trials
Some Evidence	Evidence Statement	Design
	Telephone-delivered collaborative care management intervention for primary care veteran patients produced clinically meaningful improvements in pain at 12-month follow-up compared with usual care by increasing non-opioid analgesic medications and without changing opioid usage for the management of chronic musculoskeletal pain. The management was directed by nurse case managers. Because the control group was usual care rather than an attention control, the non-specific effects of attention	Single-blind randomized clinical trial

Some Evidence, Continued	received in the intervention group could have contributed to the effectiveness of the intervention. If an attention control had been used as the control group, the effect size observed for improvement in pain in the intervention group may have been smaller. It is unknown how successful this would be with injured workers.	
	An integrated care program, consisting of workplace interventions and graded activity teaching that pain need not limit activity, is effective in returning patients with chronic low back pain to work, even with minimal reported reduction of pain.	Randomized clinical trial

10. MEDICATIONS AND MEDICAL MANAGEMENT

There is no single formula for pharmacological treatment of patients with chronic nonmalignant pain. A thorough medication history, including use of alternative and over-the-counter medications, should be performed at the time of the initial visit and updated periodically. The medication history may consist of evaluating patient refill records through pharmacies and the Physician Drug Monitoring Program (PDMP) to determine if the patient is receiving their prescribed regimen. Appropriate application of pharmacological agents depends on the patient's age, past history (including history of substance abuse), drug allergies, and the nature of all medical problems. It is incumbent upon the healthcare provider to thoroughly understand pharmacological principles when dealing with the different drug families, their respective side effects, drug interactions**,** and primary reason for each medication's usage. Patients should be aware that medications alone are unlikely to provide complete pain relief. In addition to pain relief, a primary goal of drug treatment is to improve the patient's function as measured behaviorally. Besides taking medications, continuing participation in exercise programs and using self-management techniques such as biofeedback, cognitive behavioral therapy, and other individualized physical and psychological practices are required elements for successful chronic pain management. Management must begin with establishing goals and expectations, including shared decision making about risks and benefits of medications.

Medication reconciliation is the process of comparing the medications that the patient is currently taking with those for which the patient has orders. This needs to include drug name, dosage, frequency, and route. The reconciliation can assist in avoiding medications errors such as omissions, duplications, dosing errors, or drug interactions. The results can also be used to assist discussion with the patient regarding prescribing or changing medications and the likelihood of side effects, drug interactions, and achieving expected goals. At a minimum, medication reconciliation should be performed for all patients upon the initial visit and whenever refilling or prescribing new medications.

Control of chronic non-malignant pain is expected to frequently involve the use of medication. Strategies for pharmacological control of pain cannot be precisely specified in advance. Rather, drug treatment requires close monitoring of the patient's response to therapy, flexibility on the part of the prescriber, and a willingness to change treatment when circumstances change. Many of the drugs discussed in the medication section were originally licensed for indications other than analgesia but are effective in the control of some types of chronic pain.

It is generally wise to begin management with lower cost non-opioid medications whose efficacy equals higher cost medications and medications with a greater safety profile. Decisions to progress to more expensive, non-generic, and/or riskier products are made

based on the drug profile, patient feedback, and improvement in function. The provider must carefully balance the untoward side effects of the different drugs with therapeutic benefits, as well as monitor for any drug interactions.

All medications should be given an appropriate trial in order to test for therapeutic effect. The length of an appropriate trial varies widely depending on the individual drug. Certain medications may take several months to determine the efficacy, while others require only a few doses. It is recommended that patients with chronic nonmalignant pain be maintained on drugs that have the least serious side effects. For example, patients need to be tried or continued on acetaminophen and/or low dose generic antidepressant medications whenever feasible, as part of their overall treatment for chronic pain. Patients with renal or hepatic disease may need increased dosing intervals with chronic acetaminophen use. Chronic use of NSAIDs is generally ***not recommended*** due to increased risk of cardiovascular events and GI bleeding.

The use of sedatives and hypnotics is not generally recommended for chronic pain patients. It is strongly recommended that such pharmacological management be monitored or managed by an experienced pain medicine physician. Multimodal therapy is the preferred mode of treatment for chronic pain patients whether or not these drugs were used acutely or sub-acutely.

Pharmaceutical neuropathic pain studies are limited. Diabetic peripheral neuropathy (DPN) and post-herpetic neuralgia (PHN) are the two most frequently studied noncancer neuropathic pain conditions in randomized clinical trials of drug treatment. Some studies enroll only DPN or PHN patients, while other studies may enroll both kinds of patients. There appear to be consistent differences between DPN and PHN with respect to placebo responses, with DPN showing greater placebo response than PHC. Thus, there is an increased likelihood of a “positive” trial result for clinical trials of drug treatment for PHN than for DPN.

Although many studies focus on mean change in pain, this may not be the most reliable result. It does not necessarily allow for subgroups that may have improved significantly. Furthermore, the DPN and PHN studies do not represent the type of neurologic pain usually seen in workers’ compensation.

For these reasons, few pharmaceutical agents listed in this Guideline are supported by high levels of evidence, but the paucity of evidence statements should not be construed as meaning that medication is not to be encouraged in managing chronic pain patients.

General Order for Trial of Neuropathic Pain Medications

Treating physician are encouraged to follow this sequence taking into consideration the patient’s individual tolerance for types of medications, their side effects, and their other medical conditions will guide pharmaceutical choices.
1. Tricyclic anti-depressants. 2. Gabapentin or pregabalin and/or serotonin norepinephrine reuptake inhibitors. 3. Other anticonvulsants as listed. 4. Opioids low dose including, tramadol, tapentadol.

It is advisable to begin with the lowest effective dose proven to be useful for neuropathic pain in the literature. If the patient is tolerating the medication and clinical benefit is appreciated, maximize the dose for that medication or add another second line medication with another mechanism of action. If a medication is not effective, taper off

the medication and start another agent. Maintain goal dosing for up to 8 weeks before determining its effectiveness. Many patients will utilize several medications from different classes to achieve maximum benefit.

It is also useful to remember that there is some evidence that in the setting of uncomplicated low back pain lasting longer than 3 months, patients who were willing to participate in a trial of capsules clearly labelled as placebo experienced short-term reductions in pain and disability after the principles of the placebo effect had been explained to them.

The preceding principles do not apply to chronic headache or trigeminal neuralgia patients. These patients should be referred to a physician specializing in the diagnosis and treatment of headache and facial pain (refer to the Division's Traumatic Brain Injury Medical Treatment Guideline).

For the clinician to interpret the following material, it should be noted that: (1) drug profiles listed are not complete; (2) dosing of drugs will depend upon the specific drug, especially for off-label use; and (3) not all drugs within each class are listed, and other drugs within the class may be appropriate for individual cases. Clinicians should refer to informational texts or consult a pharmacist before prescribing unfamiliar medications or when there is a concern for drug interactions.

Evidence Statements Regarding Medication Management		
Some Evidence	Evidence Statement	Design
	In the setting of uncomplicated low back pain lasting longer than 3 months, patients who were willing to participate in a trial of capsules clearly labelled as placebo experienced short-term reductions in pain and disability after the principles of the placebo effect had been explained to them.	Randomized clinical trial

The following drug classes are listed in alphabetical order, not in order of suggested use, which is outlined above for neuropathic pain.

a. **Alpha-Acting Agents**: Noradrenergic pain-modulating systems are present in the central nervous system and the alpha-2 adrenergic receptor may be involved in the functioning of these pathways. Alpha-2 agonists may act by stimulating receptors in the substantia gelatinosa of the dorsal horn of the spinal cord, inhibiting the transmission of nociceptive signals. Spasticity may be reduced by presynaptic inhibition of motor neurons. Given limited experience with their use, they cannot be considered first-line or second-line analgesics for neurogenic pain, but a trial of their use may be warranted in some cases of refractory pain.

i. Clonidine (Catapres, Kapvay, Nexiclon)

A) Description – central alpha 2 agonist.

B) Indications – sympathetically mediated pain, treatment of withdrawal from opioids.

As of the time of this guideline writing, formulations of clonidine have been FDA approved for hypertension.

C) Major Contraindications – severe coronary insufficiency, renal impairment.

D) Dosing and Time to Therapeutic Effect – increase dosage weekly to therapeutic effect.

E) Major Side Effects – sedation, hypotension, sexual dysfunction, thrombocytopenia, weight gain, agitation, rebound hypertension with cessation.

F) Drug Interactions – beta adrenergics, tricyclic antidepressants.

G) Laboratory Monitoring – renal function, blood pressure.

b. **Anticonvulsants**: Although the mechanism of action of anticonvulsant drugs in neuropathic pain states remains to be fully defined, some appear to act as channel blocking agents. A large variety of sodium channels are present in nervous tissue, and some of these are important mediators of nociception, as they are found primarily in unmyelinated fibers and their density increases following nerve injury. While the pharmacodynamic effects of the various anticonvulsant drugs are similar, the pharmacokinetic effects differ significantly. Gabapentin and pregablin, by contrast, are relatively non-significant enzyme inducers, creating fewer drug interactions. Because anticonvulsant drugs may have more problematic side-effect profiles, their use should usually be deferred until tricyclic-related medications have failed to relieve pain. All patients on these medications should be monitored for suicidal ideation. Many of these medications are ***not recommended*** for women of child bearing age due to possible teratogenic effects.

Gabapentin and pregabalin are commonly prescribed for neuropathic pain. There is an association between older anticonvulsants including gabapentin and non-traumatic fractures for patients older than 50; this should be taken into account when prescribing these medications.

Gabapentin and pregabalin have indirect (not GABA A or GABA B receptor mediated) GABA-mimetic qualities rather than receptor mediated actions. This can potentially result in euphoria, relaxation, and sedation. It is likely that they also affect the dopaminergic “reward” system related to addictive disorders. Misuse of these medications usually involves doses 3-20 times that of the usual therapeutic dose. The medication is commonly used with alcohol or other drugs of abuse. Providers should be aware of the possibility and preferably screen patients for abuse before prescribing these medications. Withdrawal symptoms, such as insomnia, nausea, headache, or diarrhea, are likely when high doses of pregabalin have been used. Tolerance can also develop.

i. Gabapentin (Fanatrex, Gabarone, Gralise, Horizant, Neurontin)

A) Description: structurally related to gamma-aminobutyric acid (GABA) but does not interact with GABA receptors. Gabapentin affects the alpha-2-delta-1 ligand of voltage gated calcium channels, thus inhibiting neurotransmitter containing intra-cellular vesicles from fusing with the pre-synaptic membranes and

reducing primary afferent neuronal release of neurotransmitters (glutamate, CGRP, and substance P). It may also modulate transient receptor potential channels, NMDA receptors, protein kinase C and inflammatory cytokines, as well as possibly stimulating descending norepinephrine mediated pain inhibition.

B) Indications: As of the time of this guideline writing, formulations of gabapentin have been FDA approved for post-herpetic neuralgia and partial onset seizures.

There is strong evidence that gabapentin is more effective than placebo in the relief of painful diabetic neuropathy and post-herpetic neuralgia.

There is some evidence that gabapentin may benefit some patients with post-traumatic neuropathic pain. There is good evidence that gabapentin is not superior to amitriptyline. There is some evidence that nortriptyline (Aventyl, Pamelor) and gabapentin are equally effective for pain relief of postherpetic neuralgia. There is some evidence that the combination of gabapentin and morphine may allow lower doses with greater analgesic effect than the drugs given separately. There is strong evidence that gabapentin is more effective than placebo for neuropathic pain, even though it provides complete pain relief to a minority of patients. There is some evidence that a combination of gabapentin and nortriptyline provides more effective pain relief than monotherapy with either drug. Given the cost of gabapentin, it is recommended that patients who are medically appropriate receive a trial of tricyclics before use of gabapentin.

C) Relative Contraindications: renal insufficiency. Dosage may be adjusted to accommodate renal dysfunction.

D) Dosing and Time to Therapeutic Effect: Dosage should be initiated at a low dose in order to avoid somnolence and may require 4 to 8 weeks for titration. Dosage should be adjusted individually. It is taken 3 to 4 times per day, and the target dose is 1800 mg.

E) Major Side Effects: sedation, confusion, dizziness, peripheral edema. Patients should also be monitored for suicidal ideation and drug abuse.

F) Drug Interactions: antacids.

G) Laboratory Monitoring: renal function.

ii. Pregabalin (Lyrica)

A) Description: structural derivative of the inhibitory neuro transmitter gamma aminobutyric acid which inhibits calcium influx at the alpha-2-subunit of voltage-gated calcium channels of neurons. By inhibiting calcium influx, there is inhibition of release for excitatory neurotransmitters.

B) Indications: As of the time of this guideline writing, pregabalin is FDA approved for the treatment of neuropathic pain, post-herpetic neuralgia, fibromyalgia, diabetic peripheral neuropathy, and partial-onset seizure in adults with epilepsy.

There is an adequate meta-analysis supporting strong evidence that in the setting of painful diabetic neuropathy, pregabalin as a stand-alone treatment is more effective than placebo in producing a 50% pain reduction, but this goal is realized in only 36% of patients treated with pregabalin compared with 24% of patients treated with placebo. There is an absence of published evidence regarding its effectiveness in improving physical function in this condition. There is also some evidence that pregabalin may be effective in treating neuropathic pain due to spinal cord injury. Unfortunately, most of the studies reviewed used pain as the primary outcome. Only one study considered function and found no improvement.

When pregabalin is compared with other first line medications for the treatment of neuropathic pain and diabetic peripheral neuropathy, such as amitriptyline and duloxetine, there is good evidence that it is not superior to these medications. Additionally, amitriptyline was found more effective compared to pregabalin for reducing pain scores and disability. Side effects were similar for the two medications. Therefore, amitriptyline is recommended as a first line drug for patients without contraindications, followed by duloxetine or pregabalin. This is based on improved effectiveness in treating neuropathic pain and a favorable side effect profile compared to pregabalin. Pregabalin may be added to amitriptyline therapy.

Pregabalin seems to be not effective and/or not well tolerated in a large percentage of patients. This is evident in several of the studies using run-in phases, enrichment, and partial enrichment techniques to strengthen the results. This analysis technique excludes placebo responders, non-responders, and adverse events prior to the treatment part of the study. This was done in the large meta-analysis, and one study had 60% of participants excluded in the run-in phase.

Duloxetine, pregabalin, and amitriptyline are approximately of equal benefit with respect to pain relief in the setting of diabetic peripheral neuropathy. There is some evidence that they exert different effects with respect to sleep variables. Total sleep time and REM sleep duration are likely to be greater with pregabalin than with duloxetine or amitriptyline. However, pregabalin is likely to lead to dizziness and fatigue more frequently than the other drugs, and oxygen desaturation during sleep also appears to be greater with pregabalin.

C) Relative Contraindications: Avoid use with hypersensitivity to pregabalin or other similar class of drugs, avoid abrupt withdrawal, avoid use with a CNS depressant or alcohol, and exercise caution when using:

- in the elderly,
- with renal impairment,
- with CHF class III/IV,
- with a history of angioedema,
- with depression.

D) Dosing and Time to Therapeutic Effect: Pregabalin comes in dosages ranging from 25mg to 300mg in 25mg and 50mg increments. For neuropathic pain, start at 75mg twice daily for one week and then increase to 150mg twice daily for 2 to 3 weeks if needed, with a possible final increase to 300mg twice daily with a max dose of 600mg/day. The full benefit may be achieved as quickly as 1 week, but it may take 6-8 weeks. To discontinue, taper the dose down for at least 1 week.

E) Major Side Effects: dizziness (≤ 45%), somnolence (≤ 36%), peripheral edema (≤ 16%), weight gain (≤ 16%), xerostomia (≤ 15%), headache (≤ 14%), fatigue (≤ 11%), tremor (≤ 11%), blurred vision/diplopia (≤ 12%), constipation (≤ 10%), confusion (≤ 7%), euphoria (≤ 7%), impaired coordination (≤ 6%), thrombocytopenia (≥ 1%). Patients should be monitored for hypersensitivity reactions, angioedema, suicidality, withdrawal symptoms, and seizures during abrupt discontinuation.

F) In regards to euphoria, pregabalin has higher rates compared to gabapentin in patients with history of substance misuse. Thus, prescribers should be aware that there is a potential for misuse.

G) Drug Interactions: Avoid use with antiepileptic agents and any CNS depression medications. Specifically avoid use with carbinoxamine, doxylamine, and gingko. Monitor closely when pregabalin is use with opioids.

H) Laboratory Monitoring: creatinine at baseline.

iii. Other Anticonvulsants with Limited Third Line Use:

It is recommended that a physician experienced in pain management be involved in the care when these medications are used.

A) Topiramate (Topamax, Topiragen): sulfamate substitute monosacchride. FDA approved for epilepsy or prophylaxis for migraines. Topiramate is without evidence of efficacy in diabetic neuropathic pain, the only neuropathic condition in which it has been adequately tested. The data we have includes the likelihood of major bias due to last observation carried forward imputation, where adverse event withdrawals are much higher with active treatment than placebo control. Despite the strong potential for bias, no difference in efficacy between topiramate and placebo was apparent. There is good evidence that

topiramate demonstrates minimal effect on chronic lumbar radiculopathy or other neuropathic pain. If it is utilized, this would be done as a third or fourth line medication in appropriate patients.

B) Lamotrigine (Lamictal): This anti-convulsant drug is not FDA approved for use with neuropathic pain. Due to reported deaths from toxic epidermal necrolysis and Stevens Johnson syndrome, increased suicide risk, and incidents of aseptic meningitis, it is used with caution for patients with seizure or mood disorders. There is insufficient evidence that lamotrigine is effective in treating neuropathic pain and fibromyalgia at doses of about 200 to 400 mg daily. Given the availability of more effective treatments including antiepileptics and antidepressant medicines, lamotrigine does not have a significant place in therapy based on the available evidence. The adverse effect profile of lamotrigine is also of concern. If it is utilized, this would be done as a third or fourth line medication in appropriate patients.

C) Zonisamide: There is insufficient evidence that zonisamide provides pain relief in any neuropathic pain condition. There are a number of drug interactions and other issues with its use. If it is utilized, this would be done as a third or fourth line medication in appropriate patients.

D) Carbamazepine: Has important effects as an inducer of hepatic enzymes and may influence the metabolism of other drugs enough to present problems in patients taking interacting drugs. Dose escalation must be done carefully, since there is good evidence that rapid dose titration produces side-effects greater than the analgesic benefits. Carbamazepine is likely effective in some people with chronic neuropathic pain but with caveats. No trial was longer than 4 weeks, had good reporting quality, nor used outcomes equivalent to substantial clinical benefit. In these circumstances, caution is needed in interpretation, and meaningful comparison with other interventions is not possible. Carbamazepine is generally ***not recommended***; however, it may be used as a third or fourth line medication. It may be useful for trigeminal neuralgia.

E) Valproic Acid: There is insufficient evidence to support the use of valproic acid or sodium valproate as a first-line treatment for neuropathic pain. It should be avoided in women of child bearing age. There is more robust evidence of greater efficacy for other medications. However, some guidelines continue to recommend it. If it is utilized, this would be done as a third or fourth line medication in appropriate patients.

F) Levetiracetam: There is no evidence that levetiracetam is effective in reducing neuropathic pain. It is associated with an increase in participants who experienced adverse events and who withdrew due to adverse events. Therefore, this is ***not recommended***.

G) Lacosamide: Has limited efficacy in the treatment of peripheral diabetic neuropathy. Higher doses did not give consistently better efficacy but were associated with significantly more adverse event withdrawals. Where adverse event withdrawals are high with active treatment compared with placebo and when last observation carried forward imputation is used, as in some of these studies, significant overestimation of treatment efficacy can result. It is likely, therefore, that lacosamide is without any useful benefit in treating neuropathic pain; any positive interpretation of the evidence should be made with caution if at all. Therefore, this is ***not recommended***.

Evidence Statements Regarding Anticonvulsants: Gabapentin (Fanatrex, Gabarone, Gralise, Horizant, Neurontin)		
Strong Evidence	Evidence Statement	Design
	Gabapentin is more effective than placebo in the relief of painful diabetic neuropathy and post-herpetic neuralgia.	Meta-analysis of randomized clinical trials
	Gabapentin is more effective than placebo for neuropathic pain, even though it provides complete pain relief to a minority of patients.	Randomized clinical trial, Meta-analysis of randomized trials
Good Evidence	Evidence Statement	Design
	Gabapentin is not superior to amitriptyline.	Randomized crossover trial, Meta-analysis of randomized trials
Some Evidence	Evidence Statement	Design
	Gabapentin may benefit some patients with post-traumatic neuropathic pain.	Randomized clinical trial
	Nortriptyline (Aventyl, Pamelor) and gabapentin are equally effective for pain relief of post-herpetic neuralgia.	Randomized clinical trial
	The combination of gabapentin and morphine may allow lower doses with greater analgesic effect than the drugs given separately.	Randomized crossover trial
	A combination of gabapentin and nortriptyline provides more effective pain relief than monotherapy with either drug.	Randomized crossover trial

Evidence Statements Regarding Anticonvulsants: Pregabalin (Lyrica)		
Strong Evidence	Evidence Statement	Design
	In the setting of painful diabetic neuropathy, pregabalin as a stand-alone treatment is more effective than placebo in producing a 50% pain reduction, but this goal is realized in only 36% of patients treated with pregabalin compared with 24% of patients treated with placebo.	Meta-analysis of randomized clinical trials
Good Evidence	Evidence Statement	Design
	When pregabalin is compared with other first line medications for the treatment of neuropathic pain and diabetic peripheral neuropathy, such as amitriptyline and duloxetine, it is not superior to these medications. Additionally, amitriptyline was found more effective compared to pregabalin for reducing pain scores and disability. Side effects were similar for the two medications.	Randomized clinical trial, Open label parallel randomized clinical trial, Randomized clinical trial
Some Evidence	Evidence Statement	Design
	Pregabalin may be effective in treating neuropathic pain due to spinal cord injury.	Randomized parallel group clinical trial
	Duloxetine, pregabalin, and amitriptyline exert different effects with respect to sleep variables. Total sleep time and REM sleep duration are likely to be greater with pregabalin than with duloxetine or amitriptyline. However, pregabalin is likely to lead to dizziness and fatigue more frequently than the other drugs, and oxygen desaturation during sleep also appears to be greater with pregabalin.	Randomized clinical trial

Evidence Statements Regarding Anticonvulsants: Topiramate (Topamax, Topiragen)		
Good Evidence	Evidence Statement	Design
	Topiramate demonstrates minimal effect on chronic lumbar radiculopathy or other neuropathic pain.	Randomized crossover trial, Randomized clinical trials

Evidence Statements Regarding Anticonvulsants: Carbamazepine		
Good Evidence	Evidence Statement	Design
	Rapid dose titration produces side-effects greater than the analgesic benefits.	Randomized clinical trials

c. **Antidepressants**: Are classified into a number of categories based on their chemical structure and their effects on neurotransmitter systems. Their effects on depression are attributed to their actions on disposition of norepinephrine and serotonin at the level of the synapse; although these synaptic actions are immediate, the symptomatic response in depression is delayed by several weeks. When used for chronic pain, the effects may in part arise from treatment of underlying depression, but may also involve additional neuromodulatory effects on endogenous opioid systems, raising pain thresholds at the level of the spinal cord.

Pain responses may occur at lower drug doses with shorter times to symptomatic response than are observed when the same compounds are used in the treatment of mood disorders. Neuropathic pain, diabetic neuropathy, post-herpetic neuralgia, and cancer-related pain may respond to antidepressant doses low enough to avoid adverse effects that often complicate the treatment of depression. First line drugs for neuropathic pain are the tricyclics with the newer formulations having better side effect profiles. SNRIs are considered second line drugs due to their costs and the number needed to treat for a response. Duloxetine may be considered for first line use in a patient who is a candidate for pharmacologic treatment of both chronic pain and depression. SSRIs are used generally for depression rather than neuropathic pain and should not be combined with moderate to high-dose tricyclics.

All patients being considered for anti-depressant therapy should be evaluated and continually monitored for suicidal ideation and mood swings.

i. Tricyclics and Older Agents (e.g., amitriptyline, nortriptyline, doxepin (Adapin, Silenor, Sinequan), desipramine (Norpramin, Pertofrane), imipramine (Tofranil), trazodone (Desyrel, Oleptro)).

A) Description: Serotonergics, typically tricyclic antidepressants (TCAs), are utilized for their serotonergic properties as increasing CNS serotonergic tone can help decrease pain perception in non-antidepressant dosages. TCAs decrease reabsorption of both serotonin and norepinephrine. They also impact Na channels. Amitriptyline is known for its ability to repair Stage 4 sleep architecture, a frequent problem found in chronic pain patients and to treat depression, frequently associated with chronic pain. However, higher doses may produce more cholinergic side effects than newer tricyclics such as nortriptyline and desipramine. Doxepin and trimipramine also have sedative effects.

There is some evidence that in the setting of chronic low back pain with or without radiculopathy, amitriptyline is more effective than pregabalin at reducing pain and disability after 14 weeks of treatment. There is some evidence that in the setting of neuropathic pain, a combination of morphine plus nortriptyline produces better pain relief than either monotherapy alone, but morphine monotherapy is not superior to nortriptyline monotherapy, and it is possible that it is actually less effective than nortriptyline. There is insufficient low quality evidence supporting the use of desipramine to treat neuropathic pain. Effective medicines with much greater supportive evidence are available. There may be a role for desipramine in patients who

have not obtained pain relief from other treatments. There is no good evidence of a lack of effect; therefore, amitriptyline should continue to be used as part of the treatment of neuropathic pain. Only a minority of people will achieve satisfactory pain relief. Limited information suggests that failure with one antidepressant does not mean failure with all. There is insufficient evidence to support the use of nortriptyline as a first line treatment. However, nortriptyline has a lower incidence of anticholinergic side effects than amitriptyline. It may be considered for patients who are intolerant to the anticholinergic effects of amitriptyline. Effective medicines with greater supportive evidence are available, such as duloxetine and pregabalin.

There is some evidence that a combination of some gabapentin and nortriptyline provides more effective pain relief than monotherapy with either drug, without increasing side effects of either drug.

B) Indications: Some formulations are FDA approved for depression and anxiety. For the purposes of this guideline, they are recommended for neuropathic pain and insomnia. They are ***not recommended*** as a first line drug treatment for depression. There is good evidence that gabapentin is not superior to amitriptyline. Given the cost of gabapentin, it is recommended that patients who are medically appropriate to undergo a trial of lower cost tricyclic before use of gabapentin.

C) Major Contraindications: cardiac disease or dysrhythmia, glaucoma, prostatic hypertrophy, seizures, high suicide risk, uncontrolled hypertension and orthostatic hypotension. A screening cardiogram may be done for those 40 years of age or older, especially if higher doses are used. Caution should be utilized in prescribing TCAs. They are not recommended for use in elderly patients 65 years of age or older, particularly if they are at fall risk.

D) Dosing and Time to Therapeutic Effect: varies by specific tricyclic. Low dosages, less than 100 mg are commonly used for chronic pain and/or insomnia. Lower doses decrease side effects and cardiovascular risks.

E) Major Side Effects: Side effects vary according to the medication used; however, the side effect profile for all of these medications is generally higher in all areas except GI distress, which is more common among the SSRIs and SNRIs. Anticholinergic side effects include, but not limited to, dry mouth, sedation, orthostatic hypotension, cardiac arrhythmia, urinary retention, and weight gain. Dry mouth leads to dental and periodontal conditions (e.g., increased cavities). Patients should also be monitored for suicidal ideation and drug abuse. Anticholinergic side effects are more common with tertiary amines (amitriptyline, imipramine, doxepin) than with secondary amines (nortriptyline and desipramine).

F) Drug Interactions: Tramadol (may cause seizures, both also increase serotonin/norepinephrine, so serotonin syndrome is a concern), clonidine, cimetidine (Tagemet), sympathomimetics, valproic acid (Depakene, Depakote, Epilim, Stavzor), warfarin (Coumadin, Jantoven, Marfarin), carbamazepine, bupropion (Aplezin, Budeprion, Buproban, Forfivo, Wellbutrin, Zyban), anticholinergics, quinolones.

G) Recommended Laboratory Monitoring: renal and hepatic function. EKG for those on high dosages, or with cardiac risk.

ii. Selective serotonin reuptake inhibitors (SSRIs) (e.g., citalopram (Celexa), fluoxetine (Prozac, Rapiflux, Sarafem, Selfemra), paroxetine (Paxil, Pexeva), sertraline (Zoloft)) are ***not recommended*** for neuropathic pain. They may be used for depression.

iii. Selective Serotonin Nor-epinephrine Reuptake Inhibitor (SSNRI) /Serotonin Nor-epinephrine Reuptake Inhibitors (SNRI).

A) Description: Venlafaxine (Effexor), desvenlafaxine (Pristiq), duloxetine, and milnacipran (Savella).

There is strong evidence that duloxetine monotherapy is more effective than placebo in relieving the pain of diabetic peripheral neuropathy; however, monotherapy leads to a 50% pain reduction in only half of patients who receive a therapeutic dose.

AHRQ supports the use of duloxetine for chronic low back pain.

There is good evidence that in patients with painful diabetic neuropathy who have not had good responses to monotherapy with 60 mg of duloxetine or 300 mg of pregabalin, a clinically important benefit can be achieved by either of two strategies: doubling the dose of either drug, or combining both drugs at the same dose. It is likely that the strategy of combining the two drugs at doses of 60 and 300 mg respectively is more beneficial overall.

There was no evidence to support the use of milnacipran to treat neuropathic pain conditions, although it is used for fibromyalgia. It is not generally recommended but may be used if patients cannot tolerate other medications.

There is insufficient evidence to support the use of venlafaxine in neuropathic pain. However, it may be useful for some patients who fail initial recommended treatments. Venlafaxine is generally reasonably well tolerated, but it can precipitate fatigue, somnolence, nausea, and dizziness in a minority of people. The sustained release formulations are generally more tolerable as inter-dose withdrawal symptoms can be avoided. They should be trialed if the patient cannot tolerate the immediate release formulation.

B) Indications: At the time of writing this guideline, duloxetine has been FDA approved for treatment of diabetic neuropathic pain

and chronic musculoskeletal pain. Therefore, best evidence supports the use of duloxetine alone or with pregabalin if patients do not have sufficient relief from a tricyclic or cannot take a tricyclic.

C) Relative Contraindications: seizures, eating disorders.

D) Major Side Effects: depends on the drug, but commonly includes dry mouth, nausea, fatigue, constipation, and abnormal bleeding. Serotonin syndrome is also a risk. GI distress, drowsiness, sexual dysfunction less than other classes. Hypertension and glaucoma with venlafaxine. Cardiac issues with venlafaxine and withdrawal symptoms unless tapered. Studies show increased suicidal ideation and attempts in adolescents and young adults. Patients should also be monitored for suicidal ideation and drug abuse.

E) Drug Interactions: drug specific.

F) Laboratory Monitoring: drug specific. Hepatic and renal monitoring, venlafaxine may cause cholesterol or triglyceride increases.

iv. Atypical Antidepressants/Other Agents. May be used for depression; however, are not appropriate for neuropathic pain.

Evidence Statements Regarding Antidepressants: Tricyclics and older agents (e.g., amitriptyline, nortriptyline, doxepin (Adapin, Silenor, Sinequan), desipramine (Norpramin, Pertofrane), imipramine (Tofranil), trazodone (Desyrel, Oleptro))		
Good Evidence	Evidence Statement	Design
	Gabapentin is not superior to amitriptyline.	Randomized crossover trial, Meta-analysis of randomized trials
Some Evidence	Evidence Statement	Design
	In the setting of chronic low back pain with or without radiculopathy, amitriptyline is more effective than pregabalin at reducing pain and disability after 14 weeks of treatment.	Open label parallel randomized clinical trial
	In the setting of neuropathic pain, a combination of morphine plus nortriptyline produces better pain relief than either monotherapy alone, but morphine monotherapy is not superior to nortriptyline monotherapy, and it is possible that it is actually less effective than nortriptyline.	Crossover randomized trial
	A combination of some gabapentin and nortriptyline provides more effective pain relief than monotherapy with either drug, without increasing side effects of either drug.	Randomized crossover trial

Evidence Statements Regarding Antidepressants: Selective Serotonin Nor-epinephrine Reuptake Inhibitor (SSNRI)/Serotonin Nor-epinephrine Reuptake Inhibitors (SNRI).		
Strong Evidence	Evidence Statement	Design
	Duloxetine monotherapy is more effective than placebo in relieving the pain of diabetic peripheral neuropathy; however, monotherapy leads to a 50% pain reduction in only half of patients who receive a therapeutic dose.	Meta-analysis of randomized clinical trials
Good Evidence	Evidence Statement	Design
	In patients with painful diabetic neuropathy who have not had good responses to monotherapy with 60 mg of duloxetine or 300 mg of pregabalin, a clinically important benefit can be achieved by either of two strategies: doubling the dose of either drug, or combining both drugs at the same dose. It is likely that the strategy of combining the two drugs at doses of 60 and 300 mg respectively is more beneficial overall.	Randomized clinical trial

d. **Cannabinoid Products**:

At the time of writing, marijuana use is illegal under federal law and ***cannot be recommended*** for use in this guideline. The Colorado Constitution also states that insurers are not required to pay for marijuana.

Marijuana produces many cannabinoids. Only a few of these substances have been explored in detail. Cannabis is currently procured in Colorado through a registry program. Products are labeled for strength of tetrahydrocannabinol (THC) and cannabidiol (CBD). THC content increased from 2% in 1980 to 8.5% in 2007 and is likely higher in current products. Individual strains and products may have an even higher THC potency, thus making it difficult to correctly determine effects of a specific plant on an individual. Because smoked marijuana reaches its effect quickly, it is thought that most smokers titrate their dosage when using higher potency agents. Edible products increase the time to effect. Generally, products with higher CBD are marketed for chronic pain, epilepsy, and sleep, while products with higher THC are used for the psychoactive effects. Higher CBD products are believed to have better efficacy for chronic pain without creating the psychoactive effects of higher concentrated THC. It has been suggested that elevated THC in the presence of elevated CBD may be associated with less cognitive impairment.

There are a number of studies evaluating the health effects of cannabinoids. Cannabis is associated with the subsequent development of psychosis in adolescents and can cause transient episodes of paranoia and psychotic symptoms in some individuals. It is not known whether or not the association with psychosis is causal. Cannabis increases heart rate in a dose related fashion and some studies suggest it may increase the risk for myocardial infarction and stroke in those less than 55 years. Because smoked marijuana contains many of the same carcinogens as smoked tobacco, it has been postulated that cancer risk may be increased in heavy marijuana smokers. However, the association

has not been established epidemiologically. Cannabis dependence occurs in some users. In some individuals, withdrawal symptoms have been demonstrated after 20 days of high dose use and consist of decreased mood and appetite with irritability, insomnia, anxiety, and depression.

Unlike alcohol and many other sedating drugs of abuse, marijuana does not appear to be lethal for adults at any dose consumed by heavier users when used in isolation, probably because it is not a respiratory depressant. There is only one study that evaluated the use of marijuana in conjunction with chronic opioid management, thus no recommendations can be made to clinicians regarding this combination. Clinicians should keep in mind that there are an increasing number of deaths due to the toxic misuse of opioids with other medications and alcohol. Drug screening is a mandatory component of chronic opioid management. It is appropriate to screen for alcohol and marijuana use and to have a contractual policy regarding both alcohol and marijuana use during chronic opioid management. A recent study of chronic pain patients in Michigan using marijuana found decreased use of opioids and other medication and increased quality of life. Another multi-state study of chronic pain patients on marijuana found a decrease in prescription drug use in states with legal marijuana.

There is good evidence that cannabinoids containing THC are associated with a small to moderate improvement in chronic pain compared to placebo; however, the dosage needed to produce an analgesic effect is undefined and uncertain.

Marijuana is likely to increase work-related driving accidents. It is recommended that less than weekly users wait 6 hours after smoking and 8 hours after eating to drive. Some studies have shown a decrease in reaction time and some association with motor vehicle accidents. However, the risk appears to be less than half the risk of driving under alcohol intoxication. A number of studies suggest that chronic use of THC results in some tolerance to effects on cognitive function.

The contraindications and major side effects for cannabinoid are listed below. No laboratory monitoring is necessary.

i. Relative Contraindications: history of psychosis or risk factors for psychosis, seizure history, cardiovascular risk history, history of addiction, hypersensitivity to cannabinoids.

ii. Major Side Effects: dizziness or fatigue, rapid heart rate, dry mouth, euphoria. Less common effects: paranoia or hallucinations, seizures. A withdrawal reaction can occur when high doses are discontinued. It may include sweating and rhinorrhea with anorexia. Cyclic vomiting (cannabinoid hyperemesis) may occur with daily users.

iii. Psychological Reactions: Intoxication from cannabis frequently results in impaired motor coordination, euphoria, anxiety, sensation of slowed time, impaired judgment, social withdrawal, and hallucinations. Psychotic and anxiety disorders can occur from the use of cannabis. Paranoid ideation ranging from suspiciousness to frank delusions, hallucinations, and depersonalization or derealization has been reported. Use of THC cannabinoids in adolescents may create or unmask schizophrenia**.** Some of these findings may be related to the higher level of THC (delta-9-tetrahydrocannabinol) found in the marijuana currently sold.

There are only two oral pharmaceutical cannabinoid products on the market. These medications were developed initially for nausea due to oncological drug therapy but have been trialed in other settings and are described below. A buccal spray is accepted in Europe and Canada and may be approved by the FDA for use with neuropathic pain. Initial studies were done on neuropathic pain associated with multiple sclerosis. The following pharmaceutical cannabinoid products are ***generally not recommended for pain***, but providers may choose to prescribe them off-label.

i. Dronabinal (Marinol):

A) Description: Dronabinol is a synthetic delta-9-tetrahydrocannabinol, which is also a naturally occurring component of Cannabis sativa L. (marijuana).

B) Indications: As of the time of writing this guideline, formulations of dronabinol have been FDA approved for nausea and vomiting with cancer therapy and weight loss associated with AIDS.

C) Dosing and Time to Therapeutic Effect: 2.5 mg twice a day titrated up to 20 mg total per day.

ii. Nabilone (Cesamet):

A) Description: Nabilone is a synthetic cannabinoid which is also a naturally occurring component of Cannabis sativa L. (marijuana).

B) Indications: As of the time of writing this guideline, formulations of nabilone have been FDA approved for nausea and vomiting with cancer therapy.

C) Dosing and Time to Therapeutic Effect: 1 to 2 mg twice a day titrated up to 6 mg per day.

iii. Nabiximols (Sativex):

A) Description: tetrahydrocannabinol (THC) and cannabidiol (CBD) in a one-to-one ratio, plus other components of cannabis extracts such as terpenoids and flavonoids mixed in a tincture. In the UK, nabiximols has just been approved for spasticity due to multiple sclerosis. In Canada, nabiximols is approved under Health Canada's Notice of Compliance with Conditions (NOC/c) policy for the relief of neuropathic pain and advanced cancer pain. It has not been approved in the United States as of the time of writing this guideline. This drug is not intended to provide the euphoria produced with smoking marijuana.

B) Indications: in other countries, for neuropathic pain and spasticity of multiple sclerosis (MS), cancer pain. There is some evidence that nabiximols can modestly decrease peripheral neuropathic pain with allodynia in some patients who were concomitantly treated with opioids or anticonvulsants; however, the drop-out rate for those who continued the medication longer term was high.

C) Dosing and Time to Therapeutic Effect: spray administered under the tongue. Up to 8 sprays every 3 hours with a maximum of 48 per day.

Evidence Statements Regarding Cannabinoid Products		
Good Evidence	Evidence Statement	Design
	Cannabinoids containing THC are associated with a small to moderate improvement in chronic pain compared to placebo; however, the dosage needed to produce an analgesic effect is undefined and uncertain.	Systematic review and meta-analysis of randomized clinical trials
Some Evidence	Evidence Statement	Design
	Nabiximols can modestly decrease peripheral neuropathic pain with allodynia in some patients who were concomitantly treated with opioids or anticonvulsants; however, the drop-out rate for those who continued the medication longer term was high.	Randomized clinical trial

e. **Hypnotics and Sedatives**: Sedative and hypnotic drugs decrease activity and induce drowsiness and may cause moderate agitation in some individuals. Many other medications, such as antihistamines and antidepressants also produce these side effects. Due to the addiction potential, withdrawal symptoms, and sedating side effects, benzodiazepines and other similar drugs found in this class, are not generally recommended to be initiated or continued if previously prescribed for another condition. There is an increased likelihood of death when opioids and benzodiazepines are used together; therefore, it is recommended that no more than 30 morphine milligram equivalents (MMEs) should be used when hypnotics or sedatives are prescribed. If a patient has been regularly taking these medications prior to the injury, they should be assessed by a psychiatrist to determine the need for continued treatment. When used, extensive patient education should be documented. Some of these medications have long half-lives and sleep apnea can occur or be aggravated on these medications. Many unintentional drug deaths are related to concomitant opioid and benzodiazepine drug use. Retrograde amnesia can occur and is implicated in “sleep driving,” “sleep eating,” and other activities. Nocturnal oximetry or other sleep studies may be appropriate to identify hypoxia.

Most insomnia in chronic pain patients should be managed primarily through behavioral interventions. Medications are a rare secondary measure (refer to Section G.5, Disturbances of Sleep). Episodic use should be limited to 2 weeks.

i. Zaleplon (Sonata), Eszopiclone (Lunesta, Lunestar), Zolpidem (Ambien, Edluar, Intermezzo, Zolpimist).

A) Description: a nonbenzodiazepine hypnotic.

B) Indications: As of the time of this guideline writing, formulations of zaleplon, eszopiclonem, and zolpidem have been FDA approved for insomnia. There is some evidence that zolpidem

does not appreciably enhance the effectiveness of Cognitive Behavioral Therapy.

C) Dosing and Time to Therapeutic Effect: time of onset is 30 to 60 minutes.

D) Major Side Effects: dizziness, dose-related amnesia.

E) Drug Interactions: increases sedative effect of other central nervous system (CNS) depressant drugs.

F) Laboratory Monitoring: none required, based on individual patient history.

ii. Benzodiazepine-based hypnotics include temazepam (Restoril, Temazepam, Gelthix), triazolam (Halcion), and flurazepam (Dalmane). None are recommended because of habit-forming potential, withdrawal symptoms, and sedating side effects. Flurazepam has an active metabolite with a very long half-life, resulting in drug accumulation and next-day somnolence. These medications are ***not recommended*** for use in the working populations.

Evidence Statements Regarding Hypnotics and Sedatives		
Some Evidence	Evidence Statement	Design
	Zolpidem does not appreciably enhance the effectiveness of Cognitive Behavioral Therapy.	Randomized clinical trial

f. **Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)**:
NSAIDs are useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs. The response of the individual injured worker to a specific medication is unpredictable. For this reason, a range of NSAIDs may be tried in each case, with the most effective preparation being continued. Patients should be closely monitored for adverse reactions. The FDA advises that many NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Administration of proton pump inhibitors, Histamine 2 Blockers, or prostaglandin analog misoprostol along with these NSAIDs may reduce the risk of duodenal and gastric ulceration in patients at higher risk for this adverse event (e.g., age > 60, concurrent antiplatelet or corticosteroid therapy). They do not impact possible cardiovascular complications. Due to the cross-reactivity between aspirin and NSAIDs, NSAIDs should not be used in aspirin-sensitive patients, and they should be used with caution in all asthma patients. NSAIDs are associated with abnormal renal function, including renal failure, as well as abnormal liver function. Patients with renal or hepatic disease may need increased dosing intervals with chronic use. Chronic use of NSAIDs is generally ***not recommended*** due to increased risk of cardiovascular events and GI bleeding.

Topical NSAIDs may be more appropriate for some patients as there is some evidence that topical NSAIDs are associated with fewer systemic adverse events

than oral NSAIDs.

NSAIDs may be associated with non-unions. Thus, their use with fractures is questionable.

Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent on the patient's age and general health status and should be within parameters listed for each specific medication. Complete Blood Count (CBC) and liver and renal function should be monitored at least every 6 months in patients on chronic NSAIDs and initially when indicated.

There is no evidence to support or refute the use of oral NSAIDs to treat neuropathic pain conditions.

AHRQ supports the use of NSAIDs for chronic low back pain.

i. Non-Selective Non-Steroidal Anti-Inflammatory Drugs: Includes NSAIDs and acetylsalicylic acid. Serious GI toxicity, such as bleeding, perforation, and ulceration can occur at any time, with or without warning symptoms, in patients treated with traditional NSAIDs. Physicians should inform patients about the signs and/or symptoms of serious GI toxicity and what steps to take if they occur. Anaphylactoid reactions may occur in patients taking NSAIDs. NSAIDs may interfere with platelet function. Fluid retention and edema have been observed in some patients taking NSAIDs.

Time Frames for Non-Selective Non-Steroidal Anti-Inflammatory Drugs	
Optimum Duration	1 week.
Maximum Duration	1 year. Use of these substances long-term (3 days per week or greater) is associated with rebound pain upon cessation.

ii. Selective Cyclo-oxygenase-2 (COX-2) Inhibitors: COX-2 inhibitors differ from the traditional NSAIDs in adverse side effect profiles. The major advantages of selective COX-2 inhibitors over traditional NSAIDs are that they have less GI toxicity and no platelet effects. COX-2 inhibitors can worsen renal function in patients with renal insufficiency; thus, renal function may need monitoring.

There is good evidence that celecoxib (Celebrex) in a dose of 200 mg per day, administered over a long period, does not have a worse cardiovascular risk profile than naproxen at a dose of up to 1000 mg per day or ibuprofen at a dose of up to 2400 mg per day. There is good evidence that celecoxib has a more favorable safety profile than ibuprofen or naproxen with respect to serious GI adverse events, and it has a more favorable safety profile than ibuprofen with respect to renal adverse events. There is an absence of evidence concerning the relative safety of celecoxib at doses greater than 200 mg per day.

COX-2 inhibitors should not be first-line for low risk patients who will be using an NSAID short-term. COX-2 inhibitors are indicated in select patients who do not tolerate traditional NSAIDs. Serious upper GI adverse events can occur even in asymptomatic patients. Patients at high risk for GI bleed include those who use alcohol, smoke, are older than 65 years of age, take corticosteroids or anti-coagulants, or have a longer duration of therapy. Celecoxib is contraindicated in sulfonamide allergic patients.

Time Frames for Selective Cyclo-oxygenase-2 (COX-2) Inhibitors	
Optimum Duration	7 to 10 days.
Maximum Duration	Chronic use is appropriate in individual cases. Use of these substances long-term (3 days per week or greater) is associated with rebound pain upon cessation.

Evidence Statements Regarding Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Good Evidence	Evidence Statement	Design
	Celecoxib in a dose of 200 mg per day, administered over a long period, does not have a worse cardiovascular risk profile than naproxen at a dose of up to 1000 mg per day or ibuprofen at a dose of up to 2400 mg per day.	Randomized noninferiority trial
	Celecoxib has a more favorable safety profile than ibuprofen or naproxen with respect to serious GI adverse events, and it has a more favorable safety profile than ibuprofen with respect to renal adverse events.	
Some Evidence	Evidence Statement	Design
	Topical NSAIDs are associated with fewer systemic adverse events than oral NSAIDs.	Meta-analysis of randomized clinical trials

g. **Opioids**: Opioids are the most powerful analgesics. Their use in acute pain and moderate-to-severe cancer pain is well accepted. Their use in chronic nonmalignant pain, however, is fraught with controversy and lack of scientific research. Deaths in the United States from opioids have escalated in the last 15 years. The CDC states the following in their 2016 guideline for prescribing opioids: Opioid pain medication use presents serious risk, including overdose and opioid use disorder. From 1999 to 2014, more than 165,000 persons died from overdose related to opioid pain medication in the United States. In the past decade, while the death rates for the top leading causes of death such as heart disease and cancer have decreased substantially, the death rate associated with opioid pain medication has increased markedly. Sales of opioid pain medication have increased in parallel with opioid-related overdose deaths. The Drug Abuse Warning Network estimated that >420,000 emergency department visits were

related to the misuse or abuse of narcotic pain relievers in 2011, the most recent year for which data are available. Opioid poisoning has also been identified in work-related populations.

Effectiveness and Side Effects: Opioids include some of the oldest and most effective drugs used in the control of severe pain. The discovery of opioid receptors and their endogenous peptide ligands has led to an understanding of effects at the binding sites of these naturally occurring substances. Most of their analgesic effects have been attributed to their modification of activity in pain pathways within the central nervous system; however, it has become evident that they also are active in the peripheral nervous system. Activation of receptors on the peripheral terminals of primary afferent nerves can mediate anti-nociceptive effects, including inhibition of neuronal excitability and release of inflammatory peptides. Some of their undesirable effects on inhibiting GI motility are peripherally mediated by receptors in the bowel wall.

Most studies show that only around 50% of patients tolerate opioid side effects and receive an acceptable level of pain relief. Depending on the diagnosis and other agents available for treatment, the incremental benefit can be small.

There is strong evidence that in the setting of chronic nonspecific low back pain, the short and intermediate term reduction in pain intensity of opioids, compared with placebo, falls short of a clinically important level of effectiveness. There is an absence of evidence that opioids have any beneficial effects on function or reduction of disability in the setting of chronic nonspecific low back pain. AHRQ found that opioids are effective for treating chronic low back pain. However, the report noted no evidence regarding the long-term effectiveness or safety for chronic opioids.

There is good evidence that opioids are more efficient than placebo in reducing neuropathic pain by clinically significant amounts. There is a lack of evidence that opioids improve function and quality of life more effectively than placebo. There is good evidence that opioids produce significantly more adverse effects than placebo such as constipation, drowsiness, dizziness, nausea, and vomiting. There is a lack of evidence that they are superior to gabapentin or nortriptyline for neuropathic pain reduction.

Patients should have a thorough understanding of the need to pursue many other pain management techniques in addition to medication use in order to function with chronic pain. They should also be thoroughly aware of the side effects and how to manage them. There is strong evidence that adverse events such as constipation, dizziness, and drowsiness are more frequent with opioids than with placebo. Common side effects are drowsiness, constipation, nausea, and possible testosterone decrease with longer term use.

There is some evidence that in the setting of chronic low back pain with disc pathology, a high degree of anxiety or depressive symptomatology is associated with relatively less pain relief in spite of higher opioid dosage than when these symptoms are absent. A study comparing Arkansas Medicaid and a national commercial insurance population found that the top 5% of opioid users accounted for 48-70% of total opioid use. Utilization was increased among those with mental health and substance use disorders and those with multiple pain conditions. Psychological issues should always be screened for and treated in chronic pain patients. Therefore, for the majority of chronic pain patients, chronic opioids are unlikely to provide meaningful increase in function in daily activities.

However, a subpopulation of patients may benefit from chronic opioids when properly prescribed and all requirements from medical management are followed.

Hyperalgesia: Administration of opioid analgesics leads not only to analgesia, but may also lead to a paradoxical sensitization to noxious stimuli. Opioid induced hyperalgesia has been demonstrated in animals and humans using electrical or mechanical pain stimuli. This increased sensitivity to mildly painful stimuli does not occur in all patients and appears to be less likely in those with cancer, clear inflammatory pathology, or clear neuropathic pain. When hyperalgesia is suspected, opioid tapering is appropriate.

Opioid Induced Constipation (OIC): Some level of constipation is likely ubiquitous among chronic opioid users. An observational study of chronic opioid users who also used some type of laxative at least 4 times per week noted that approximately 50% of the patients were dissatisfied and they continue to report stool symptoms. Seventy-one percent used a combination of natural and dietary treatment, 64.3% used over-the-counter laxatives, and 30% used prescription laxatives. Other studies report similar percentages. There are insufficient quality studies to recommend one specific type of laxative over others.

The easiest method for identifying constipation, which is also recommended by a consensus, multidisciplinary group, is the Bowel Function Index. It assesses the patient's impression over the last 7 days for ease of defecation, feeling of incomplete bowel evacuation, and personal judgment re-constipation.

Stepwise treatment for OIC is recommended, and all patients on chronic opioids should receive information on treatment for constipation. Dietary changes increasing soluble fibers are less likely to decrease OIC and may cause further problems if GI motility is decreased. Stool softeners may be tried, but stimulant and osmotic laxatives are likely to be more successful. Osmotic laxatives include lactulose and polyethylene glycol. Stimulants include bisacodyl, sennosides, and sodium picosulfate, although there may be some concern regarding use of stimulants on a regular basis.

Opioid rotation or change in opioids may be helpful for some patients. It is possible that sustained release opioid products cause more constipation than short acting agents due to their prolonged effect on the bowel opioid receptors. Tapentadol is a u-opioid agonist and norepinephrine reuptake inhibitor. It is expected to cause less bowel impairment then oxycodone or other traditional opioids. Tapentadol may be the preferred opioid choice for patients with OIC.

Other prescription medications may be used if constipation cannot adequately be controlled with the previous measures. Naloxegol is a pegylaped naloxone molecule that does not pass the blood brain barrier and thus can be given with opioid therapy. There is good evidence that it can alleviate OIC and that 12.5 mg starting dose has an acceptable side effect profile.

Methylnaltrexone does not cross the blood brain barrier and can be given subcutaneously or orally. It is specifically recommended for opioid induced constipation for patients with chronic non-cancer pain.

Misoprostol is a synthetic prostaglandin E1 agonist and has the side effect of diarrhea in some patients. It also has been tried for opioid induced constipation, although it is not FDA approved for this use.

Lubiprostone is a prostaglandin E1 approved for use in opioid constipation.

Most patients will require some therapeutic control for their constipation. The stepwise treatment discussed should be followed initially. If that has failed and the patient continues to have recurrent problems with experiencing severe straining, hard or lumpy stool with incomplete evacuation, or infrequent stools for 25% of the time despite the more conservative measures, it may be appropriate to use a pharmaceutical agent.

Evidence Statements Regarding Effectiveness and Side Effects of Opioids		
Strong Evidence	Evidence Statement	Design
	In the setting of chronic nonspecific low back pain, the short and intermediate term reduction in pain intensity of opioids, compared with placebo, falls short of a clinically important level of effectiveness.	Systematic review and meta-analysis
	Adverse events such as constipation, dizziness, and drowsiness are more frequent with opioids than with placebo.	
Good Evidence	Evidence Statement	Design
	Opioids are more efficient than placebo in reducing neuropathic pain by clinically significant amounts.	Systematic review and meta-analysis of randomized clinical trials
	Opioids produce significantly more adverse effects than placebo such as constipation, drowsiness, dizziness, nausea, and vomiting.	
	Naloxegol can alleviate opioid induced constipation and that 12.5 mg starting dose has an acceptable side effect profile.	Two identical and simultaneous multicenter randomized double-blind studies
Some Evidence	Evidence Statement	Design
	In the setting of chronic low back pain with disc pathology, a high degree of anxiety or depressive symptomatology is associated with relatively less pain relief in spite of higher opioid dosage than when these symptoms are absent.	Prospective cohort study

Physiologic Responses to Opioids: Physiologic responses to opioids are influenced by variations in genes which code for opiate receptors, cytochrome P450 enzymes, and catecholamine metabolism. Interactions between these gene products significantly affect opiate absorption, distribution, and excretion. Hydromorphone, oxymorphone, and morphine are metabolized through the glucuronide system. Other opioids generally use the cytochrome P450 system. Allelic variants in the mu opiate receptor may cause increased analgesic responsiveness to lower drug doses in some patients. The genetic type can

predict either lower or higher needs for opioids. For example, at least 10% of Caucasians lack the CYP450 2D6 enzyme that converts codeine to morphine. In some cases genetic testing for cytochrome P450 type may be helpful. When switching patients from codeine to other medications, assume the patient has little or no tolerance to opioids. Many gene-drug associations are poorly understood and of uncertain clinical significance. The treating physician needs to be aware of the fact that the patient's genetic makeup may influence both the therapeutic response to drugs and the occurrence of adverse effects.

Adverse Events: Physicians should be aware that deaths from unintentional drug overdoses exceed the number of deaths from motor vehicle accidents in the US. Most of these deaths are due to the use of opioids, usually in combination with other respiratory depressants such as alcohol or benzodiazepines. The risk for out of hospital deaths not involving suicide was also high. The prevalence of drug abuse in the population of patients undergoing pain management varies according to region and other issues. One study indicated that ¼ of patients being monitored for chronic opioid use have abused drugs occasionally, and ½ of those have frequent episodes of drug abuse. Eighty percent of patients admitted to a large addiction program reported that their first use of opioids was from prescribed medication.

There is good evidence that in generally healthy patients with chronic musculoskeletal pain, treatment with long-acting opioids, compared to treatments with anticonvulsants or antidepressants, is associated with an increased risk of death of approximately 69%, most of which arises from non-overdose causes, principally cardiovascular in nature. The excess cardiovascular mortality principally occurs in the first 180 days from starting opioid treatment.

There is some evidence that compared to an opioid dose under 20 MME per day, a dose of 20-50 mg nearly doubles the risk of death, a dose of 50 to 100 mg may increase the risk more than fourfold, and a dose greater than 100 mg per day may increase the risk as much as sevenfold. However, the absolute risk of fatal overdose in chronic pain patients is fairly low and may be as low as 0.04%. There is good evidence that prescription opioids in excess of 200 MME average daily doses are associated with a near tripling of the risk of opioid-related death, compared to average daily doses of 20 MME. Average daily doses of 100-200 mg and doses of 50-99 mg per day may be associated with a doubling of mortality risk, but these risk estimates need to be replicated with larger studies.

Doses of opioids in excess of 120 MME have been observed to be associated with increased duration of disability, even when adjusted for injury severity in injured workers with acute low back pain. Higher doses are more likely to be associated with hypo-gonadism, and the patient should be informed of this risk. Higher doses of opioids also appear to contribute to the euphoric effect. The CDC recommends limiting to 90 MME per day to avoid increasing risk of overdose.

In summary, there is strong evidence that any dose above 50 MME per day is associated with a higher risk of death and 100 mg or greater appears to significantly increase the risk.

Workers who eventually are diagnosed with opioid abuse after an injury are also more likely to have higher claims cost. A retrospective observational cohort study of workers' compensation and short-term disability cases found that those with at least one diagnosis of opioid abuse cost significantly more in days lost from work

for both groups and in overall healthcare costs for the short-term disability groups. About 0.5% of eligible workers were diagnosed with opioid abuse.

Evidence Statements Regarding Opioids and Adverse Events		
Good Evidence	Evidence Statement	Design
	In generally healthy patients with chronic musculoskeletal pain, treatment with long-acting opioids, compared to treatments with anticonvulsants or antidepressants, is associated with an increased risk of death of approximately 69%, most of which arises from non-overdose causes, principally cardiovascular in nature. The excess cardiovascular mortality principally occurs in the first 180 days from starting opioid treatment.	Retrospective matched cohort study
	Prescription opioids in excess of 200 MME average daily doses are associated with a near tripling of the risk of opioid-related death, compared to average daily doses of 20 MME. Average daily doses of 100-200 mg and doses of 50-99 mg per day may be associated with a doubling of mortality risk, but these risk estimates need to be replicated with larger studies.	Nested case-control study with incidence density sampling
Some Evidence	Evidence Statement	Design
	Compared to an opioid dose under 20 MME per day, a dose of 20-50 mg nearly doubles the risk of death, a dose of 50 to 100 mg may increase the risk more than fourfold, and a dose greater than 100 mg per day may increase the risk as much as sevenfold. However, the absolute risk of fatal overdose of in chronic pain patients is fairly low, and may be as low as 0.04%.	Case-cohort study
Summary of Evidence Regarding Opioids and Adverse Events		
Based on the studies with good evidence and some evidence listed above, there is strong evidence that any dose above 50 MME per day is associated with a higher risk of death and 100 mg or greater appears to significantly increase the risk.		

Dependence versus Addiction: The central nervous system actions of these drugs account for much of their analgesic effect and for many of their other actions, such as respiratory depression, drowsiness, mental clouding, reward effects, and habit formation. With respect to the latter, it is crucial to distinguish between two distinct phenomena: dependence and addiction.

- Dependence is a physiological tolerance and refers to a set of disturbances in body homeostasis that leads to withdrawal symptoms, which can be produced with abrupt discontinuation, rapid reduction, decreasing blood levels, and/or by administration of an antagonist.
- Addiction is a primary, chronic, neurobiological disease, with genetic,

psychological, and environmental factors influencing its development and manifestations. It is a behavioral pattern of drug craving and seeking which leads to a preoccupation with drug procurement and an aberrant pattern of use. The drug use is frequently associated with negative consequences.

Dependence is a physiological phenomenon, which is expected with the continued administration of opioids, and need not deter physicians from their appropriate use. Before increasing the opioid dose, the physician should review other possible causes for the decline in analgesic effect. Increasing the dose may not result in improved function or decreased pain. Remember that it is recommended for total morphine milligram equivalents (MME) per day to remain at 50 or below. Consideration should be given to possible new psychological stressors or an increase in the activity of the nociceptive pathways. Other possibilities include new pathology, low testosterone level that impedes delivery of opioids to the central nervous system, drug diversion, hyperalgesia, or abusive use of the medication.

Choice of Opioids: No long-term studies establish the efficacy of opioids over one year of use or superior performance by one type. There is no evidence that one long-acting opioid is more effective than another, or more effective than other types of medications, in improving function or pain. There is some evidence that long-acting oxycodone (Dazidox, Endocodone, ETH-oxydose, Oxycontin, Oxyfast, OxyIR, Percolone, Roxicodone) and oxymorphone have equal analgesic effects and side effects, although the milligram dose of oxymorphone (Opana) is ½ that of oxycodone. There is no evidence that long-acting opioids are superior to short-acting opioids for improving function or pain or causing less addiction. A number of studies have been done assessing relief of pain in cancer patients. A recent systematic review concludes that oxycodone does not result in better pain relief than other strong opioids including morphine and oxymorphone. It also found no difference between controlled release and immediate release oxycodone. There is some evidence that extended release hydrocodone has a small and clinically unimportant advantage over placebo for relief of chronic low back pain among patients who are able to tolerate the drug and that 40% of patients who begin taking the drug do not attain a dose which provides pain relief without unacceptable adverse effects. Hydrocodone ER does not appear to improve function in comparison with placebo. A Cochrane review of oxycodone in cancer pain also found no evidence in favor of the longer acting opioid. There does not appear to be any significant difference in efficacy between once daily hydromorphone and sustained release oxycodone. Nausea and constipation are common for both medications between 26-32%.

There is some evidence that in the setting of neuropathic pain, a combination of morphine plus nortriptyline produces better pain relief than either monotherapy alone, but morphine monotherapy is not superior to nortriptyline monotherapy, and it is possible that it is actually less effective than nortriptyline.

Long-acting opioids should not be used for the treatment of acute, sub-acute, or post-operative pain, as this is likely to lead to drug dependence and difficulty tapering the medication. Additionally, there is a potential for respiratory depression to occur. The FDA requires that manufacturers develop Risk Evaluation and Mitigation Strategies (REMS) for most opioids. Physicians should carefully review the plans or educational materials provided under this program. Clinical considerations should determine the need for long-acting opioids given their lack of evidence noted above.

Addiction and abuse potentials of commonly prescribed opioid drugs may be estimated in a variety of ways, and their relative ranking may depend on the measure which is used. One systematic study of prescribed opioids estimated rates of drug misuse were estimated at 21-29% and addiction at 8-12%. There is good evidence that in the setting of new onset chronic non-cancer pain, there is a clinically important relationship between opioid prescription and subsequent opioid use disorder. Compared to no opioid use, short-term opioid use approximately triples the risk of opioid use disorder in the next 18 months. Use of opioids for over 90 days is associated with very pronounced increased risks of the subsequent development of an opioid use disorder, which may be as much as one hundredfold when doses greater than 120 MME are taken for more than 90 days. The absolute risk of these disorders is very uncertain but is likely to be greater than 6.1% for long duration treatment with a high opioid dose.

Hydrocodone is the most commonly prescribed opioid in the general population and is one of the most commonly abused opioids in the population. However, the abuse rate per 1000 prescriptions is lower than the corresponding rates for extended release oxycodone, hydromorphone (Dilaudid, Palladone), and methadone. Extended release oxycodone appears to be the most commonly abused opioid, both in the general population and in the abuse rate per 1000 prescriptions. Tramadol, by contrast, appears to have a lower abuse rate than for other opioids. Newer drug formulations such as oxymorphone, have been assumed to be relatively abuse-resistant, but their abuse potential is unknown and safety cannot be assumed in the absence of sound data.

Types of opioids are listed below:

i. Buprenorphine: (various formulations) is prescribed as an intravenous injection, transdermal patch, buccal film, or sublingual tablet due to lack of bioavailability of oral agents. Depending upon the formulation, buprenorphine may be indicated for the treatment of pain or for the treatment of opioid dependence (addiction).

   Buprenorphine for Opioid Dependence (addiction): FDA has approved a number of buccal films including those with naloxone and a sublingual tablet to treat opioid dependence (addiction).

   Buprenorphine for Pain: The FDA has approved specific forms of an intravenous and subcutaneous injectable, transdermal patch, and a buprenorphine buccal film to treat pain. However, by law, the transdermal patch and the injectable forms cannot be used to treat opioid dependence (addiction), even by DATA-2000 waivered physicians authorized to prescribe buprenorphine for addiction. Transdermal forms may cause significant skin reaction. Buprenorphine is ***not recommended*** for most chronic pain patients due to methods of administration, reports of euphoria in some patients, and lack of proof for improved efficacy in comparison with other opioids.

   There is insufficient evidence to support or refute the suggestion that buprenorphine has any efficacy in any neuropathic pain condition.

   There is good evidence transdermal buprenorphine is noninferior to oral tramadol in the treatment of moderate to severe musculoskeletal pain arising from conditions like osteoarthritis and low back pain. The

population of patients for whom it is more appropriate than tramadol is not established but would need to be determined on an individual patient basis if there are clear reasons not to use oral tramadol.

In a well done study, 63% of those on buccal buprenorphine achieved a 30% or more decrease in pain at 12 weeks compared to a 47% placebo response. Approximately 40% of the initial groups eligible for the study dropped out during the initial phase when all patients received the drug to test for incompatibility.

There is strong evidence that in patients being treated with opioid agonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidenced by positive urines, are equivalent between methadone and buprenorphine. There is strong evidence that buprenorphine is superior to placebo with respect to retention in treatment, and good evidence that buprenorphine is superior to placebo with respect to positive urine testing for opiates.

There is an adequate meta-analysis supporting good evidence that transdermal fentanyl and transdermal buprenorphine are similar with respect to analgesia and sleep quality, and they are similar with respect to some common adverse effects such as constipation and discontinuation due to lack of effect. However, buprenorphine probably causes significantly less nausea than fentanyl, and it probably carries a lower risk of treatment discontinuation due to adverse events. It is also likely that both transdermal medications cause less constipation than oral morphine.

Overall, due to cost and lack of superiority, buprenorphine is not a front line opioid choice. However, it may be used in those with a history of addiction or at high risk for addiction who otherwise qualify for chronic opioid use. It is also appropriate to consider buprenorphine products for tapering strategies and those on high dose morphine 90 MME

ii. Codeine with Acetaminophen: Some patients cannot genetically metabolize codeine and therefore have no response. Codeine is not generally used on a daily basis for chronic pain. Acetaminophen dose per day should be limited to 2 grams.

iii. Fentanyl (Actiq, Duragesic, Fentora, Sublimaze): is ***not recommended*** for use with musculoskeletal chronic pain patients. It has been associated with a number of deaths and has high addiction potential. Fentanyl should never be used transbuccally in this population. If it is being considered for a very specific patient population, it requires support from a pain specialist.

iv. Meperidine (Demerol): is ***not recommended*** for chronic pain. It and its active metabolite, normeperidine, present a serious risk of seizure and hallucinations. It is not a preferred medication for acute pain as its analgesic effect is similar to codeine.

v. Methadone: requires special precautions given its unpredictably long half-life and non-linear conversion from other opioids such as morphine. It may also cause cardiac arrhythmias due to QT prolongation and has

been linked with a greater number of deaths due to its prolonged half-life. No conclusions can be made regarding differences in efficacy or safety between methadone and placebo, other opioids, or other treatments. There is strong evidence that in patients being treated with opioid agonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidenced by positive urines, are equivalent between methadone and buprenorphine. Methadone should only be prescribed by those with experience in managing this medication. Conversion from another opioid to methadone (or the other way around) can be very challenging, and dosing titration must be done very slowly (no more than every 7 days). Unlike many other opioids, it should not be used on an "as needed" basis, as decreased respiratory drive may occur before the full analgesic effect of methadone is appreciated. If methadone is being considered, genetic screening is appropriate. CYP2B6 polymorphism appears to metabolize methadone more slowly than the usual population and may cause more frequent deaths.

vi. Morphine: may be used in the non-cancer pain population. A study in chronic low back pain suggested that individuals with a greater amount of endogenous opioids will have a lower pain relief response to morphine.

vii. Oxycodone and Hydromorphone: There is no evidence that oxycodone (as oxycodone CR) is of value in treating people with painful diabetic neuropathy, postherpetic neuralgia, or other neuropathic conditions. There was insufficient evidence to support or refute the suggestion that hydromorphone has any efficacy in any neuropathic pain condition. Oxycodone was not associated with greater pain relief in cancer patients when compared to morphine or oxymorphone.

viii. Propoxyphene (Darvon, Davon-N, PP-Cap): has been withdrawn from the market due to cardiac effects including arrhythmias.

ix. Tapentadol (Nucynta): is a mu opioid agonist which also inhibits serotonin and norepinephrine reuptake activity. It is currently available in an intermediate release formulation and may be available as extended release if FDA approved. Due to its dual activity, it can cause seizures or serotonin syndrome, particularly when taken with other SSRIs, SNRIs, tricyclics, or MAO inhibitors. It has not been tested in patients with severe renal or hepatic damage. It has similar opioid abuse issues as other opioid medication; however, it is promoted as having fewer GI side effects, such as constipation. There is good evidence that extended release tapentadol is more effective than placebo and comparable to oxycodone. In that study, the percent of patients who achieved 50% or greater pain relief was: placebo, 18.9%, tapentadol, 27.0%, and oxycodone, 23.3%. There is some evidence that tapentadol can reduce pain to a moderate degree in diabetic neuropathy, average difference 1.4/10 pain scale, with tolerable adverse effects. However, a high quality systematic review found inadequate evidence to support tapentadol to treat chronic pain. Tapentadol is ***not recommended*** as a first line opioid for chronic, subacute, or acute pain due to the cost and lack of superiority over other analgesics. There is some evidence that tapentadol causes less constipation than oxycodone. Therefore, it may

be appropriate for patients who cannot tolerate other opioids due to GI side effects.

x. Tramadol (Rybix, Ryzolt, Ultram):

A) Description: an opioid partial agonist that does not cause GI ulceration or exacerbate hypertension or congestive heart failure. It also inhibits the reuptake of norepinephrine and serotonin which may contribute to its pain relief mechanism. There are side effects similar to opioid side effects and may limit its use. They include nausea, sedation, and dry mouth.

B) Indications: mild to moderate pain relief. As of the time of this guideline writing, formulations of tramadol has been FDA approved for management of moderate to moderately severe pain in adults. This drug has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs. Unlike other pure opioids agonists, there is a ceiling dose to tramadol due to its serotonin activity (usually 300-400 mg per day). There is some evidence that it alleviates neuropathic pain following spinal cord injury. There is inadequate evidence that extended-release tramadol/acetaminophen in a fixed-dose combination of 75mg/650 mg is more effective than placebo in relieving chronic low back pain; it is not more effective in improving function compared to placebo. There is some evidence that tramadol yields a short-term analgesic response of little clinical importance relative to placebo in post-herpetic neuralgia which has been symptomatic for approximately 6 months. However, given the effectiveness of other drug classes for neuropathic pain, tramadol should not be considered a first line medication. It may be useful for patients who cannot tolerate tricyclic antidepressants or other medications.

C) Contraindications: use cautiously in patients who have a history of seizures, who are taking medication that may lower the seizure threshold, or taking medications that impact serotonin reuptake and could increase the risk for serotonin syndrome, such as monoamine oxidase inhibitors (MAO) inhibitors, SSRIs, TCAs, and alcohol. Use with caution in patients taking other potential QT prolonging agents. ***Not recommended*** in those with prior opioid addiction. Has been associated with deaths in those with an emotional disturbance or concurrent use of alcohol or other opioids. Significant renal and hepatic dysfunction requires dosage adjustment.

D) Side Effects: may cause impaired alertness or nausea. This medication has physically addictive properties, and withdrawal may follow abrupt discontinuation.

E) Drug Interactions: opioids, sedating medications, any drug that affects serotonin and/or norepinephrine (e.g., SNRIs, SSRIs, MAOs, and TCAs).

F) Laboratory Monitoring: renal and hepatic function.

Health care professionals and their patients must be particularly conscientious regarding the potential dangers of combining over-the-counter acetaminophen with prescription medications that also contain acetaminophen. Opioid and acetaminophen combination medication are limited due to the acetaminophen component. Total acetaminophen dose per day should not exceed 4 grams per any 24-hour period and is preferably limited to 2 grams per day to avoid possible liver damage.

Indications: The use of opioids is well accepted in treating cancer pain, where nociceptive mechanisms are generally present due to ongoing tissue destruction, expected survival may be short, and symptomatic relief is emphasized more than functional outcomes. In chronic non-malignant pain, by contrast, tissue destruction has generally ceased, meaning that central and neuropathic mechanisms frequently overshadow nociceptive processes. Expected survival in chronic pain is relatively long, and return to a high-level of function is a major goal of treatment. Therefore, approaches to pain developed in the context of malignant pain may not be transferable to chronic non-malignant pain. Opioids are generally not the best choice of medication for controlling neuropathic pain. Tricyclics, SNRIs, and anticonvulsants should be tried before considering opioids for neuropathic pain.

In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs. While maximum efficacy is modest, they may reduce pain sufficiently to permit adequate function. When these drugs do not satisfactorily reduce pain, medications specific to the diagnosis should be used (e.g., neuropathic pain medications as outlined in Section G.10, Medications).

There is good evidence from a prospective cohort study that in the setting of common low back injuries, when baseline pain and injury severity are taken into account, a prescription for more than 7 days of opioids in the first 6 weeks is associated with an approximate doubling of disability one year after the injury. Therefore, prescribing after 2 weeks in a non-surgical case requires a risk assessment. If prescribing beyond 4 weeks, a full opioid trial is suggested including toxicology screen. **Best practice suggests that whenever there is use of opioids for more than 7 days, providers should follow all recommendations for screening and follow-ups of chronic pain use.**

Consultation or referral to a pain specialist behavioral therapist should be considered when the pain persists but the underlying tissue pathology is minimal or absent and correlation between the original injury and the severity of impairment is not clear. Consider consultation if suffering and pain behaviors are present and the patient manifests risk behaviors described below, or when standard treatment measures have not been successful or are not indicated.

A psychological consultation including psychological testing (with validity measures) is indicated for all chronic pain patients as these patients are at high risk for unnecessary procedures and treatment and prolonged recovery.

Many behaviors have been found related to prescription-drug abuse patients. None of these are predictive alone, and some can be seen in patients whose pain is not under reasonable control; however, the behaviors should be considered warning signs for higher risk of abuse or addiction by physicians prescribing chronic opioids. Refer to subsection ix, High Risk Behavior, below.

Recommendations for Opioid Use: When considering opioid use for moderate to

moderately severe chronic pain, a trial of opioids must be accomplished as described below and the patient must have failed other chronic pain management regimes. Physicians should complete the education recommended by the FDA, risk evaluation and mitigation strategies (REMS) provided by drug manufacturing companies.

i. General Indications: There must be a clear understanding that opioids are to be used for a limited term as a trial (see trial indications below). The patient should have a thorough understanding of all of the expectations for opioid use. The level of pain relief is expected to be relatively small, 2 to 3 points on a VAS pain scale, although in some individual patients it may be higher. For patients with a high response to opioid use, care should be taken to assure that there is no abuse or diversion occurring. The physician and patient must agree upon defined functional goals as well as pain goals. If functional goals are not being met, the opioid trial should be reassessed. The full spectrum of side effects should be reviewed. The shared decision making agreement signed by the patient must clarify under what term the opioids will be tapered. Refer to subsection vii.E, on the shared decision making agreement, below.

ii. Therapeutic Trial Indications: A therapeutic trial of opioids should not be employed unless the patient has begun multi-disciplinary pain management. The trial shall last one month. If there is no functional effect, the drug should be tapered.

Chronic use of opioids should not be prescribed until the following have been met:

A) The failure of pain management alternatives by a motivated patient including active therapies, cognitive behavioral therapy, pain self-management techniques, and other appropriate medical techniques.

B) Physical and psychological and/or psychiatric assessment including a full evaluation for alcohol or drug addiction, dependence or abuse, performed by two specialists including the authorized treating physician and a physician or psychologist specialist with expertise in chronic pain. The patient should be stratified as to low, medium, or high risk for abuse based on behaviors and prior history of abuse. High risk patients are those with active substance abuse of any type or a history of opioid abuse. These patients should generally not be placed on chronic opioids. If it is deemed appropriate to do so, physician addiction specialists should be monitoring the care. Moderate risk factors include a history of non-opioid substance abuse disorder, prior trauma particularly sexual abuse, tobacco use, widespread pain, poor pain coping, depression, and dysfunctional cognitions about pain and analgesic medications (see below). Pre-existing respiratory or memory problems should also be considered. Patients with a past history of substance abuse or other psychosocial risk factors should be co-managed with a physician addiction specialist.

C) Risk Factors to Consider:

History of severe post-operative pain
Opioid analgesic tolerance (daily use for months)
Current mixed opioid agonist/antagonist treatment (e.g., buprenorphine, naltrexone)
Chronic pain (either related or unrelated to the surgical site)
Psychological comorbidities (e.g., depression, anxiety, catastrophizing)
History of substance use disorder
History of “all over body pain”
History of significant opioid sensitivities (e.g., nausea, sedation)
History of intrathecal pump use or nerve stimulator implanted for pain control

D) Employment requirements are outlined. The patient’s employment requirements should also be discussed as well as the need to drive. It is generally ***not recommended*** to allow workers in safety sensitive positions to take opioids. Opioid naïve patients or those changing doses are likely to have decreased driving ability. Some patients on chronic opioids may have nominal interference with driving ability; however, effects are specific to individuals. Providers may choose to order certified driver rehabilitation assessment.

E) Urine drug screening for substances of abuse and substances currently prescribed. Clinicians should keep in mind that there are an increasing number of deaths due to the toxic misuse of opioids with other medications and alcohol. Drug screening is a mandatory component of chronic opioid management. It is appropriate to screen for alcohol and marijuana use and have a contractual policy regarding both alcohol and marijuana use during chronic opioid management. Alcohol use in combination with opioids is likely to contribute to death.

F) Review of the Physician Prescription Drug Monitoring Program.

Informed, written, witnessed consent by the patient including the aspects noted above. Patients should also be counseled on safe storage and disposal of opioids.

G) The trial, with a short-acting agent, should document sustained improvement of pain control, at least a 30% reduction, and of functional status, including return-to-work and/or increase in activities of daily living. It is necessary to establish goals which are specific, measurable, achievable, and relevant prior to opioid trial or adjustment to measure changes in activity/function. Measurement of functional goals may include patient completed validated functional tools such as those recommended by the Division as part of Quality Performance and Outcomes Payments (QPOP, see Rule 18-8) and/or the Patient Specific Functional Scale can provide useful additional confirmation. Frequent follow-up at least every 2 to 4 weeks may be necessary to titrate dosage and assess clinical efficacy.

iii. On-Going, Long-Term Management after a successful trial should include:

A) Prescriptions from a single practitioner;

B) Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects; full review at least every 3 months;

C) Ongoing effort to gain improvement of social and physical function as a result of pain relief;

D) Review of the Physician Drug Monitoring Program (PDMP);

E) Shared decision making agreement detailing the following:

- Side effects anticipated from the medication;
- Requirement to continue active therapy;
- Need to achieve functional goals including return to work for most cases;
- Reasons for termination of opioid management, referral to addiction treatment, or for tapering opioids (tapering is usually for use longer than 30 days). Examples to be included in the contract include, but are not limited to:
  - Diversion of medication
  - Lack of functional effect at higher doses
  - Non-compliance with other drug use
  - Drug screening showing use of drugs outside of the prescribed treatment or evidence of non-compliant use of prescribed medication
  - Requests for prescriptions outside of the defined time frames
  - Lack of adherence identified by pill count, excessive sedation, or lack of functional gains
  - Excessive dose escalation with no decrease in use of short-term medications
  - Apparent hyperalgesia
  - Shows signs of substance use disorder (including but not limited to work or family problems related to opioid use, difficulty controlling use, craving)

- Experiences overdose or other serious adverse event
- Shows warning signs for overdose risk such as confusion, sedation, or slurred speech

Patient Agreements should be written at a 6th grade reading level to accommodate the majority of patients.

F) Use of drug screening initially, randomly at least once a year and as deemed appropriate by the prescribing physician. Drug screening is suggested for any patients who have been receiving opioids for 8 to 90 days. A discussion regarding how screens positive for marijuana or alcohol will be handled should be included in the opioid contract. The concept of opioid misuse encompasses a variety of problems distinct from the development of addiction, such as nonmedical use, diversion, consultation with multiple prescribers, and unintentional overdose. In office only drug screening is insufficient as it does not identify metabolites of drugs prescribed.

Urine testing, when included as one part of a structured program for pain management, has been observed to reduce abuse behaviors in patients with a history of drug misuse. Clinicians should keep in mind that there are an increasing number of deaths due to the toxic misuse of opioids with other medications and alcohol. Drug screening is a mandatory component of chronic opioid management. Clinicians should determine before drug screening how they will use knowledge of marijuana use. It is appropriate to screen for alcohol and marijuana use and have a contractual policy regarding both alcohol and marijuana use during chronic opioid management. Alcohol use in combination with opioids is likely to contribute to death. From a safety standpoint, it is more important to screen for alcohol use than marijuana use as alcohol is more likely to contribute to unintended overdose***.***

Physicians should recognize that occasionally patients may use non-prescribed substances because they have not obtained sufficient relief on the prescribed regime.

Although drug screens done for chronic pain management should not be routinely available to employers, as screens are part of the treatment record to which employers have limited access, patients should be aware that employers might obtain the records through attorneys or the insurer.

G) Chronic use limited to 2 oral opioids.

H) Transdermal medication use, other than buprenorphine, is generally ***not recommended***.

I) Use of acetaminophen-containing medications in patients with liver disease should be limited, including over-the-counter medications. Acetaminophen dose should not exceed 4 grams

per day for short-term use or 2-3 grams/day for long-term use in healthy patients. A safer chronic dose may be 1800mg/day.

J) Continuing review of overall therapy plan with regard to non-opioid means of pain control and functional status.

K) Tapering of opioids may be necessary for many reasons including the development of hyperalgesia, decreased effects from an opioid, lack of compliance with the opioid contract, or intolerance of side effects. Some patients appear to experience allodynia or hyperalgesia on chronic opioids. This premise is supported by a study of normal volunteers who received opioid infusions and demonstrated an increase in secondary hyperalgesia. Options for treating hyperalgesia include withdrawing the patient from opioids and reassessing their condition. In some cases, the patient will improve when off of the opioid. In other cases, another opioid may be substituted.

Tapering may also be appropriate by patient choice, to accommodate “fit-for-duty” demands, prior to major surgery to assist with post-operative pain control, to alleviate the effects of chronic use including hypogonadism, medication side effects, or in the instance of a breach of drug agreement, overdose, other drug use aberrancies, or lack of functional benefit. It is also appropriate for any of the tapering criteria listed in section E above.

Generally tapering can be accomplished by decreasing the dose 10% per week. This will generally take 6 to 12 weeks and may need to be done one drug class at a time. Behavioral support is required during this service. Tapering may occur prior to MMI or in some cases during maintenance treatment.

L) Medication assisted treatment with buprenorphine or methadone may be considered for opioid abuse disorder, in addition to behavioral therapy. Refer to Section G.12, Opioid Addiction Treatment.

M) Inpatient treatment may be required for addiction or opioid tapering in complex cases. Refer to Section G.9, Interdisciplinary Rehabilitation Programs, for detailed information on inpatient criteria.

iv. Relative Contraindications: Extreme caution should be used in prescribing controlled substances for workers with one or more “relative contraindications.” Consultation with a pain or addiction specialist may be useful in these cases.

A) History of alcohol or other substance abuse, or a history of chronic, benzodiazepine use.

B) Sleep apnea: If patient has symptoms of sleep apnea, diagnostic tests should be pursued prior to chronic opioid use.

C) Off work for more than 6 months with minimal improvement in function from other active therapy.

D) Severe personality disorder or other known severe psychiatric disease per psychiatrist or psychologist.

E) Monitoring of behavior for signs of possible substance abuse indicating an increased risk for addiction and possible need for consultation with an addiction specialist.

v. High Risk Behavior: The following are high risk warning signs for possible drug abuse or addiction. Patients with these findings may need a consultation by a physician experienced in pain management and/or addiction. Behaviors in the left hand column are warning signs, not automatic grounds for dismissal, and should be followed up by a reevaluation with the provider. Repeated behaviors in the left hand column may be more indicative of addiction. Behaviors in the right hand column should be followed by a substance abuse evaluation.

Less suggestive for addiction but are increased in depressed patients	More suggestive of addiction and are more prevalent in patients with substance use disorder
• Frequent requests for early refills; claiming lost or stolen prescriptions • Opioid(s) used more frequently, or at higher doses than prescribed • Using opioids to treat non-pain symptoms • Borrowing or hoarding opioids • Using alcohol or tobacco to relieve pain • Requesting more or specific opioids • Recurring emergency room visits for pain • Concerns expressed by family member(s) • Unexpected drug test results • Inconsistencies in the patient's history	• Buying opioids on the street; stealing or selling drugs • Multiple prescribers ("doctor shopping") • Trading sex for opioids • Using illicit drugs, + urine drug tests for illicit drugs • Forging prescriptions • Aggressive demands for opioids • Injecting oral/topical opioids • Signs of intoxication (ETOH odor, sedation, slurred speech, motor instability, etc.)

Both daily and monthly users of nicotine were at least 3 times more likely to report non-medical use of opioid in the prior year. At least one study

has demonstrated a prevalence of smokers and former smokers among those using opioids and at higher doses compared to the general population. It also appeared that smokers and former smokers used opioids more frequently and in higher doses than never smokers. Thus, tobacco use history may be a helpful prognosticator.

In one study, four specific behaviors appeared to identify patients at risk for current substance abuse: increasing doses on their own, feeling intoxicated, early refills, and oversedating oneself. A positive test for cocaine also appeared to be related.

One study found that half of patients receiving 90 days of continuous opioids remained on opioids several years later and that factors associated with continual use included daily opioid greater than 120 MME prior opioid exposure, and likely opioid misuse.

One study suggested that those scoring at higher risk on the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), also had greater reductions in sensory low back pain and a greater desire to take morphine. It is unclear how this should be viewed in practice.

vi. Dosing and Time to Therapeutic Effect: Oral route is the preferred route of analgesic administration because it is the most convenient and cost-effective method of administration. Transbuccal administration should be avoided other than for buprenorphine. A daily dosage above 50 MME may be appropriate for certain patients. However, when the patient's dosage exceeds 50 MME per day and/or the patient is sedentary with minimal function, consideration should be given to lowering the dosage. Some patients may require dosages above 90 MME per day. However, if the patient reaches a dosage above 90 MME per day, it is appropriate to taper or refer to a pain or addiction specialist. The provider should also adhere to all requirements in this guideline and closely monitor the patient as this is considered a high risk dosage. In some cases buprenorphine may be a preferred medication for pain control in those patients. Consultation may be necessary.

vii. Major Side Effects: There is great individual variation in susceptibility to opioid-induced side effects and clinicians should monitor for these potential side effects. Common initial side-effects include nausea, vomiting, drowsiness, unsteadiness, and confusion. Occasional side-effects include dry mouth, sweating, pruritus, hallucinations, and myoclonus. Rare side effects include respiratory depression and psychological dependence. Constipation and nausea/vomiting are common problems associated with long-term opioid administration and should be anticipated, treated prophylactically, and monitored constantly. Stool softeners, laxatives, and increased dietary fluid may be prescribed. Refer to Section G.10.g, Opioid Induced Constipation. Chronic sustained release opioid use is associated with decreased testosterone in males and females and estradiol in pre-menopausal females. Patients should be asked about changes in libido, sexual function, and fatigue.

viii. Naloxone: may be prescribed when any risk factors are present. The correct use of Naloxone should be discussed with the patient and family.

ix. Benzodiazepines: should not be prescribed when opioids are used. Refer to Section G.10.e, Hypnotics and Sedatives, for more information.

x. Sedation: driving and other tasks – Although some studies have shown that patients on chronic opioids do not function worse than patients not on medication, caution should be exerted, and patients should be counseled never to mix opioids with the use of alcohol or other sedating medication. When medication is increased or trials are begun, patients should not drive for at least 5 days. Chronic untreated pain and disordered sleep can also impair driving abilities.

xi. Drug Interactions: Patients receiving opioid agonists should not be given a mixed agonist-antagonist such as pentazocine (Talacen, Talwin) or butorphanol (Stadol) because doing so may precipitate a withdrawal syndrome and increase pain.

All sedating medication, especially benzodiazepines, should be avoided or limited to very low doses. Over-the-counter medications such as antihistamines, diphenhydramine, and prescription medications such as hydroxyzine (Anx, Atarax, Atazine, Hypam, Rezine, Vistaril) should be avoided except when being used to manage withdrawal during tapering of opioids. Alcohol should not be used.

xii. Recommended Laboratory Monitoring: Primary laboratory monitoring is recommended for acetaminophen/aspirin/NSAIDs combinations (renal and liver function, blood dyscrasia), although combination opioids are ***not recommended*** for long-term use. Morphine and other medication may require renal testing and other screening.

xiii. Sleep Apnea Testing: Both obstructive and central sleep apnea are likely to be exaggerated by opioid use or may occur secondary to higher dose chronic opioid use and combination medication use, especially benzodiazepines and sedative hypnotics. Patients should be questioned about sleep disturbance and family members or sleeping partners questioned about loud snoring or gasping during sleep. If present, qualified sleep studies and sleep medicine consultation should be obtained. Portable sleep monitoring units are generally not acceptable for diagnosing primary central sleep apnea. Type 3 portable units with 2 airflow samples and an 02 saturation device may be useful for monitoring respiratory depression secondary to opioids, although there are no studies on this topic.

xiv. Regular consultation of the Prescription Drug Monitoring Program (PDMP): Physicians should review their patients on the system whenever drug screens are done. This information should be used in combination with the drug screening results, functional status of the patient, and other laboratory findings to review the need for treatment and level of treatment appropriate for the patient. There is a separate billing code created by the DOWC to cover this service. Refer to Rule 18, Medical Fee Schedule.

xv. Addiction: If addiction occurs, patients will require treatment. Refer to Section G.12, Opioid Addiction Treatment. After detoxification, they may need long-term treatment with naltrexone (Depade, ReVia), an antagonist which can be administered in a long-acting form or

buprenorphine which requires specific education per the Drug Enforcement Agency (DEA).

xvi. Potentiating Agents: There is some evidence that dextromethorphan does not potentiate the effect of morphine opioids and therefore is ***not recommended*** to be used with opioids.

Evidence Statements Regarding Choice of Opioids, Indications, and Recommendations for Use		
Strong Evidence	Evidence Statement	Design
	In patients being treated with opioid agonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidenced by positive urines, are equivalent between methadone and buprenorphine.	Meta-analysis of randomized clinical trials
	Buprenorphine is superior to placebo with respect to retention in treatment.	
Good Evidence	Evidence Statement	Design
	Buprenorphine is superior to placebo with respect to positive urine testing for opiates.	Meta-analysis of randomized clinical trials
	In the setting of new onset chronic noncancer pain, there is a clinically important relationship between opioid prescription and subsequent opioid use disorder. Compared to no opioid use, short-term opioid use approximately triples the risk of opioid use disorder in the next 18 months. Use of opioids for over 90 days is associated with very pronounced increased risks of the subsequent development of an opioid use disorder, which may be as much as one hundredfold when doses greater than 120 MME are taken for more than 90 days. The absolute risk of these disorders is very uncertain but is likely to be greater than 6.1% for long duration treatment with a high opioid dose.	Retrospective cohort study using claims data from a large health care database
	Extended release tapentadol is more effective than placebo and comparable to oxycodone. The percent of patients who achieved 50% or greater pain relief was: placebo, 18.9%, tapentadol, 27.0%, and oxycodone, 23.3%.	Randomized clinical trial
	Transdermal buprenorphine is noninferior to oral tramadol in the treatment of moderate to severe musculoskeletal pain arising from conditions like osteoarthritis and low back pain. The population of patients for whom it is more appropriate than tramadol is not established but would need to be determined on an individual patient basis if there are clear reasons not to use oral tramadol.	Phase III noninferiority trial

Evidence Statements Regarding Choice of Opioids, Indications, and Recommendations for Use		
Good Evidence, Continued	Transdermal fentanyl and transdermal buprenorphine are similar with respect to analgesia and sleep quality, and they are similar with respect to some common adverse effects such as constipation and discontinuation due to lack of effect. However, buprenorphine probably causes significantly less nausea than fentanyl, and it probably carries a lower risk of treatment discontinuation due to adverse events. It is also likely that both transdermal medications cause less constipation than oral morphine.	Network meta-analysis of randomized clinical trials
	In the setting of common low back injuries, when baseline pain and injury severity are taken into account, a prescription for more than seven days of opioids in the first 6 weeks is associated with an approximate doubling of disability one year after the injury.	Prospective cohort study
Some Evidence	Evidence Statement	Design
	Long-acting oxycodone (Dazidox, Endocodone, ETH-oxydose, Oxycontin, Oxyfast, OxyIR, Percolone, Roxicodone) and oxymorphone have equal analgesic effects and side effects, although the milligram dose of oxymorphone (Opana) is ½ that of oxycodone.	Randomized clinical trial
	Extended release hydrocodone has a small and clinically unimportant advantage over placebo for relief of chronic low back pain among patients who are able to tolerate the drug and that 40% of patients who begin taking the drug do not attain a dose which provides pain relief without unacceptable adverse effects. Hydrocodone ER does not appear to improve function in comparison with placebo.	Randomized trial with a screening period of 7-14 days followed by an open-label titration period of up to 6 weeks followed by a double blind treatment period of up to 12 weeks
	In the setting of neuropathic pain, a combination of morphine plus nortriptyline produces better pain relief than either monotherapy alone, but morphine monotherapy is not superior to nortriptyline monotherapy, and it is possible that it is actually less effective than nortriptyline.	Crossover randomized trial
	Tapentadol can reduce pain to a moderate degree in diabetic neuropathy, average difference 1.4/10 pain scale, with tolerable adverse effects.	Randomized clinical trial
	Tapentadol causes less constipation than oxycodone.	Meta-analysis of randomized clinical trials
	Dextromethorphan does not potentiate the effect of morphine opioids and therefore is ***not recommended*** to be used with opioids.	Three randomized clinical trials

Evidence Statements Regarding Choice of Opioids, Indications, and Recommendations for Use		
Some Evidence, Continued	Tramadol alleviates neuropathic pain following spinal cord injury.	Randomized clinical trial
	Tramadol yields a short-term analgesic response of little clinical importance relative to placebo in postherpetic neuralgia which has been symptomatic for approximately 6 months.	Randomized clinical trial

h. **Post-Operative Pain Management**: Proper post-operative pain management may avoid overuse and misuse of opioids. A recent practice guideline strongly recommends a multi-modal approach to post-operative pain. Suggestions include use of TENS, cognitive behavioral therapy, use of oral medication over parenteral medication and patient controlled analgesia when parenteral medication is used, use of NSAIDS (for appropriate procedures) or acetaminophen, gabapentin or pregabalin may also be used, and peripheral regional anesthesia when appropriate. Ketamine is also suggested for major surgeries, patients with high opioid tolerance or those who have difficulty tolerating opioids. However, ketamine does have side effects such as hallucination and nightmares. It is ***not recommended*** as a first line medication for most patients.

Pre-operative psychological preparation or neuroscience education may improve post-operative pain management. Pre-operative cognitive-behavioral therapy or other psychological intervention likely improves in-hospital mobilization and analgesic use for lumbar spinal fusion patients and for other surgical patients. One randomized study compared patients who received one session of pre-operative pain neuroscience education from physical therapist prior to lumbar discectomy and those who did not. There was no change in the primary outcomes from surgery. However, significant changes occurred in secondary outcomes which included preparation for surgery, surgery meeting their expectations, and a 45% decrease in health expenditure for the follow up year. Thus, pre-operative pain neuroscience education may prove a useful addition for any patient prior to surgical decisions. Refer to Section G.18, Therapy-Active, for a description of Pain Neuroscience Education. Optimal surgical outcomes are more likely when the patient commits to a post-operative active therapy program.

Generally, post-operative pain management is under the supervision of the surgeon and hospitalist with the goal of returning to the pre-operative level of pharmaceutical management. For a specific procedure's post-operative management, refer to the related medical treatment guideline.

Surgical procedures may be necessary for patients already taking chronic opioids, and they may encounter difficulty with pain control post-operatively. These patients will usually require higher doses of opioids during their post-operative phase and may benefit the most from multimodal therapy and/or ketamine as described in Section G.10.k., Topical Drug Delivery. It is strongly advised that physicians consult a pain specialist or addiction specialist when caring for post-operative patients with a history of substance abuse or previous addiction. Refer to Section G.10.h, Post-Operative Pain Management.

i. **Skeletal Muscle Relaxants**: are most useful for acute musculoskeletal injury or exacerbation of injury. Refer to Section G.10.e, Hypnotics and Sedatives, for

benzodiazepines. Chronic use of benzodiazepines or any muscle relaxant is ***not recommended*** due to their habit-forming potential, seizure risk following abrupt withdrawal, and documented contribution to deaths of patients on chronic opioids due to respiratory depression.

i. Baclofen (intrathecal):

A) Description: may be effective due to stimulation of Gamma Aminobutyric Acid (GABA) receptors.

B) Indications: pain from muscle rigidity. As of the time of this guideline writing, formulations of baclofen injection have been FDA approved for the management of severe spasticity of a spinal cord or cerebral origin.

C) Side Effects: exacerbation of psychotic disorders, may precipitate seizures in epileptics, dry mouth, and sexual dysfunction.

D) Recommended Laboratory Monitoring: renal and hepatic function.

E) Caution: Abrupt discontinuation of baclofen can precipitate a withdrawal syndrome and has been seen with both low and high doses. The most common side effects of baclofen withdrawal include pruritis, tremor, and mood disturbance. In extreme circumstances, seizures, muscle rigidity (resembling neuroleptic malignant syndrome), and even death can occur.

ii. Cyclobenzaprine (Amrix, Fexmid, Flexeril):

A) Description: structurally related to tricyclics.

B) Indications: acute exacerbated chronic pain associated with muscle spasm. As of the time of this guideline writing, formulations of this drug are FDA approved as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. It should only be used for short periods (less than 2 weeks) because of lack of evidence for effectiveness with prolonged use.

C) Major Contraindications: cardiac dysrhythmias.

D) Dosing and Time to Therapeutic Effect: variable, onset of action is 1 hour.

E) Major Side Effects: sedation, anticholinergic, blurred vision. Patients should also be monitored for suicidal ideation and drug abuse.

F) Drug Interactions: contraindicated for use with MAO inhibitors; interacts with tramadol, duloxetine, escitalopram, and fluoxetine. Likely interactions with other SSRIs and SNRIs. Drug

interactions are similar to those for tricyclics. Refer also to information on tricyclics in Section G.10, Medications.

G) Recommended Laboratory Monitoring: hepatic and renal function.

iii. Carisoprodol (Soma, Soprodal, Vanadom): This medication should not be used in chronic pain patients due to its addictive nature secondary to the active metabolite meprobamate.

iv. Metaxalone (Skelaxin):

A) Description: central acting muscle relaxant.

B) Indications: acute exacerbated chronic pain associated with muscle spasm. As of the time of this guideline writing, formulations of this drug are FDA approved as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. It should only be used for short periods (less than 2 weeks) because of lack of evidence for effectiveness with prolonged use.

C) Major Contraindications: significantly impaired renal or hepatic disease, pregnancy, and disposition to drug induced hemolytic anemia.

D) Dosing and Time to Therapeutic Effect: 800 mg, 3 to 4 times per day, onset of action 1 hour.

E) Major Side Effects: sedation, hematologic abnormalities.

F) Drug Interactions: other sedating drugs (e.g., opioids, benzodiazepines).

G) Recommended Laboratory Monitoring:hepatic function, CBC.

v. Methocarbamol:

A) Description: central action muscle relaxant.

B) Indications: muscle spasm.

C) Major Contraindications: hypersensitivity, possible renal compromise.

D) Dosing and Time to Therapeutic Effect: 1500 mg. 4 times per day. Longer dosing 4000 to 4500 mg per day.

E) Major Side Effects: decreased cognition, light headedness, GI effects among other.

F) Drug Interactions: alcohol and other CNS depressants.

vi. Tizanidine (Zanaflex):

A) Description: alpha 2 adrenergic agonist.

B) Indications: true centrally mediated spasticity, musculoskeletal disorders. As of the time of this guideline writing, formulations of tizanidine have been FDA approved for the management of spasticity in spinal cord injury and multiple sclerosis.

C) Major Contraindications: concurrent use with ciprofloxacin (Cipro, Proquin) or fluvoxamine (Luvox); or hepatic disease.

D) Dosing and Time to Therapeutic Effect: 4 mg/day orally and gradually increase in 2-4 mg increments on an individual basis over 2 to 4 weeks; maintenance, 8 mg orally every 6 to 8 hr (max dose 36 mg/day).

E) Major Side Effects: hypotension, sedation, hepatotoxicity, hallucinations and psychosis, dry mouth.

F) Drug Interactions: Alcohol can increase sedation, and concurrent use with ciprofloxacin or fluvoxamine is contraindicated. Several other medications increase tizanidine plasma concentrations (e.g., oral contraceptives, verapamil, and cimetidine). Use with caution with other alpha agonists and other antihypertensives as they may increase the risk of hypotension.

G) Laboratory Monitoring: hepatic function, blood pressure.

j. **Smoking Cessation Medications and Treatment**: Tobacco dependence is chronic and may require repeated attempts to quit. All smoking cessation programs should be accompanied by behavioral support which may include practical counseling sessions and social support, which usually includes telephone follow-up. A variety of medications have been used including Bupropion SR, nicotine patches, gum, inhaler, lozenges or nasal spray, and varenicline. When nicotine supplements are used, cotinine testing will be positive. Urine anabasine or exhaled carbon monoxide 5 ppm or less may be used to check tobacco abstinence.

There is some evidence that among adults motivated to quit smoking, 12 weeks of open-label treatment including counseling and one of the following: nicotine patch, varenicline, or combination nicotine replacement therapy (nicotine patch and nicotine lozenge) are equally effective in assisting motivated smokers to quit smoking over a period of one year.

There is some evidence that among adults motivated to quit smoking, abrupt smoking cessation is the more effective method that leads to lasting abstinence over a period of 4 weeks to 6 months compared to gradual cessation, even for smokers who initially prefer to quit by gradual reduction.

Evidence Statements Regarding Smoking Cessation Medications and Treatment		
Some Evidence	Evidence Statement	Design
	Among adults motivated to quit smoking, 12 weeks of open-label treatment including counseling and one of the following: nicotine patch, varenicline, or combination nicotine replacement therapy (nicotine patch and nicotine lozenge) are equally effective in assisting motivated smokers to quit smoking over a period of one year.	Randomized clinical trial
	Among adults motivated to quit smoking, abrupt smoking cessation is the more effective method that leads to lasting abstinence over a period of 4 weeks to 6 months compared to gradual cessation, even for smokers who initially prefer to quit by gradual reduction.	Randomized controlled non-inferiority trial

k. Topical Drug Delivery:

i. Description: topical creams and patches may be an alternative treatment of localized musculoskeletal and neuropathic disorders. If ordered compounded topicals are reviewed by the payer, the payer must evaluate and approve or deny each ingredient separately.

ii. Indications: neuropathic pain for many agents; episodic use of NSAIDs and salicylates for joint pain or musculoskeletal disorders. All topical agents should be used with strict instructions for application as well as maximum number of applications per day to obtain the desired benefit and avoid potential toxicity.

iii. Dosing and Time to Therapeutic Effect: all topical agents should be prescribed with clear instructions for application and maximum number of applications per day to obtain the desired benefit and avoid potential toxicity. For most patients, the effects of long-term use are unknown. Thus, episodic use may be preferred for some agents.

iv. Side Effects: localized skin reactions may occur, depending on the medication agent used.

v. Topical Agents:

A) Capsaicin: As of the time of this guideline writing, formulations of capsaicin have been FDA approved for management of pain associated with post-herpetic neuralgia. Capsaicin offers a safe and effective alternative to systemic NSAID therapy. Although it is quite safe, effective use of capsaicin is limited by the local stinging or burning sensation that typically dissipates with regular use, usually after the first 7 to 10 days of treatment. Patients should be advised to apply the cream on the affected area with a plastic glove or cotton applicator and to avoid inadvertent contact with eyes and mucous membranes.

There is good evidence that low dose capsaicin (0.075%)

applied 4 times per day will decrease pain up to 50%. There is strong evidence that a single application of 8% capsaicin is more effective than a control preparation of 0.04% capsaicin for up to 12 weeks. However, there may be a need for frequent application, and it is not known whether subsequent applications of capsaicin are likely to be as effective as the first application. There is some evidence that in patients who are being treated with capsaicin 8% patches, two methods of pre-treatment are equally effective in controlling application pain and in enabling patients to tolerate the patch: topical 4% lidocaine cream applied to the area for one hour before placement of the capsaicin patch and 50 mg oral tramadol taken 30 minutes before patch placement.

B) Clonidine: There is good evidence that topical clonidine gel 0.1% is likely to alleviate pain from diabetic peripheral neuropathy in patients who display a nociceptive response to the application of 0.1% capsaicin applied to the pretibial area. It is likely that patients who do not display a pain response to pretibial capsaicin are not likely to have a clinically meaningful analgesic response to clonidine gel. It is unknown if this screening test applies to other types of neuropathic pain. Clonidine gel may be used for neuropathic pain.

C) Ketamine and Tricyclics: Topical medications, such as the combination of ketamine and amitriptyline, have been proposed as an alternative treatment for neuropathic disorders including CRPS. A study using a 10% concentration showed no signs of systemic absorption. This low-quality study demonstrated decreased allodynia at 30 minutes for some CRPS patients. However, as of the time of this guideline writing, neither tricyclic nor ketamine topicals are FDA approved for topical use in neuropathic pain. Furthermore, there is good evidence that neither 2% topical amitriptyline nor 1% topical ketamine reduces neuropathic pain syndromes. Despite the lack of evidence, it is physiologically possible that topical tricyclics and a higher dose of ketamine could have some effect on neuropathic pain. Other less expensive topicals and compounds, including over-the-counter, should be trialed before more expensive compounds are ordered. The use of topical tricyclics and/or ketamine should be limited to patients with neuritic and/or sympathetically mediated pain with documented supporting objective findings such as allodynia and/or hyperalgesia. Continued use of these agents beyond the initial prescription requires documentation of effectiveness, including functional improvement, and/or decreased use of other medications, particularly decreased use of opioids or other habituating medications.

D) Lidocaine: As of the time of this guideline writing, formulations of lidocaine (patch form) have been FDA approved for pain associated with post-herpetic neuralgia. Evidence is mixed for long-term use of lidocaine topically. Physicians should always take into account the blood level that may be achieved with topical use as toxic levels have been reported and there is variability and systemic absorption among individuals. There is

good evidence that lidocaine 5% plasters, applied for up to 12 hours to the lower extremities of patients with post-herpetic neuralgia and diabetic painful neuropathy, is non-inferior to pregabalin for the same indications. The topical lidocaine is associated with significantly fewer drug-related adverse events over 4 weeks of observation. There is some evidence that a 5% lidocaine patch may be used as a secondary option for patients with focal neuropathic pain. A 30 to 50% pain reduction may be achieved in those who tolerate the patch. Up to three patches may be used simultaneously for 12 hours per day. It should be applied only to intact skin. Metered dose 8% pump sprays have also been used and usually require a three times per day reapplication. There is some evidence that the 8% sprays are effective for short-term, 2 week use. However, the effects of long-term use are unknown.

E) Topical Salicylates and Nonsalicylates: have been shown to be effective in relieving pain in acute musculoskeletal conditions and single joint osteoarthritis. Topical salicylate and nonsalicylates achieve tissue levels that are potentially therapeutic, at least with regard to COX inhibition.

There is insufficient evidence to support the use of topical rubefacients containing salicylates for acute injuries or chronic conditions. They seem to be relatively well tolerated in the short-term, based on limited data. The amount and quality of the available data mean that uncertainty remains about the effects of salicylate-containing rubefacients.

There is good evidence that diclofenac gel (Voltaren, Solaraze) reduces pain and improves function in mild-to-moderate hand osteoarthritis. There is good evidence that topical diclofenac and ketoprofen are more effective than placebo preparations for purposes of relieving pain attributable to knee osteoarthritis. There is good evidence that topical NSAIDs probably reduce the risk of GI adverse effects by approximately 1/3 compared to oral NSAIDs. Topical diclofenac does not appear to affect the anti-platelet properties of aspirin unlike the oral version. The topical solution of 2% sodium diclofenac applied thrice a day is equal to 1.5% 4 times per day.

Diclofenac gel has been FDA approved for acute pain due to minor strains, pains, and contusions and for relief of pain due to osteoarthritis of the joints amenable to topical treatment, such as those of the knees and hands (refer to the Division's Cumulative Trauma Conditions Medical Treatment Guideline). It is likely that other NSAIDs would also be effective topically. Thus, topical NSAIDs are permitted when patients show functional improvement.

Other than local skin reactions, the side effects of therapy are minimal, although not non-existent. The usual contraindications to use of these compounds needs to be considered. Local skin reactions are rare and systemic effects are even less common. Their use in patients receiving warfarin therapy may result in

alterations in bleeding time. Overall, the low level of systemic absorption can be advantageous. This allows the topical use of these medications when systemic administration is relatively contraindicated, such as is the case in patients with hypertension, cardiac failure, or renal insufficiency (refer to the Division's Cumulative Trauma Conditions Medical Treatment Guideline). Both topical salicylates and NSAIDs are appropriate for many chronic pain patients. However, in order to receive refills, patients should demonstrate increased function, decreased pain, or decreased need for oral medications.

F) Other Compounded Topical Agents: At the time of writing this guideline, no studies identified evidence for the effectiveness of compounded topical agents other than those recommended above. Therefore, other compounded topical agents are not generally recommended. In rare cases, they may be appropriate for patients who prefer a topical medication to chronic opioids or who have allergies or side effects from other more commonly used oral agents.

G) Prior authorization is required for all agents that have not been recommended above. Please refer to Rule 18-6(N), Prescription Strength Topical Compounds regarding requirements for reviewing, approving, denying, and refilling.

Evidence Statements Regarding Topical Drug Delivery: Capsaicin		
Strong Evidence	Evidence Statement	Design
	A single application of 8% capsaicin is more effective than a control preparation of 0.04% capsaicin for up to 12 weeks. However, there may be a need for frequent application, and it is not known whether subsequent applications of capsaicin are likely to be as effective as the first application.	Meta-analysis of randomized clinical trials
Good Evidence	Evidence Statement	Design
	Low dose capsaicin (0.075%) applied 4 times per day will decrease pain up to 50%.	Meta-analysis of randomized trials
Some Evidence	Evidence Statement	Design
	In patients who are being treated with capsaicin 8% patches, two methods of pre-treatment are equally effective in controlling application pain and in enabling patients to tolerate the patch: topical 4% lidocaine cream applied to the area for one hour before placement of the capsaicin patch and 50 mg oral tramadol taken 30 minutes before patch placement.	Randomized clinical trial

Evidence Statements Regarding Topical Drug Delivery: Clonidine		
Good Evidence	Evidence Statement	Design
	Topical clonidine gel 0.1% is likely to alleviate pain from diabetic peripheral neuropathy in patients who display a nociceptive response to the application of 0.1% capsaicin applied to the pretibial area. It is likely that patients who do not display a pain response to pretibial capsaicin are not likely to have a clinically meaningful analgesic response to clonidine gel. It is unknown if this screening test applies to other types of neuropathic pain.	Randomized clinical trial

Evidence Statements Regarding Topical Drug Delivery: Ketamine and Tricyclics		
Good Evidence	Evidence Statement	Design
	Neither 2% topical amitriptyline nor 1% topical ketamine reduces neuropathic pain syndromes.	Randomized clinical trial

Evidence Statements Regarding Topical Drug Delivery: Lidocaine		
Good Evidence	Evidence Statement	Design
	Lidocaine 5% plasters, applied for up to 12 hours to the lower extremities of patients with post-herpetic neuralgia and diabetic painful neuropathy, is non-inferior to pregabalin for the same indications. The topical lidocaine is associated with significantly fewer drug-related adverse events over 4 weeks of observation.	Non-inferiority randomized trial
Some Evidence	Evidence Statement	Design
	A 5% lidocaine patch may be used as a secondary option for patients with focal neuropathic pain.	Randomized crossover trial
	The 8% sprays are effective for short-term, 2 week use.	Randomized crossover trial and open label study

Evidence Statements Regarding Topical Drug Delivery: Topical Salicylates and Nonsalicylates		
Good Evidence	Evidence Statement	Design
	Diclofenac gel (Voltaren, Solaraze) reduces pain and improves function in mild-to-moderate hand osteoarthritis.	Randomized clinical trial

Evidence Statements Regarding Topical Drug Delivery: Topical Salicylates and Nonsalicylates		
Good Evidence, Continued	Topical diclofenac and ketoprofen are more effective than placebo preparations for purposes of relieving pain attributable to knee osteoarthritis.	Meta-analysis of randomized clinical trials
	Topical NSAIDs probably reduce the risk of GI adverse effects by approximately 1/3 compared to oral NSAIDs.	

I. Other Agents:

i. Glucosamine:

There is good evidence that glucosamine does not improve pain related disability in those with chronic low back pain and degenerative changes on radiologic studies; therefore, it is ***not recommended*** for chronic lower spinal or non-joint pain. For chronic pain related to joint osteoarthritis, see specific extremity guidelines. Glucosamine should not be combined with chondroitin as it is ineffective.

ii. Oral Herbals:

There is insufficient evidence due to low quality studies that an oral herbal medication, Compound Qishe Tablet, reduced pain more than placebo. There is also insufficient evidence that Jingfukang and a topical herbal medicine, Compound Extractum Nucis Vomicae, reduced pain more than Diclofenac Diethylamine Emulgel. Further research is very likely to change both the effect size and our confidence in the results. Currently, no oral herbals are recommended.

iii. Vitamin D:

A large beneficial effect of vitamin D across different chronic painful conditions is unlikely. Therefore, it is ***not recommended***.

iv. Alpha-Lipoic Acid:

An adequate meta-analysis shows that there is some evidence that alpha-lipoic acid at a dose of 600 mg per day may reduce the symptoms of painful diabetic neuropathy in the short term of 3 to 5 weeks. The effect of the intravenous route appears to be greater than that of the oral route, but the oral route may have a clinically relevant effect. Doses of 1200 or 1800 mg have not been shown to have additional therapeutic benefit. This medication may be used for neuropathic pain.

Evidence Statements Regarding Other Agents: Glucosamine		
Good Evidence	Evidence Statement	Design
	Glucosamine does not improve pain related disability in those with chronic low back pain and degenerative changes on radiologic studies; therefore, it is ***not recommended*** for chronic lower spinal or non-joint pain.	Randomized clinical trial

Evidence Statements Regarding Other Agents: Alpha-Lipoic Acid		
Some Evidence	Evidence Statement	Design
	Alpha-lipoic acid at a dose of 600 mg per day may reduce the symptoms of painful diabetic neuropathy in the short term of 3 to 5 weeks. The effect of the intravenous route appears to be greater than that of the oral route, but the oral route may have a clinically relevant effect.	Meta-analysis of randomized clinical trials

11. **NON-INVASIVE BRAIN STIMULATION**: This has been proposed as a treatment for chronic pain. Varieties include repetitive transcranial magnetic stimulation (rTMS), cranial electrotherapy stimulation (CES), and transcranial direct current stimulation (tDCS).

Single doses of high-frequency rTMS of the motor cortex may have small short-term effects on chronic pain. It is likely that multiple sources of bias may exaggerate this observed effect. The effects do not meet the predetermined threshold of minimal clinical significance and multiple-dose studies do not consistently demonstrate effectiveness. The available evidence suggests that low-frequency rTMS, rTMS applied to the pre-frontal cortex, CES, and tDCS are not effective in the treatment of chronic pain.

Therefore, these devices are ***not recommended*** due to lack of evidence and safety concerns.

12. **OPIOID ADDICTION TREATMENT**:

The DSM-V renames opioid addiction as substance use disorder (SUD) and classifies opioid use disorder according to categories defined as mild (2 – 3 features of stated criteria), moderate (4 – 5 features of stated criteria), or severe (6 – 7 features of stated criteria).

Definitions:

- Opioid physical dependence: opioid withdrawal symptoms (withdrawals) which occur as a result of abrupt discontinuation of an opioid in an individual who became habituated to the medication or through administration of an antagonist. Opioid physical dependency is not in and of itself consistent with the diagnosis of addiction/substance use disorder.

- Tolerance: a physiologic state caused by the regular use of an opioid in which increasing doses are needed to maintain the same affect. In patients with

"analgesic tolerance," increased doses of the opioid may be needed to maintain pain relief.

- Opioid misuse: the utilization of opioid medications outside of the prescribing instructions for which it was originally prescribed. Misuse may be as innocuous as taking slightly more or less medications than prescribed to crushing or snorting an opioid.

- Opioid abuse: the use of any substance for a non-therapeutic purpose or the use of a medication for purposes other than those for which the agent is prescribed. Abuse includes intentional use for altering a state of consciousness. Abuse frequently affects the individual's ability to fulfill normal societal roles, resulting in difficulty with employment, or legal, or interpersonal problems.

- Pseudo-addiction: addiction-like behaviors consistent with overutilization of medications outside of the prescribing provider's instructions and recommendations for the express purpose of improved pain management. This occurs when a patient believes there is insufficient pain relief. Once pain is adequately managed with a higher dose of medications than initially prescribed or with improved therapy, the behaviors consistent with addiction are discontinued.

- Addiction: a primary chronic neurobiological disease influenced by genetic, psychosocial, and/or environmental factors. It is characterized by impaired control over drug use, compulsive drug use, and continued drug use despite harm and because of craving.

Substance use disorder/addiction in the workers' compensation system can be encountered in three ways. First, the individual has an active substance use disorder at the time of injury. The party responsible for treatment of the substance use disorder may be outside of the workers' compensation system. However, if there is no other paying party and the treatment is necessary in order to recover from the current workers' compensation injury, treatment may be covered by the workers' compensation payor. The second possibility is that a patient with a substance use disorder, who is currently in recovery at the time of the workers' compensation injury, relapses as a result of the medications which are prescribed by the treating provider. This patient may become re-addicted and will manifest substance use disorder characteristics and symptoms consistent with the diagnosis. The third possibility is an individual with no history of substance use disorder who is injured as a result of an occupational accident. This particular individual becomes "addicted" to the medications as a result of the medications being prescribed. This is most likely to occur with the use of opioids but could possibly occur with use of other medications such as benzodiazepines or specific muscle relaxants such as carisoprodol.

If the treating provider is suspicious of a patient exhibiting opioid misuse, abuse, or addiction, the patient should preferably be evaluated by a specialist in the field of addiction medicine. It would be the responsibility of the specialist to identify medication misuse, abuse, addiction, or pseudo-addiction and to determine what additional treatment, if any, needs to be implemented.

During the initial injury evaluation, an authorized treating provider should obtain an addiction history as part of a complete history and physical. If it is determined at the time of the initial evaluation by the treating provider that there is the pre-existing condition of active SUD or history of opioid addiction/SUD, then it is prudent to consider an evaluation

with an addiction medicine physician prior to issuing opioid treatments if possible. The addiction medication specialist will be able to counsel the patient accordingly, determine medication needs, and determine the appropriate follow-up to hopefully avoid aggravation or relapse of substance abuse disorders which will complicate the recovery process. Many patients exhibit opioid misuse, opioid abuse, and pseudo-addictive behaviors. These issues can be managed once the problem is identified and a discussion is carried out with the patient regarding these abnormal behaviors.

Once the diagnosis of SUD is confirmed, an addiction medicine specialist familiar with addiction treatment should assist in co-managing the patient's care and the problematic drug prescriptions. This co-management technique is critical for the injured worker with a SUD diagnosis during the initial injury phase, recovery, and stabilization phase until he/she has reached MMI. If it is determined during the active treatment and recovery phase that there is no longer a need for opioids, then the addiction medicine specialist will be in charge of the transition from use of opioids to safe taper/discontinuation of the opioids while monitoring for relapse of addiction.

Co-management is equally important for managing the chronic pain patient that has a concomitant opioid addiction/SUD with a legitimate need for analgesic medications. The addiction medicine specialist in all likelihood will monitor the patient more closely including judicious prescribing, PDMP reviews, urine drug testing, drug counts, and clarifying functional improvement as a result of the medications prescribed and frequent follow-ups which may initially seem excessive.

All abstinence addiction treatment begins with a discontinuation of the addicting substance; this is referred to as the detox phase of the treatment and can be performed in a number of ways. However, detoxification alone is not considered adequate addiction treatment. Detoxification is simply a method of discontinuing the medications in an effort to stabilize the patient prior to more extensive treatment.

Phase 1:

The methods of detoxification can include 1) abrupt discontinuation – ***not recommended*** due to high rate of relapse due to craving and withdrawal symptoms, 2) slow but progressive taper – 10% of total dosage per week as an outpatient treatment, 3) conversion to a different medication opioid (buprenorphine/naloxone) to enable a more stable and comfortable taper occasionally done as an outpatient but commonly done as part of a more comprehensive treatment program, and 4) rapid detox under anesthesia – ***not recommended*** due to relatively high incidence of complications and high expense. The methodology chosen for phase 1 detoxification is left up to the specialist and is simply the initial phase of stabilization prior to considering the need for a phase 2 of addiction treatment program.

Phase 2:

Once a patient is safely through the detoxification phase and the condition is stabilized regardless of the method chosen, then successful addiction treatment begins generally utilizing a number of techniques to prevent the return to active substance use and addiction. This phase of treatment generally involves teaching the patient to develop control over the compulsions, psychosocial factors, and associated mental health issues which are critical to maintain abstinence. This phase of treatment is generally managed in a 30 – 90 day non-hospital residential treatment program. The treatment prescribed in a residential treatment program generally includes individual and group therapy with certified addiction counselors and psychologists. Phase 2 of treatment may or may not be combined with opioid substitution therapy with medications such as

buprenorphine/naloxone (partial agonist of the opioid receptor), methadone, or naltrexone. Injectable depot naltrexone may be used.

Buprenorphine/naloxone therapy utilizes a sublingual partial opioid receptor agonist which binds to the opioid receptor, reducing craving and resulting in analgesia when necessary. Due to its high affinity to the opioid receptor, it blocks the effect of non-approved additional opioid use. The buprenorphine is administered either sublingually or, when FDA approved, as a subcutaneous implant. Naloxone was added to the sublingual drug formulation to discourage using this medication intravenously. With intravenous administration of buprenorphine/naloxone, the naloxone becomes absorbed neutralizing the effects of opioids. Buprenorphine/naloxone can be an excellent option in patients requiring analgesic medications with a prior history of opioid addiction because buprenorphine results in less sedation and euphoria then the other standard schedule II opioid medications. Prescribing Suboxone film (buprenorphine/naloxone) for addiction purposes can only be done by a physician and requires special training and certification. Once special training is completed, an application is filed with the DEA to obtain a special DEA license referred to as an X-DEA number. This X–DEA number needs to accompany all prescription for Suboxone when delivered to the pharmacy and identifies the prescription is being issued specifically for the treatment of addiction/SUD.

Methadone may be an option if the patient is admitted to a federally licensed methadone treatment facility where a daily dose of medication is administered and the patient continues to utilize therapeutic treatments/cognitive behavioral therapies as noted above. There is strong evidence that in patients being treated with opioid agonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidenced by positive urines, are equivalent between methadone and buprenorphine. The methodology and rationale for methadone treatment is to saturate the opioid receptors with methadone (a slow onset and prolonged duration opioid), reducing the opioid craving. The majority of the opioid receptors are bound by the methadone leaving very few unbound opioid receptors available in the event additional opioids are utilized in an attempt to achieve the euphoric effect. When the patient is stabilized on a methadone dose determined by the federally licensed methadone clinic and their associated physicians, the patient's drug-seeking, craving, legal issues, and attempts to utilize non-approved medications is reduced. Patients will frequently return to more productive lives free of the compulsions, cravings, and legal issues and are usually able to maintain jobs and improve family dynamics.

Other medications which may be useful and can be utilized during the phase 2 and 3 treatment include opioid receptor antagonists such as naltrexone (ReVia, Vivitrol) which produces no euphoria. The purpose of naltrexone therapy is to add an additional layer of protection and treatment for the patients by allowing them to receive a daily oral dose of naltrexone (ReVia) or a monthly injection of naltrexone (Vivitrol). Administration of naltrexone will bind with very high affinity to the opioid receptor resulting in the opioid receptors being non-responsive to other opioid utilization thereby preventing any euphoric response or reinforcement with unsanctioned opioid use. This treatment method can be problematic in an individual receiving intramuscular naltrexone therapy especially if that individual requires surgery and post-operative pain management because the analgesics needed for post-operative pain management will be significantly less effective because of the prolonged opioid antagonist properties of the naltrexone.

In Summary:

Medication assisted treatment for patients addicted to opioids is the treatment recommended by most experts. A Canadian evidence-based guideline recommends long-term treatment with buprenorphine/naloxone, or methadone for some patients,

based on the high relapse rate without medication assistance. The likelihood of relapse in the workers' compensation population for individuals who have become addicted through prescription drug use is unknown. Buprenorphine implants are likely equally effective as sublingual buprenorphine for preventing illicit opioid use. Implants are significantly more costly. Naltrexone treatment, an opioid agonist, has also been used to maintain abstinence. It can be provided in monthly injections or orally 3 times per week. Choice of these medications should be made by the addiction specialist.

Phase 3:

Aftercare begins after discharge from the non-hospital residential treatment program and is designed for long-term management of addiction. This phase is potentially the time when relapse is most likely to occur if the patient has not developed significant skills necessary to deal with the compulsions, cravings, and associated psychosocial factors contributing to SUD. Long-term strategies include 1) intense outpatient programs (IOP), 2) group therapy/meetings such as Narcotics Anonymous, and 3) residential communities (RC) which are groups of patients living together in a community for up to 6 months for the express purpose of maintaining abstinence from their drug of choice but at the same time transitioning and learning how to live in the general community. Residential communities are extremely useful to give patients an opportunity to be reintroduced to employment and psychosocial interactions with family and friends while maintaining contact with the community supporting their addiction recovery. In addition, phase 3 medication treatment may include utilization of opioid substitution therapy (buprenorphine/naloxone) or opioid receptor antagonist therapy as noted above.

It must be noted that relapse is common despite the utilization of intense cognitive behavioral therapy, addiction treatment strategies, and long-term phase 3 treatment and medication. Risk monitoring should be continued, including checking for behavioral aberrancies, checking the PDMP, and drug testing,. Additional treatment or readmission for repeat treatment is not uncommon.

Evidence Statements Regarding Opioid Addiction Treatment		
Strong Evidence	Evidence Statement	Design
	In patients being treated with opioid agonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidenced by positive urines, are equivalent between methadone and buprenorphine.	Meta-analysis of randomized clinical trials

13. OPIOID/CHEMICAL TREATMENT PROGRAM REQUIREMENTS:

Chemical dependency for workers' compensation issues will usually be related to opioids, anxiolytics, or hypnotics as prescribed for the original workers' compensation injury. Chemical dependency should be treated with specific programs providing medical and psychological assessment, treatment planning, and individual as well as group counseling and education. Established functional goals which are measurable, achievable, and time specific are required.

Inpatient or outpatient programs may be used, depending upon the level of intensity of services required. Formal inpatient treatment programs are appropriate for patients who have more intense (e.g., use extraordinarily excessive doses of prescription drugs to

which they have developed tolerance) or multiple drug abuse issues (e.g., benzodiazepines and/or alcohol) and those with complex medical conditions or psychiatric issues related to drug misuse. A medical physician with appropriate training and preferably board certified in addiction medicine should provide the initial evaluation and oversee the program. Full primary assessment should include behavioral health assessment; medical history; physical examination; mental status; current level of functioning; employment history; legal history; history of abuse, violence, and risk taking behavior; education level; use of alcohol, tobacco and other drugs; and social support system. The initial medical exam should include appropriate laboratory testing such as liver function, screening for sexual diseases, etc.

Addiction specialists, alcohol and drug counselors, psychologists, psychiatrists, and other trained health care providers as needed, are involved in the program. Peer and group support is an integral part of the program and families are encouraged to attend. Peer support specialists should receive competency based training. A designated individual is assigned to each worker to assist in coordinating care. There should be good communication between the program and other external services, external health care providers, Al-Anon, Alcoholics Anonymous (AA), and pain medicine providers. Drug screening should be performed as appropriate for the individual, at least weekly during the initial detoxification and intensive treatment phases. At least 8 random drug screens per year should be completed for those on medication assisted treatment and drug diversion control methods should be in place.

Clear withdrawal procedures are delineated for voluntary, against medical advice, and involuntary withdrawal. Withdrawal programs must have a clear treatment plan and include description of symptoms of medical and emotional distress, significant signs of opioid withdrawal, and actions taken. All programs should have clear direction on how to deal with violence in order to assure safety for all participants. Transition and discharge should be carefully planned with full communication to outside resources. Duration of inpatient programs are usually 4 weeks while outpatient programs may take 12 weeks.

Drug detoxification may be performed on an outpatient or inpatient basis. Detoxification is unlikely to succeed in isolation when not followed by prolonged chemical dependency treatment. Isolated detoxification is usually doomed to failure with very high recidivism rates.

Both ultra-rapid and rapid-detoxification are ***not recommended*** due to possible respiratory depression and death and the lack of evidence for long range treatment success. Refer to Section G.12, Opioid Addiction Treatment, for more specific details on treatment plans.

Tapering opioids on an outpatient basis requires a highly motivated patient and diligent treatment team and may be accomplished by decreasing the current dose 10% per day or per week. Tapering programs under the supervision of physicians with pain expertise may proceed more aggressively. Tapering should be accompanied by addiction counseling. Failing a trial of tapering, a patient should be sent to a formal addiction program. When the dose has reached 1/3 of the original dose, the taper should proceed at half or less of the initial rate. Doses should be held or possibly increased if severe withdrawal symptoms, pain, or reduced treatment failure otherwise occurs. This method is tedious, time consuming, and more likely to fail than more rapid and formalized treatment programs.

Time Frames for Opioid / Chemical Treatment Programs	
Time to Produce Effect	3 to 4 weeks
Frequency	Full time programs - no less than 5 hours/day, 5 days/week; part time programs - 4 hours/day for 2-3 days per week.
Optimum Duration	2 to 12 weeks at least 2-3 times a week. With follow-up visits weekly or every other week during the first 1 to 2 months after the initial program is completed.
Maximum Duration	4 months for full time programs and up to 6 months for part-time programs. Periodic review and monitoring thereafter for 1 year, additional follow-up based upon the documented maintenance of functional gains.

14. **ORTHOTICS/PROSTHETICS/EQUIPMENT**: Devices and adaptive equipment may be necessary in order to reduce impairment and disability, to facilitate medical recovery, to avoid re-aggravation of the injury, and to maintain maximum medical improvement. Indications would be to provide relief of the industrial injury, prevent further injury, and control neurological and orthopedic injuries for reduced stress during functional activities. In addition, they may be used to modify tasks through instruction in the use of a device or physical modification of a device. Equipment needs may need to be reassessed periodically. Refer to Section G.17, Return-to-work, for more detailed information.

Equipment may include high and low technology assistive devices, computer interface or seating, crutch or walker training, and self-care aids. It should improve safety and reduce risk of re-injury. Standard equipment to alleviate the effects of the injury on the performance of activities of daily living may vary from simple to complex adaptive devices to enhance independence and safety. Certain equipment related to cognitive impairments may also be required.

Ergonomic modifications may be necessary to facilitate medical recovery, to avoid re-aggravation of the injury, and to maintain maximum medical improvement. Ergonomic evaluations with subsequent recommendations may assist with the patient's return-to-work. (Refer to Section F.6.c, Jobsite Evaluation and Alterations, for further information.)

For chronic pain disorders, equipment such as foot orthoses may be helpful. The injured worker should be educated as to the potential harm from using a lumbar support for a period of time greater than which it is prescribed. Harmful effects include de-conditioning of the trunk musculature, skin irritation, and general discomfort. Use of cervical collars is ***not recommended*** for chronic cervical myofascial pain. Special cervical orthosis and/or equipment may have a role in the rehabilitation of a cervical injury such as those injuries to a cervical nerve root resulting in upper extremity weakness, a spinal cord injury with some degree of paraparesis or tetraparesis, or post spinal fusion surgery. Use of such devices would be in a structured rehabilitation setting as part of a comprehensive rehabilitation program.

Fabrication/modification of orthotics, including splints, would be used when there is need to normalize weight-bearing, facilitate better motion response, stabilize a joint with insufficient muscle or proprioceptive/reflex competencies, to protect subacute conditions as needed during movement, and correct biomechanical problems. Orthotic/prosthetic training is the skilled instruction (preferably by qualified providers) in the proper use of

orthotic devices and/or prosthetic limbs.

For information regarding specific types of orthotics/prosthetics/equipment, refer to individual medical treatment guideline.

15. PERSONALITY/PSYCHOLOGICAL/PSYCHOSOCIAL INTERVENTION

a. Introduction

Psychosocial treatment is a well-established therapeutic and diagnostic intervention with selected use in acute pain populations and more widespread use in sub-acute and chronic pain populations. Psychosocial treatment is recommended as an important component in the total management of a patient with chronic pain and should be implemented as soon as the problem is identified.

Studies have noted that there is not a direct connection between impairment and disability nor is there a direct connection been lumbar imaging and pain. It appears that the lack of connections is likely accounted for by differences among individuals in level of depression, coping strategies, or other psychological distress.

There is some evidence that in the setting of chronic low back pain when disc pathology is present, a high degree of anxiety or depressive symptomatology is associated with relatively less pain relief in spite of higher opioid dosage than when these symptoms are absent. Therefore, psychological issues should always be screened for and treated in chronic pain patients.

Psychological treatments for pain can be conceptualized as having a neuropsychological basis. These treatments for pain have been shown to decrease physiological reactivity to stress, alter patterns of brain activation as demonstrated by functional MRI (fMRI), alter the volume of grey matter and other structures in the brain, and alter blood flow patterns in the brain. The most researched psychological treatment is Cognitive Behavioral Therapy (CBT) which is summarized in this section.

The screening or diagnostic workup should clarify and distinguish between pre-existing, aggravated, and/or purely causative psychological conditions. Therapeutic and diagnostic modalities include, but are not limited to, individual counseling and group therapy. Treatment can occur within an individualized model, a multi-disciplinary model, or a structured pain management program.

A psychologist with a PhD, PsyD, or EdD credentials or a psychiatric MD/DO may perform psychosocial treatments. The following professionals may also perform treatment in consultation with a psychologist with a PhD, PsyD, or EdD or psychiatric MD/DO: other licensed mental health providers, licensed health care providers with training in CBT, or providers certified as CBT therapists who have experience in treating chronic pain disorders in injured workers.

If a diagnosis consistent with the standards of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) or most current ICD has been determined, the patient should be evaluated for the potential need for psychiatric medications. Use of any medication to treat a diagnosed condition may be ordered by an authorized treating physician or by the consulting psychiatrist. Visits for management of psychiatric medications are

medical in nature and are not a component of psychosocial treatment. Therefore, separate visits for medication management may be necessary, depending on the patient and medications selected.

Psychosocial interventions include psychotherapeutic treatments for behavioral health conditions, as well as behavioral medicine treatments. These interventions may similarly be beneficial for patients without psychiatric conditions but who may need to make major life changes in order to cope with pain or adjust to disability. Examples of these treatments include Cognitive Behavioral Therapy (CBT), relaxation training, mindfulness training, and sleep hygiene psychoeducation.

CBT refers to a group of psychological therapies that are sometimes referred to by more specific names such as Rational Emotive Behavior Therapy, Rational Behavior Therapy, Rational Living Therapy, Cognitive Therapy, and Dialectic Behavior Therapy. Variations of CBT methods can be used to treat a variety of conditions, including chronic pain, depression, anxiety, phobias, and post-traumatic stress disorder (PTSD). For patients with multiple diagnoses, more than one type of CBT might be needed. The CBT used in research studies is often “manualized CBT,” meaning that the treatment follows a specific protocol in a manual. In clinical settings, CBT may involve the use of standardized materials, but it is also commonly adapted by a psychologist or psychiatrist to the patient’s unique circumstances. If the CBT is being performed by a non-mental health professional, a manual approach would be strongly recommended.

CBT must be distinguished from neuropsychological therapies used to teach compensatory strategies to brain injured patients, which are also called “cognitive therapy.” Many other clinical providers also provide a spectrum of cognitive interventions including: motivational interviewing, pain neuroscience education, and other interventions aimed at patient education and change in behavior. Refer to patient education in Section G.18, Therapy-Active, for details.

It should be noted that most clinical trials on CBT exclude subjects who have significant psychiatric diagnoses. Consequently, the selection of patients for CBT should include the following considerations. CBT is instructive and structured, using an educational model with homework to teach inductive rational thinking. Because of this educational model, a certain level of cognitive ability and literacy is assumed for most CBT protocols. Patients who lack the cognitive and educational abilities required by a CBT protocol are unlikely to be successful. Further, given the highly structured nature of CBT, it is more effective when a patient’s circumstances are relatively stable. For example, if a patient is about to be evicted, is actively suicidal, or is coming to sessions intoxicated, these matters will generally preempt CBT treatment for pain and require other types of psychotherapeutic response. Conversely, literate patients whose circumstances are relatively stable, but who catastrophize or cope poorly with pain or disability, are often good candidates for CBT for pain. Similarly, literate patients whose circumstances are relatively stable, but who exhibit unfounded medical phobias, are often good candidates for CBT for anxiety.

CBT is often combined with active therapy in an interdisciplinary program, whether formal or informal. It must be coordinated with a psychologist or psychiatrist. CBT can be done in a small group or individually, and the usual number of treatments varies between 8 and 16 sessions.

Before CBT or other psychological treatments are performed, the patient must

have a full psychological evaluation. The CBT program must be done under the supervision of a psychologist with a PhD, PsyD, or EdD or a psychiatric MD/DO.

Psychological disorders associated with distress and dysfunction are common in chronic pain. One study demonstrated that the majority of patients who had failed other therapy and participated in an active therapy program also suffered from major depression. However, in a program that included CBT and other psychological counseling, the success rate for return to work was similar for those with and without an ICD diagnosis. This study further strengthens the argument for having some psychological intervention included in all chronic pain treatment plans.

b. Hypnosis

i. The term hypnosis can encompass a number of therapy types including relaxation, imagery, focused attention, interpersonal processing, and suggestion. Hypnosis has been used in depression and for distress related to medical procedures.

ii. A number of studies support the use of hypnosis for chronic pain management. At least one pilot study suggested that hypnotic cognitive therapy assists recovery in chronic pain. Other imaging studies support the concept that hypnosis can actively affect cortical areas associated with pain. Thus, this therapy may be used at the discretion of the psychologist. A more recent meta-analysis was completed which purported to show evidence for hypnosis. However, the heterogeneity of the studies included prevents this study from meeting our standards for evidence.

For all psychological/psychiatric interventions, an assessment and treatment plan must be provided to the treating physician prior to initiating treatment. The treatment plan must include specific, measurable, achievable, and realistic behavioral goals, with specific interventions and time frames to achieve those goals. The report should also address pertinent issues such as pre-existing, exacerbated or aggravated, and/or causative issues, as well as a realistic functional prognosis.

Evidence Statements Regarding Psychosocial Intervention		
Good Evidence	Evidence Statement	Design
	Cognitive behavioral therapy, but not behavioral therapy such as biofeedback, shows weak to small effects in reducing pain and small effects on improving disability, mood, and catastrophizing in the treatment of patients with chronic pain.	Meta-analysis of randomized clinical trials
	CBT may reduce pain and disability in patients with chronic pain, but the magnitude of the benefit is uncertain.	Meta-analysis of randomized clinical trials
	There are no clinically significant differences for pain and disability between physical versus	Systematic review and meta-analyses of

Evidence Statements Regarding Psychosocial Intervention		
	behavioral/psychologically informed and combined interventions for nonspecific chronic spinal pain.	randomized clinical trials
Good Evidence, Continued	Psychological interventions, especially CBT, are superior to no psychological intervention for chronic low back pain.	Meta-analysis of controlled clinical trials
	Self-regulatory interventions, such as biofeedback and relaxation training, may be equally effective.	Meta-analysis of controlled clinical trials
	Six group therapy sessions lasting 90 minutes each focused on CBT skills improved function and alleviated pain in uncomplicated sub-acute and chronic low back pain patients.	Group randomized clinical trial
	In the setting of chronic low back pain, 8 weeks of 2 hour weekly group sessions of either mindfulness based stress reduction meditation program with yoga or CBT results in small, significant improvements in physical function and reduction in pain compared to usual care at 26 weeks with no significant differences in outcomes between the 2 treatments.	Single-blind randomized clinical trial
	A stepped care program including CBT is more effective than usual care in veterans with chronic musculoskeletal pain. The stepped care program consists of (1) 12 weeks during which nurse case managers take a medication use history and adjust medication dosage and scheduling through telephone contacts with patients every other week, followed by (2) a 12 week step in which CBT is administered by 45 minute individual sessions by telephone every other week. Disability and pain interference with daily activity with stepped care were both superior to usual care in which patients were given printed handouts and were followed for all care by their primary treating physicians.	Randomized clinical trial
	In the short-term, operant therapy focused on increasing function shows small effects in reducing pain compared to waiting list controls. Most studies demonstrated a positive effect. However, it was usually below the minimal clinical significant standard. There is good evidence that no specific type of behavioral therapy is more effective than another in the treatment of patients with chronic pain.	Meta-analyses of randomized clinical trials
Some Evidence	Evidence Statement	Design
	A 6-week program of cognitive-behavioral group intervention with or without physical therapy can reduce sick leave, health care utilization, and the risk for developing long-term sick leave disability ($\geq$ 15 days) in workers with nonspecific low back or neck pain compared with simple verbal instruction by a physician.	Randomized clinical trial

Evidence Statements Regarding Psychosocial Intervention		
Some Evidence, Continued	Intensive exercise coupled with CBT is as effective as posterolateral fusion for chronic un-operated low back pain.	Randomized clinical trial
	In the setting of chronic pain, both an 8-week mindfulness based stress reduction meditation program with yoga and an 8-week multidisciplinary pain intervention program with exercise resulted in small, significant reductions in pain intensity and pain-related distress post-intervention. However, there were no significant differences in outcomes between the 2 programs.	Single-blind randomized clinical trial
	CBT provided in 7 2-hour small group sessions can reduce the severity of insomnia in chronic pain patients.	Randomized clinical trial
	In the setting of chronic low back pain for older adults (mean age 74.5 years), an 8-week mind-body program that taught mindfulness meditation methods resulted in significant, but clinically small improvements in (1) physical function in the short-term (8 weeks) and (2) current and most severe pain in the past week in the long term (6 months) compared to a healthy aging education program.	Single-blind randomized clinical trial

Additional Studies Not Resulting in Evidence Statements
A study using functional magnetic imaging compared mindful practitioners with controls and found that mindfulness did not decrease pain but did decrease pain unpleasantness by 22% and anxiety by 23%. Further studies would be needed to establish this as a recommendation.
Another recent Cochrane review found only low quality studies of cognitive behavioral therapy for chronic neck pain which suggested some benefit but with low clinical significance.

Summary of Evidence Regarding Psychosocial Intervention
Based on the multiple studies with good evidence listed above, there is strong evidence supporting CBT, particularly in conjunction with other active therapy, to decrease pain and disability for chronic pain patients. However, the magnitude of the change is not likely to be large.

Time Frames for Cognitive Behavioral Therapy (CBT) or Similar Treatment	
Time to Produce Effect	12-16 hours of treatment (1-hour individual sessions or alternately 1- to 2-hour group sessions).

Time Frames for Cognitive Behavioral Therapy (CBT) or Similar Treatment	
Frequency	1 to 2 times weekly for the first 2 weeks, decreasing to 1 time per week thereafter.
Maximum Duration	24 1-hour sessions.
Note	Before CBT or other psychological/psychiatric interventions are done, the patient must have a full psychological evaluation. The CBT program must be done under the supervision of a psychologist with a PhD, PsyD, or EdD, or a Psychiatric MD/DO.

Time Frames for Other Psychological/Psychiatric Interventions	
Time to Produce Effect	6 to 8 weeks.
Frequency	1 to 2 times weekly for the first 2 to 4 weeks (excluding hospitalization, if required), decreasing to 1 time per week for the second month. Thereafter, 2 to 4 times monthly with the exception of exacerbations, which may require increased frequency of visits. Not to include visits for medication management.
Optimum Duration	2 to 6 months.
Maximum Duration	Commonly 6 months for most cases. Extensions under conditions as noted below. (Not to include visits for medication management). For select patients (e.g., ongoing medical procedures or complications, medication dependence, diagnostic uncertainty, delays in care due to patient or systemic variables), less intensive but longer supervised psychological/psychiatric treatment may be required. If counseling beyond 6 months is indicated, the nature of the psychosocial risks being managed or functional progress must be documented. Progress notes for each appointment should include goal setting, with specific, measurable, achievable, and realistic goals, and a timetable with an expected end point. In complex cases, goal setting may include maintaining psychological equilibrium while undergoing invasive procedures.

16. **RESTRICTION OF ACTIVITIES**: Continuation of normal daily activities is the recommendation for most patients since immobility will negatively affect rehabilitation. Prolonged immobility results in a wide range of deleterious effects, such as a reduction in aerobic capacity and conditioning, loss of muscle strength and flexibility, increased segmental stiffness, promotion of bone demineralization, impaired disc nutrition, and the facilitation of the illness role.

Some level of immobility may occasionally be appropriate which could include splinting/casting or as part of a structured schedule that includes energy conservation or intentional rest breaks between activities. While these interventions may occasionally have been ordered in the acute phase, the provider should be aware of their impact on the patient's ability to adequately comply with and successfully complete rehabilitation. Activity should be increased based on the improvement of core strengthening.

Patients should be educated regarding the detrimental effects of immobility versus the efficacious use of limited rest periods. Adequate rest allows the patient to comply with

active treatment and benefit from the rehabilitation program. In addition, complete work cessation should be avoided, if possible, since it often further aggravates the pain presentation and promotes disability. Modified return to work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers.

17. **RETURN-TO-WORK**: Return-to-work and/or work-related activities whenever possible is one of the major components in treatment and rehabilitation. Return to work is a subject that should be addressed by each workers' compensation provider at the first meeting with the injured employee and updated at each additional visit. A return-to-work format should be part of a company's health plan, knowing that return to work can decrease anxiety, reduce the possibility of depression, and reconnect the worker with society.

A prolonged time off work is likely to lead to chronic disability. In complex cases, experienced nurse case managers may be required to assist in return to work. Other services, including psychological evaluation and/or treatment, jobsite analysis, and vocational assistance, may be employed.

Two counseling sessions with an occupational physician, and work site visit if necessary, may be helpful for workers who are concerned about returning to work.

At least one study suggests that health status is worse for those patients who do not return to work than those who do. Self-employment and injury severity predict return to work. Difficulty with pain control, ADLs, and anxiety and depression were common among patients who did not return to work.

The following should be considered when attempting to return an injured worker with chronic pain to work.

a. **Job History Interview**: An authorized treating physician should perform a job history interview at the time of the initial evaluation and before any plan of treatment is established. Documentation should include the worker's job demands, stressors, duties of current job, and duties of job at the time of the initial injury. In addition, cognitive and social issues should be identified, and treatment of these issues should be incorporated into the plan of care.

b. **Coordination of Care**: Management of the case is a significant part of return to work and may be the responsibility of an authorized treating physician, occupational health nurse, risk manager, or others. Case management is a method of communication between the primary provider, referral providers including occupational and physical therapists, insurer, employer, and employee. Because case management may be coordinated by a variety of professionals, the case manager should be identified in the medical record.

c. **Communication**: This is essential between the patient, authorized treating physician, employer, and insurer. Employers should be contacted to verify employment status, job duties and demands, and policies regarding injured workers. In addition, the availability and duration of temporary and permanent restrictions, as well as other placement options, should be discussed and documented. All communications in the absence of the patient are required to be documented and made available to the patient.

d. **Establishment of Return-To-Work Status**: Return to work for persons with chronic pain should be considered therapeutic, assuming that work is not likely to aggravate the basic problem or increase the discomfort. In some cases of chronic pain, the worker may not be currently working or even employed. The

goal of return to work would be to return the worker to any level of employment with the current employer or to return him/her to any type of new employment. Temporary restrictions may be needed while recommended ergonomic or adaptive equipment is obtained; employers should obtain recommended equipment in a timely manner.

e. **Establishment of Activity Level Restrictions**: A formal job description for the injured worker is necessary to identify physical demands at work and assist in the creation of modified duty. A jobsite evaluation may be utilized to identify applicable tasks such as pushing, pulling, lifting, reaching, grasping, pinching, sitting, standing, posture, and ambulatory distance and terrain. If applicable, a job site evaluation may also be utilized to assess temperature, air flow, noise, and the number of hours worked per day in a specific environment. Also refer to Section F.6.c, Jobsite Evaluation and Alterations. Due to the lack of predictability regarding exacerbation of symptoms affecting function, an extended, occupationally focused functional capacity evaluation may be necessary to determine the patient's tolerance for job type tasks over a continued period of time. Job requirements should be reviewed for the entire 8 hours or more of the working day. When prescribing the FCE, the physician must assess the probability of return to work against the potential for exacerbation of the work related condition. Work restrictions assigned by an authorized treating physician may be temporary or permanent. The case manager should continue to seek out modified work until restrictions become less cumbersome or as the worker's condition improves or deteriorates. Ergonomic changes recommended by the worksite evaluation should be put in place.

Between 1 and 3 days after the evaluation, there should be a follow-up evaluation by the treating therapist and/or an authorized treating physician to assess the patient's status. Patients should be encouraged to report their status post FCE.

f. **Rehabilitation and Return-To-Work**: As part of rehabilitation, every attempt should be made to simulate work activities so that an authorized treating physician may promote adequate job performance. The use of ergonomic or adaptive equipment, therapeutic breaks, and interventional modalities at work may be necessary to maintain employment.

g. **Vocational Assistance**: Formal vocational rehabilitation is a generally accepted intervention and can assist disabled persons to return to viable employment. Assisting patients in identifying vocational goals will facilitate medical recovery and aid in the achievement of MMI by (1) increasing motivation towards treatment and (2) alleviating the patient's emotional distress. Physically limited patients will benefit most if vocational assistance is provided during the interdisciplinary rehabilitation phase of treatment. To assess the patient's vocational capacity, a vocational assessment utilizing the information from occupational and physical therapy assessments may be performed. This vocational assessment may identify rehabilitation program goals and optimize both patient motivation and utilization of rehabilitation resources. This may be extremely helpful in decreasing the patient's fear regarding an inability to earn a living, which can add to his/her anxiety and depression.

Recommendations to Employers and Employees of Small Businesses: Employees of small businesses who are diagnosed with chronic pain may not be able to perform any jobs for which openings exist. Temporary employees may fill those slots while the employee functionally improves. Some small businesses

hire other workers, and if the injured employee returns to the job, the supervisor/owner may have an extra employee. Case managers may assist with resolution of these problems and with finding modified job tasks or jobs with reduced hours, etc., depending on company philosophy and employee needs.

Recommendations to Employers and Employees of Mid-sized and Large Businesses: Employers are encouraged by the Division to identify modified work within the company that may be available to injured workers with chronic pain who are returning to work with temporary or permanent restrictions. To assist with temporary or permanent placement of the injured worker, it is suggested that a program be implemented that allows the case manager to access descriptions of all jobs within the organization.

18. THERAPY—ACTIVE:

The following active therapies are widely used and accepted methods of care for a variety of work-related injuries. Active therapy is based on the philosophy that therapeutic exercise and/or activity can alleviate discomfort and are beneficial for restoring flexibility, strength, endurance, function, and range-of-motion. All active therapy plans should be made directly with patients in the interest of achieving long-term individualized goals.

Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual, and/or tactile instruction(s). Active therapy is intended to promote independence and self-reliance in managing the physical pain as well as to improve functional status in regard to the specific diagnosis, general conditioning, and well-being. At times, a provider may help stabilize the patient or guide the movement pattern but the energy required to complete the task is predominately executed by the patient. Therapy in this section should not be merely a repeat of previous therapy but should focus specifically on the individual goals and abilities of the patient with chronic pain.

The goal of active therapy is to teach the patient exercises that they can perform regularly on their own. Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Follow-up visits to reinforce and monitor progress and proper technique are recommended. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices.

On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care, need for post-operative therapy, and co-morbidities may also extend durations of care. Specific goals with objectively measured functional improvement during treatment must be cited to justify extended durations of care. It is recommended that, if no functional gain is observed after the number of treatments under "time to produce effect" has been completed, then alternative treatment interventions, further diagnostic studies, or further consultations should be pursued.

Pain Neuroscience Education (PNE): an educational strategy used by physical therapists and other practitioners that focuses on teaching people in pain more about the neurobiological and neurophysiological processes involved in their pain experience, versus a focus on anatomical and pathoanatomical education. PNE helps patients develop an understanding of various pain processes including central sensitization, peripheral sensitization, inhibition, facilitation, the brain's processing of threat appraisal, and various biological systems involved in a pain experience. This reconceptualization of pain via PNE is then combined with various behavioral strategies including aerobic

exercise, pacing, graded exposure, graded activity, and goal setting. PNE is likely to positively influence pain ratings, disability, fear-avoidance behaviors, pain catastrophization, and limitations in movement, pain knowledge, and healthcare utilization. PNE is recommended with active therapy for chronic pain patients.

Evidence Statements Regarding Patient Education		
Good Evidence	Evidence Statement	Design
	Pain neuroscience education combined with a physical intervention is more effective in reducing pain, improving disability, and reducing healthcare utilization compared with either usual care, exercise, other education or another control group for the treatment of patients with chronic musculoskeletal pain.	Narrative systematic review of randomized clinical trials
Some Evidence	Evidence Statement	Design
	A cognitive intervention consisting of 2 consultations lasting 1 hour each with a physical medicine specialist and a physical therapist covering coping strategies and patient education on motion produces short-term reductions in sub-acute back disability.	Randomized clinical trial
	In the setting of non-specific chronic low back pain, patient-centered cognitive functional therapy from physical therapists produced superior outcomes for pain reduction and functional improvement compared with traditional manual therapy and exercise at post-intervention and at 12-month follow-up.	Single-blind randomized clinical trial

The following active therapies are listed in alphabetical order:

a. **Activities of Daily Living (ADL)**: instruction, active-assisted training, and/or adaptation of activities or equipment to improve a person's capacity in normal daily activities such as self-care, work re-integration training, homemaking, and driving.

Time Frames for Activities of Daily Living	
Time to Produce Effect	4 to 5 treatments.
Frequency	1 to 5 times per week.
Optimum Duration	4 to 6 weeks.
Maximum Duration	6 weeks.

b. **Aquatic Therapy**: is a well-accepted treatment which consists of the therapeutic use of aquatic immersion for therapeutic exercise to promote strengthening, core

stabilization, endurance, range-of-motion, flexibility, body mechanics, and pain management. Aquatic therapy is the implementation of active therapeutic procedures (individual or group) in a swimming or therapeutic pool heated to 88 to 92 degrees. The pool should be large enough to allow full extremity range-of-motion and fully erect posture. Aquatic vests, belts, and other devices can be used to provide stability, balance, buoyancy, and resistance. The water provides a buoyancy force that lessens the amount of force of gravity applied to the body. The decreased gravity effect allows the patient to have a mechanical advantage and more likely have a successful trial of therapeutic exercise. In addition, the compression of the water against the affected extremity and ability to move easier with decreased gravity allow for resulting muscular compression against vessels improving lymphatic drainage resulting in decreased edema. Aquatic Therapy may also provide an additional stimulus to assist with desensitization.

There is good evidence that aquatic exercise and land-based exercise show comparable outcomes for function and mobility among people with symptomatic osteoarthritis of the knee or hip.

Indications: The therapy may be indicated for individuals who:

- Cannot tolerate active land-based or full-weight bearing therapeutic procedures;
- Require increased support in the presence of proprioceptive deficit;
- Are at risk of compression fracture due to decreased bone density;
- Have symptoms that are exacerbated in a dry environment;
- Have a higher probability of meeting active therapeutic goals than in a dry environment.

Evidence Statements Regarding Aquatic Therapy		
Good Evidence	Evidence Statement	Design
	Aquatic exercise and land-based exercise show comparable outcomes for function and mobility among people with symptomatic osteoarthritis of the knee or hip.	Systematic Review and meta-analysis of randomized clinical trials

Time Frames for Aquatic Therapy	
Time to Produce Effect	4 to 5 treatments.
Frequency	3 to 5 times per week.
Optimum Duration	4 to 6 weeks.
Maximum Duration	6 weeks.

After the supervised aquatics program has been established, either a self-directed aquatic program or a transition to a self-directed dry environment exercise program is recommended.

c. **Functional Activities**: are well-established interventions which involve the use of therapeutic activity to enhance mobility, body mechanics, employability, coordination, and sensory motor integration.

Time Frames for Functional Activities	
Time to Produce Effect	4 to 5 treatments.
Frequency	1 to 5 times per week.
Optimum Duration	4 to 6 weeks.
Maximum Duration	8 weeks.

d. **Functional Electrical Stimulation**: is an accepted treatment in which the application of electrical current to elicit involuntary or assisted contractions of atrophied and/or impaired muscles. Indications include muscle atrophy, weakness, and sluggish muscle contraction secondary to pain, injury, neuromuscular dysfunction, peripheral nerve lesion, or radicular symptoms. This modality may be prescribed for use at home when patients have demonstrated knowledge of how to self-administer and are in an independent exercise program.

Time Frames for Functional Electrical Stimulation	
Time to Produce Effect	2 to 6 treatments.
Frequency	3 times per week.
Optimum Duration	8 weeks.
Maximum Duration	8 weeks. If beneficial, provide with home unit.

e. **Neuromuscular Re-education**: is a generally accepted treatment. It is the skilled application of exercise with manual, mechanical, or electrical facilitation to enhance strength; movement patterns, neuromuscular response, proprioception, kinesthetic sense, coordination; education of movement, balance, and posture.

There is some evidence that there is a modest benefit from adding a back school to other treatments such as NSAIDs, massage, transcutaneous electrical nerve stimulation (TENS), and other physical therapy modalities. However, a recent adequate quality systematic review found no evidence for the effectiveness of back schools for treating chronic low back pain.

Indications include the need to promote neuromuscular responses through carefully timed proprioceptive stimuli, to elicit and improve motor activity in

patterns similar to normal neurologically developed sequences, and to improve neuromotor response with independent control.

Evidence Statements Regarding Neuromuscular Re-education		
Some Evidence	Evidence Statement	Design
	There is a modest benefit from adding a back school to other treatments such as NSAIDs, massage, transcutaneous electrical nerve stimulation (TENS), and other physical therapy modalities.	Systematic review of randomized clinical trials

Time Frames for Neuromuscular Re-education	
Time to Produce Effect	2 to 6 treatments.
Frequency	1 to 3 times per week.
Optimum Duration	4 to 8 weeks.
Maximum Duration	8 weeks.

f. **Spinal Stabilization**: is a generally well-accepted treatment. The goal of this therapeutic program is to strengthen the spine in its neutral and anatomic position. The stabilization is dynamic which allows whole body movements while maintaining a stabilized spine. It is the ability to move and function normally through postures and activities without creating undue vertebral stress.

Time Frames for Spinal Stabilization	
Time to Produce Effect	4 to 8 treatments.
Frequency	1 to 3 times per week.
Optimum Duration	4 to 8 weeks.
Maximum Duration	8 weeks.

g. **Therapeutic Exercise**: with or without mechanical assistance or resistance, may include isoinertial, isotonic, isometric, and isokinetic types of exercises. May also include alternative/complementary exercise movement therapy (with oversight of a physician or appropriate healthcare professional).

Indications include the need for cardiovascular fitness, reduced edema, improved muscle strength; improved connective tissue strength and integrity, increased bone density, promotion of circulation to enhance soft tissue healing, improvement of muscle recruitment, improved proprioception, and coordination,

and increased range-of-motion are used to promote normal movement patterns.

Yoga may be an option for motivated patients with appropriate diagnoses.

Therapeutic exercise programs should be tissue specific to the injury and address general functional deficits as identified in the diagnosis and clinical assessment. Patients should be instructed in and receive a home exercise program that is progressed as their functional status improves. Upon discharge, the patient would be independent in the performance of the home exercise program and would have been educated in the importance of continuing such a program. Educational goals would be to maintain or further improve function and to minimize the risk for aggravation of symptoms in the future.

Available evidence supporting therapy mainly exists in the chronic low back literature.

Evidence Statements Regarding Therapeutic Exercise		
Strong Evidence	Evidence Statement	Design
	In the short, intermediate, and long-term, motor control exercises that emphasize the transversus abdominis and multifidi are at least as effective as other forms of exercise and manual therapy. They are possibly more effective than other minimal interventions in reducing pain and improving disability in patients for the treatment of chronic non-specific low back pain.	Meta-analyses of randomized clinical trials
	Land-based exercise shows a small clinically important benefit for the relief of pain and improvement in function at the completion of a supervised exercise program and these benefits are sustained for at least another 3 to 6 months among people with symptomatic osteoarthritis of the hip.	Meta-analysis of randomized clinical trials
Good Evidence	Evidence Statement	Design
	A 12-week course of treatment in the McKenzie method is at most modestly more effective than spinal manipulation of similar duration in reducing disability in patients with persistent (more than 6 weeks duration, mean = 95 weeks) nonspecific low back pain, although a clinically relevant difference was not apparent. The McKenzie method should not be utilized if there is severe nerve root involvement with motor, sensory, or reflex abnormality.	Randomized clinical trial
	Pilates is more effective in reducing pain and improving disability compared with a minimal intervention at intermediate term follow-up, but Pilates is equally as effective as other forms of exercise in improving disability at short- or intermediate-term follow-up for the treatment of patients with chronic non-specific low back pain.	Meta-analyses of randomized clinical trials

Evidence Statements Regarding Therapeutic Exercise		
Good Evidence, Continued	Exercise alone or as part of a multi-disciplinary program results in decreased disability for workers with non-acute low back pain.	Meta-analysis of randomized clinical trials
	Supervised exercise therapy with added manual mobilization shows moderate, clinically important reductions in pain compared to non-exercise controls in people with osteoarthritis of the knee.	Systematic review and meta-analysis of randomized clinical trials
	Land-based exercise shows a moderate clinically important benefit for the relief of pain and improvement in function at the completion of a supervised exercise program and shows that somewhat smaller benefits are sustained for at least another 2 to 6 months among people with symptomatic osteoarthritis of the knee.	Meta-analysis of randomized clinical trials
Some Evidence	Evidence Statement	Design
	An unsupervised 12-week, periodized musculoskeletal rehabilitation (PMR) program of weight training conducted 2, 3, or 4 days a week is effective at improving musculoskeletal strength and quality of life and at reducing pain and disability in untrained persons with chronic low back pain. The 4 days a week training volume is most effective. The volume (total number of reps) of PMR exercise prescribed is important.	Randomized clinical trial
	Trunk balance exercises combined with flexibility exercises are more effective than a combination of strength and flexibility exercises in reducing disability and improving physical function in patients with chronic low back pain.	Single-blind randomized clinical trial
	An exercise program which includes resistance training of the cervical and scapulothoracic muscles, combined with stretching of the same muscles, is likely to be beneficial for mechanical neck pain. Cervicolscapular endurance exercises are beneficial for chronic cervicogenic headache. General fitness exercises and upper extremity exercises are unlikely by themselves to be beneficial for mechanical neck pain and are therefore ***not recommended***.	Meta-analysis of randomized clinical trials

Evidence Statements Regarding Therapeutic Exercise		
Some Evidence, Continued	There is no significant difference in the effectiveness of an 12-week, 20 session comprehensive supervised exercise program and an unsupervised simple exercise program with advice for improvement in average pain intensity in the preceding week in people with a mild chronic whiplash-associated disorder even though both interventions resulted in small reductions of pain over 12 months.	Assessor single-blind randomized clinical trial
	A 4-month intervention for chronic neck pain patients containing pain education, specific exercises and graded activity training shows a significant effect, although clinically small, on improved physical and mental health related quality of life compared with controls receiving pain education alone. Good adherence increased the effect in favor of the exercise group.	Assessor single-blind randomized controlled superiority multicenter clinical trial
	12 weeks of supervised high-dose exercise, spinal manipulative therapy, or low-dose home exercise with advice are all equally effective for reducing pain in the short- and long-term (1 year) in those who have chronic low back pain.	Assessor single-blinded randomized controlled trial
	Intensive exercise coupled with cognitive behavioral therapy is as effective for chronic un-operated low back pain as posterolateral fusion.	Randomized clinical trial
	In the setting of non-specific chronic low back pain, patient-centered cognitive functional therapy from physical therapists produced superior outcomes for pain reduction and functional improvement compared with traditional manual therapy and exercise at post-intervention and at 12-month follow-up.	Single-blind randomized clinical trial
	There is no significant difference in the effectiveness of an 8-week supervised walking program, an evidence-based group exercise class, and usual physiotherapy for improvement in functional disability after 6 months for people with chronic low back pain even though all 3 interventions resulted in small, significant improvements in physical function, reduction of pain, quality of life, and fear avoidance over time.	Assessor single-blind randomized clinical trial
	Twelve weeks of behavioral graded activity does not result in better long-term effectiveness in reducing pain or improving function at 5 years than usual exercise therapy in patients with osteoarthritis (OA) of the hip or knee.	Randomized clinical trial

Evidence Statements Regarding Yoga		
Strong Evidence	Evidence Statement	Design
	Yoga has small to moderate advantages over providing only a booklet in reducing low back pain and back-specific disability, but there is no evidence that yoga is superior to stretching and strengthening classes led by a licensed physical therapist.	Meta-analysis of randomized clinical trials
Good Evidence	Evidence Statement	Design
	In the setting of chronic low back pain, 8 weeks of 2 hour weekly group sessions of either mindfulness based stress reduction meditation program with yoga or CBT results in small, significant improvements in physical function and reduction in pain compared to usual care at 26 weeks with no significant differences in outcomes between the 2 treatments.	Single-blind randomized clinical trial
Some Evidence	Evidence Statement	Design
	Iyengar yoga, which avoids back bending, results in improved function and decreased chronic mechanical low back pain for up to 6 months. Instruction occurred 2 times per week for 24 weeks and was coupled with home exercise. One quarter of the participants dropped out.	Randomized clinical trial
	In the setting of chronic pain, both an 8-week mindfulness based stress reduction meditation program with yoga and an 8-week multidisciplinary pain intervention program with exercise resulted in small, significant reductions in pain intensity and pain-related distress post intervention but with no significant differences in outcomes between the 2 programs.	Single-blind randomized clinical trial

Time Frames for Therapeutic Exercise	
Time to Produce Effect	2 to 6 treatments.
Frequency	2 to 5 times per week.
Optimum Duration	4 to 8 weeks and concurrent with an active daily home exercise program.
Maximum Duration	8 to 12 weeks of therapist oversight. Home exercise should continue indefinitely. Additional sessions may be warranted during periods of exacerbation of symptoms

Yoga may be an option for motivated patients.

Time Frames for Yoga	
Time to Produce Effect	8 sessions
Maximum Duration	48 sessions are the maximum expected duration

h. **Work Conditioning**: This program is a work-related, outcome-focused, individualized treatment program. Objectives of the program include, but are not limited to, improvement of cardiopulmonary and neuromusculoskeletal functions (strength, endurance, movement, flexibility, postural control, and motor control functions), patient education, and symptom relief. The goal is for patients to gain full- or optimal-function and return to work. The service may include the time-limited use of modalities, both active and passive, in conjunction with therapeutic exercise, functional activities, general conditioning body mechanics, and lifting techniques re-training.

This program is usually initiated once re-conditioning has been completed but may be offered at any time throughout the recovery phase. It should be initiated when imminent return of a patient to modified- or full-duty is not an option but the prognosis for returning the patient to work at completion of the program is at least fair to good.

Time Frames for Work Conditioning	
Time to Produce Effect	1 to 2 hours per day.
Frequency	2 to 5 visits per week.
Optimum Duration	2 to 4 weeks.
Maximum Duration	6 weeks. Participation in a program beyond 6 weeks must be documented with respect to need and the ability to facilitate positive symptomatic and functional gains.

i. **Work Simulation**: is a program where an individual completes specific work-related tasks for a particular job and return to work. Use of this program is appropriate when modified duty can only be partially accommodated in the work place, when modified duty in the work place is unavailable, or when the patient requires more structured supervision. The need for work place simulation should be based upon the results of a functional capacity evaluation and/or jobsite analysis.

Time Frames for Work Simulation	
Time to Produce Effect	2 to 6 hours per day.
Frequency	2 to 5 visits per week.

Time Frames for Work Simulation	
Optimum Duration	2 to 4 weeks.
Maximum Duration	6 weeks. Participation in a program beyond 6 weeks must be documented with respect to need and the ability to facilitate positive symptomatic and functional gains.

19. THERAPY—PASSIVE:

Most of the following passive therapies and modalities are generally accepted methods of care for a variety of work-related injuries. Passive therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They should be used adjunctively with active therapies such as postural stabilization and exercise programs to help control swelling, pain, and inflammation during the active rehabilitation process. Please refer to Section B.5, General Guideline Principles, Active Interventions. Passive therapies may be used intermittently as a practitioner deems appropriate or regularly if there are specific goals with objectively measured functional improvements during treatment; or if there are episodes of acute pain superimposed upon a chronic pain problem.

On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care and co-morbidities may extend durations of care. Having specific goals with objectively measured functional improvement during treatment can support extended durations of care. It is recommended that if after 6 to 8 visits no treatment effect is observed, alternative treatment interventions, further diagnostic studies or further consultations should be pursued.

The following passive therapies are listed in alphabetical order:

a. Electrical Stimulation (Unattended): low frequency transcutaneous muscle stimulator - electrical stimulation, once applied, requires minimal on-site supervision by the practitioner. Indications include pain, inflammation, muscle spasm, atrophy, decreased circulation, and the need for osteogenic stimulation. A home unit should be purchased if treatment is effective and frequent use is recommended.

Time Frames for Electrical Stimulation	
Time to Produce Effect	2 to 4 treatments.
Frequency	Varies, depending upon indication, between 2 to 3 times per day to 1 time per week. A home unit should be purchased if treatment is effective and frequent use is recommended.

Time Frames for Electrical Stimulation	
Optimum and Maximum Duration	4 treatments for clinic use.

b. **Iontophoresis**: is an accepted treatment which consists of the transfer of medication into superficial tissue, including, but not limited to, steroidal anti-inflammatories and anesthetics, through the use of electrical stimulation. Indications include pain (lidocaine), inflammation (hydrocortisone, salicylate, dexamethasone sodium phosphate), edema (mecholyl, hyaluronidase, and salicylate), ischemia (magnesium, mecholyl, and iodine), muscle spasm (magnesium, calcium), calcific deposits (acetate), scars and keloids (chlorine, iodine, acetate).

Time Frames for Iontophoresis	
Time to Produce Effect	1 to 4 treatments.
Frequency	3 times per week with at least 48 hours between treatments.
Optimum Duration	4 to 6 weeks.
Maximum Duration	6 weeks.

c. **Low Level Laser**: ***Not recommended*** as there is no proven benefit for this intervention due to lack of studies of sufficient quality. There is not enough research at this time to support this modality in the treatment of chronic pain. Results of low level laser have been mixed and often of poor quality.

d. **Manual Treatment including Manipulation**: is defined as osteopathic manipulative treatment, chiropractic manipulative treatment, manual therapy, manipulation, or mobilization. Manual treatments may be applied by osteopathic physicians (DOs), chiropractors (DCs), physical therapists (PTs), occupational therapists (OTs), or medical doctors (MDs). Some popular and useful techniques include but are not limited to: high velocity, low amplitude (HVLA); muscle energy (ME) or hold-relax; strain-counterstrain (SCS); a balanced ligamentous tension (BLT); and myofascial release (MFR). Under these different types of manipulation, many subsets of different techniques that can be described as a) direct - a forceful engagement of a restrictive/pathologic barrier, b) indirect - a gentle/non-forceful disengagement of a restrictive/pathologic barrier, c) the patient actively assists in the treatment, and d) the patient relaxing, allowing the practitioner to move and balance the body tissues. When the proper diagnosis is made and coupled with the appropriate technique, manipulation has no contraindications and can be applied to all tissues of the body, including muscles, tendons, ligaments, joints, fascia, and viscera. This may consist of a variety of techniques. Pre-treatment assessment should be performed as part of each manual treatment visit to ensure that the correct diagnosis and correct treatment is employed.

The decision to refer a patient for spinal manipulation rather than for other

treatments should be made on the basis of patient preference and relative safety, not on an expectation of a greater treatment effect. It may be the first line of treatment, in combination with active therapy for some patients, and should strongly be considered for patients with positive provocative testing for SI joint dysfunction or facet dysfunction who are not recovering in the first few weeks. Manipulation may be indicated in patients who have not had an evaluation for manual medicine or who have not progressed adequately in an exercise program.

Contraindications to HVLA manipulation include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritis, aortic aneurysm, and signs of progressive neurologic deficits.

AHRQ supports use of spinal manipulation for chronic low back pain. In addition, based on multiple studies with some and good levels of evidence, there is good evidence supporting the use of manual therapy for treating chronic low back pain and chronic neck pain. There is also good evidence that supervised exercise therapy with added manual mobilization shows moderate, clinically important reductions in pain compared to non-exercise controls in people with osteoarthritis of the knee. There is not sufficient evidence to reliably determine whether manual muscle energy technique (MET) is likely to be effective in practice. See the evidence listed below for more detail on individual studies and their comparison groups.

Evidence Statements Regarding Manual Treatment for Neck		
Good Evidence	Evidence Statement	Design
	Multiple sessions of thoracic manipulation was more effective in reducing short- and intermediate-term chronic neck pain and improving function and quality of life when compared with multiple sessions of an inactive control for the treatment of patients with chronic neck pain.	Meta-analyses of randomized clinical trials and quasi RCTs
Some Evidence	Evidence Statement	Design
	A three week program of twice weekly home neck exercises with manual physical therapy that includes joint mobilization, muscle energy, and stretching, reduces neck pain and disability compared with a minimal intervention for patients with chronic neck pain at 6 weeks follow-up. It did not persist at one year follow-up.	Randomized clinical trial
	Combination of exercise and spinal manipulation is more effective than manipulation alone in relieving chronic neck pain and that these advantages remain for more than 1 year after the end of treatment.	Randomized clinical trials
	Craniosacral therapy for chronic nonspecific neck pain, performed by a physical therapist trained in the technique, is superior to sham treatment in reducing neck pain intensity at 8 weeks and probably at 20 weeks.	Randomized clinical trial

Evidence Statements Regarding Manual Treatment for Neck		
Some Evidence, Continued	12 weeks of supervised high-dose exercise, 20 sessions 1-2 times per week, with or without spinal manipulative therapy, resulted in significantly greater pain reduction in the short-term (12 weeks) compared to low-dose home exercise with advice, in people with chronic neck pain. Disability reduction was also significantly greater. However, the low dose group had only 2 visits with a provider which would generally be expected to diminish the outcome measurements. The effect decreased at one year follow-up.	Assessor single-blinded randomized controlled trial

Evidence Statements Regarding Manual Treatment for Low Back		
Good Evidence	Evidence Statement	Design
	Spinal manipulative therapy (SMT) is comparable to exercise, standard medical care, and physiotherapy in reducing chronic low back pain, and SMT does not provide a clinically important superior pain relief over these interventions.	Meta-analysis of randomized clinical trials
	Two sessions of thrust manipulation of the thoracolumbar spine followed by an exercise regimen leads to better low back function at 6 months than oscillatory non-thrust manipulation in patients with subacute low back pain. The study found patients with the following characteristics were likely to benefit from the program: segmental hypomobility, no symptoms distal to the knee, low fear-avoidance scores, and preservation of at least 35 degrees of internal rotation in at least one hip.	Randomized controlled trial
Some Evidence	Evidence Statement	Design
	Spinal manipulation/mobilization, followed by active exercises, may be effective for the reduction of disability from nonspecific low back pain lasting more than 12 weeks.	Randomized clinical trial
	12 sessions of spinal manipulation in 6 weeks from a chiropractor yields the most favorable pain reduction and functional disability improvement compared to a hands-on control in the short-term (12 weeks) for chronic nonspecific LBP. There was little difference in pain and disability scores and no clinically important differences between spinal manipulation dose groups of 6, 12, or 18 manipulations, making it difficult to recommend one treatment dose over another.	Assessor single-blinded randomized controlled trial

Evidence Statements Regarding Manual Treatment for Low Back		
Some Evidence, Continued	12 weeks of supervised high-dose exercise, spinal manipulative therapy, or low-dose home exercise with advice are all equally effective for reducing pain in the short- and long-term (1 year) in those who have chronic low back pain	Assessor single-blinded randomized controlled trial
	A combination of spinal manipulation and exercise is more effective than exercise alone in reducing pain and improving function of low back pain for 1 year.	Randomized clinical trial

Evidence Statements Regarding Manual Treatment for Knee		
Good Evidence	Evidence Statement	Design
	Supervised exercise therapy with added manual mobilization shows moderate, clinically important reductions in pain compared to non-exercise controls in people with osteoarthritis of the knee.	Systematic review and meta-analysis of randomized clinical trials

Time Frames for Manual Treatment Including Manipulation	
Time to Produce Effect	6 to 9 treatments.
Frequency	1 to 3 times per week for the first 2 weeks as indicated by the severity of the condition. Treatment may continue at 1 treatment per week for the next 6 weeks.
Optimum Duration	4-6 weeks.
Maximum Duration	8 weeks. At week 8, patients should be re-evaluated. Care beyond 8 weeks may be indicated for certain chronic pain patients in whom manipulation is helpful in improving function, decreasing pain and improving quality of life. In these cases, treatment may be continued at 1 treatment every other week until the patient has reached MMI and maintenance treatments, using the accompanying post MMI guideline, have been determined. Refer to Section I, Maintenance Management. Extended durations of care beyond what is considered “maximum” may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities.

e. **Manipulation Under General Anesthesia (MUA)**: refers to manual manipulation of the lumbar spine in combination with the use of a general anesthetic or

conscious sedation. It is intended to improve the success of manipulation when pain, muscle spasm, guarding, and fibrosis appear to be limiting its application in patients otherwise suitable for their use.

There have been no high quality studies to justify its benefits given the risks of general anesthetic and conscious sedation. It is ***not recommended***.

f. **Manipulation Under Joint Anesthesia (MUJA)**: refers to manipulation of the lumbar spine in combination with a fluoroscopically guided injection of anesthetic with or without corticosteroid agents into the facet joint at the level being manipulated.

There are no controlled clinical trials to support its use. It is ***not recommended***.

g. **Massage—Manual or Mechanical**: Massage is manipulation of soft tissue with broad ranging relaxation and circulatory benefits. This may include stimulation of acupuncture points and acupuncture channels (acupressure), application of suction cups, and techniques that include pressing, lifting, rubbing, pinching of soft tissues by or with the practitioners' hands. Indications include edema (peripheral or hard and non-pliable edema), muscle spasm, adhesions, the need to improve peripheral circulation and range-of-motion, or to increase muscle relaxation and flexibility prior to exercise.

Evidence Statements Regarding Massage		
Good Evidence	Evidence Statement	Design
	Massage therapy in combination with exercise reduces pain and improves function short-term for patients with subacute low back pain.	Randomized clinical trial, Systematic review of controlled clinical trials, Randomized clinical trial
Some Evidence	Evidence Statement	Design
	10 weeks of either relaxation massage or structural massage are more effective than usual care and equally effective in improving functional disability and reducing symptoms of pain in people with chronic low back pain with benefits lasting at least 6 months.	Single-blind parallel group randomized controlled trial.
	In the setting of chronic neck pain, 4 weeks of weekly hour-long massage leads to benefits with both pain and function, and there are incremental benefits from multiple massage sessions per week (up to 3 sessions) over a single massage session.	Randomized clinical trial with six intervention arms.

Time Frames for Massage	
Time to Produce Effect	Immediate.
Frequency	1 to 2 times per week.
Optimum Duration	6 weeks.
Maximum Duration	2 months.

h. **Mobilization (Soft Tissue)**: is a generally well-accepted treatment. Mobilization of soft tissue is the skilled application of muscle energy, strain/counter strain, myofascial release, manual trigger point release, and manual therapy techniques designed to improve or normalize movement patterns through the reduction of soft tissue pain and restrictions. Soft tissue mobilization can also use various instruments to assist the practitioner. These are typically labeled “instrument assisted soft-tissue techniques”. These can be interactive with the patient participating or can be with the patient relaxing and letting the practitioner move the body tissues. Indications include muscle spasm around a joint, trigger points, adhesions, and neural compression. Mobilization should be accompanied by active therapy.

Time Frames for Mobilization (Soft Tissue)	
Time to Produce Effect	4 to 9 treatments.
Frequency	Up to 3 times per week.
Optimum Duration	4 to 6 weeks.
Maximum Duration	6 weeks.

i. **Percutaneous Electrical Nerve Stimulation (PENS)**: Needles are used to deliver low-voltage electrical current under the skin. Theoretically this therapy prevents pain signals traveling through small nerve fibers from reaching the brain, similar to the theory of TENS.

There is good evidence that PENS produces improvement of pain and function compared to placebo; however, there is no evidence that the effect is prolonged after the initial 3 week treatment episode. There are no well done studies that show PENS performs better than TENS for chronic pain patients. PENS is more invasive, requires a trained health care provider and has no clear long-term effect; therefore it is ***not generally recommended***.

Time Frames for Percutaneous Electrical Nerve Stimulation (PENS)	
Time to Produce Effect	1 to 4 treatments.
Frequency	2 to 3 times per week.
Optimum Duration	9 sessions.
Maximum Duration	12 sessions per year.

j. **Superficial Heat and Cold Therapy (Including Infrared Therapy)**: is a generally accepted treatment. Superficial heat and cold are thermal agents applied in various manners that lower or raise the body tissue temperature for the reduction of pain, inflammation, and/or effusion resulting from injury or induced by exercise. Includes application of heat just above the surface of the skin at acupuncture points. Indications include acute pain, edema and hemorrhage, need to increase pain threshold, reduce muscle spasm, and promote stretching/flexibility. Cold and heat packs can be used at home as an extension of therapy in the clinic setting.

Time Frames for Superficial Heat & Cold Therapy (Including Infrared Therapy)	
Time to Produce Effect	Immediate.
Frequency	2 to 5 times per week.
Optimum Duration	3 weeks as primary or intermittently as an adjunct to other therapeutic procedures up to 2 months.
Maximum Duration	2 months.

k. **Traction—Manual**: is an accepted treatment and an integral part of manual manipulation or joint mobilization. Indications include decreased joint space, muscle spasm around joints, and the need for increased synovial nutrition and response. Manual traction is contraindicated in patients with tumor, infection, fracture, or fracture dislocation.

Time Frames for Manual Traction	
Time to Produce Effect	1 to 3 sessions.
Frequency	2 to 3 times per week.
Optimum/Maximum Duration	1 month.

l. **Traction—Mechanical**: Mechanical traction is indicated for decreased joint space, muscle spasm around joints, and the need for increased synovial nutrition

and response. Traction modalities are contraindicated in patients with tumor, infections, fracture, or fracture dislocation. Non-oscillating inversion traction methods are contraindicated in patients with glaucoma or hypertension.

There is some evidence that mechanical traction, using specific, instrumented axial distraction technique, is not more effective than active graded therapy without mechanical traction. Therefore, mechanical traction is ***not recommended*** for chronic axial spine pain.

Time Frames for Mechanical Traction	
Time to Produce Effect	1 to 3 sessions up to 30 minutes. If response is negative after 3 treatments, discontinue this modality.
Frequency	2 to 3 times per week.
Optimum/Maximum Duration	1 month.

m. **Transcutaneous Electrical Nerve Stimulation (TENS)**: should include least one instructional session for proper application and use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width, and amplitude modulation.

One double-blinded, placebo-controlled study, found that low frequency TENS induces analgesia which is detected on functional MRI with change in brain activity in multiple regions. There was no functional follow-up. High-frequency TENS may be more effective than low frequency for patients on opioids.

Time Frames for Transcutaneous Electrical Nerve Stimulation (TENS)	
Time to Produce Effect	Immediate.
Frequency	Variable.
Optimum Duration	3 sessions. If beneficial, provide with home unit.
Maximum Duration	3 sessions. Purchase if effective.

n. **Trigger Point Dry Needling (TDN)**: Description: TDN is a skilled intervention performed by physical therapists that utilizes a solid filament needle to penetrate the skin and underlying tissues to treat relevant muscular, neural, and other connective tissues for the evaluation and management of neuromusculokeletal conditions, pain, movement impairments, and disability. The technique can be done with or without electrical stimulation. It has been used for tendinopathies, headaches and occipital neuralgia, plantar fasciitis, shoulder pain, lateral epicondylalgia, spinal pain, hip and knee pain. The goal of dry needling is to improve overall function and disability by decreasing pain and improving range-

of-motion, strength, and/or muscle firing patterns. It is a technique that is utilized in conjunction with other physical therapy treatments including therapeutic exercise, manual therapy, stretching, neuromuscular re-education, postural education, and pain neuroscience education.

Indications: Trigger point dry needling is indicated when myofascial trigger points are identified in muscles in conjunction with decreased range-of-motion, decreased strength, altered muscle firing patterns, and/or pain which negatively affect a patient's overall function.

Complications: Potential but rare complications of dry needling include infection and pneumothorax. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

There is some evidence that the inclusion of 2 sessions of trigger point dry needling into a twice daily 5-week exercise program was significantly more effective in improving shoulder pain-related disability than an exercise program alone at 3, 6, and 12 month follow-ups in people with chronic subacromial pain syndrome. Both interventions were equally effective in reducing pain over 12 months.

There is some evidence that 4 sessions of trigger point deep dry needling with passive stretching over 2 weeks was significantly more effective in reducing neck pain and improving neck disability than passive stretching alone in the short-term and at 6-month follow-up in people with chronic nonspecific neck pain.

Based on a number of meta-analysis and systematic reviews, studies have shown some advantage for dry needling. However, there are also a number of studies with negative results. Because of the low quality of studies and heterogeneity, no form of evidence can be drawn from these reviews, which include a number of anatomic sites.

Time Frames for Trigger Point Dry Needling (TDN)	
Time to Produce Effect	Immediately or up to 4 visits.
Frequency	1 to 2 sessions/week normally limited to 4 muscle groups.
Optimum Duration	4 treatments.
Maximum Duration	8 treatments.

o. **Ultrasound (Including Phonophoresis)**: is an accepted treatment which uses sonic generators to deliver acoustic energy for therapeutic thermal and/or non-thermal soft tissue effects. Indications include scar tissue, adhesions, collagen fiber, and muscle spasm, and the need to extend muscle tissue or accelerate the soft tissue healing. Ultrasound with electrical stimulation is concurrent delivery of electrical energy that involves dispersive electrode placement. Indications include muscle spasm, scar tissue, pain modulation, and muscle facilitation.

Phonophoresis is the transfer of medication to the target tissue to control

inflammation and pain through the use of sonic generators. These topical medications include, but are not limited to, steroidal anti-inflammatory, and anesthetics.

There is no high quality evidence to support the use of ultrasound for improving pain or quality of life in patients with non-specific chronic low back pain.

Time Frames for Ultrasound (Including Phonophoresis)	
Time to Produce Effect	6 to 15 treatments.
Frequency	3 times per week.
Optimum Duration	4 to 8 weeks.
Maximum Duration	2 months.

p. **Vertebral Axial Decompression (VAX-D)/DRX, 9000**: Motorized traction devices which purport to produce non-surgical disc decompression by creating negative intradiscal pressure in the disc space include devices with the trade names of VAX-D and DRX 9000.

There are no good studies to support their use. They are ***not recommended***.

H. THERAPEUTIC PROCEDURES – OPERATIVE

When considering operative intervention in chronic pain management, the treating physician must carefully consider the inherent risk and benefit of the procedure. All operative intervention should be based on a positive correlation with clinical findings, the clinical course, and diagnostic tests. A comprehensive assessment of these factors should have led to a specific diagnosis with positive identification of the pathologic condition. Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions.

Surgical procedures are seldom meant to be curative and should be employed in conjunction with other treatment modalities for maximum functional benefit. Functional benefit should be objectively measured and includes the following:

- Return-to-work or maintaining work status.
- Fewer restrictions at work or performing activities of daily living.
- Decrease in usage of medications prescribed for the work-related injury.
- Measurable functional gains, such as increased range-of-motion or a documented increase in strength.

Education of the patient should include the proposed goals of the surgery, expected gains, risks or complications, and alternative treatment.

Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician. If a treating physician recommends a specific smoking cessation program peri-operatively, this should be covered by the insurer. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels. The surgeon will make the final determination as to whether smoking cessation is required prior to surgery. Similarly, patients with uncontrolled diabetes are at increased risk of post-operative infection and poor wound healing. It is recommended that routine lab work prior to any surgical intervention include a hemoglobin A1c. If it is higher than the recommended range, the surgery should be postponed until optimization of blood sugars has been achieved.

Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities, and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

1. NEUROSTIMULATION

a. Description: Spinal cord stimulation (SCS) is the delivery of low-voltage electrical stimulation to the spinal cord or peripheral nerves to inhibit or block the sensation of pain. The system uses implanted electrical leads and a battery powered implanted pulse generator (IPG).

There is some evidence that SCS is superior to reoperation in the setting of persistent radicular pain after lumbosacral spine surgery, and there is some evidence that SCS is superior to conventional medical management in the same

setting. Success was defined as achieving 50% or more pain relief. However, the study could not demonstrate increased return to work. Some functional gains have been demonstrated. These findings may persist at 3 years of follow-up in patients who had an excellent initial response and who are highly motivated.

There is some evidence that a high-frequency, 10 KHz spinal cord stimulator is more effective than a traditional low frequency 50 Hz stimulator in reducing both back pain and leg pain in patients who have had a successful trial of an external stimulator. Two-thirds of the patients had radiculopathy and one-half had predominant back pain. The high frequency device appears to lead to greater patient satisfaction than the low frequency device, which is likely to be related to the fact that the high frequency device does not produce paresthesias in order to produce a pain response. In contrast to the low frequency stimulator, which requires recharging about twice per month, the high frequency stimulator is recommended for daily recharging for 30 to 45 minutes. A United Kingdom study of cost effectiveness for high frequency spinal cord stimulators found high cost effectiveness compared to traditional non-rechargeable or rechargeable stimulators, re-operation, or medical management.

Some evidence shows that SCS is superior to re-operation and conventional medical management for severely disabled patients who have failed conventional treatment and have Complex Regional Pain Syndrome (CRPS I) or failed back surgery with persistent radicular neuropathic pain.

A recent randomized trial found that patients with spinal cord stimulators for CRPS preferred different types and levels of stimulation for pain relief. No difference was found between 40,500 and 1200 Hz levels or burst stimulation.

SCS can be used for patients who have CRPS II. Spinal cord stimulation for spinal axial pain has traditionally not been very successful. It is possible that future technological advances such as high frequency and burst stimulation may demonstrate better results for axial spine pain. Currently, traditional spinal cord stimulators are ***not recommended*** for axial spine pain.

SCS may be most effective in patients with CRPS I or II who have not achieved relief with oral medications, rehabilitation therapy, or therapeutic nerve blocks, and in whom the pain has persisted for longer than 6 months.

It is particularly important that patients meet all of the indications before a permanent neurostimulator is placed because several studies have shown that workers' compensation patients are less likely to gain significant relief than other patients. As of the time of this guideline writing, spinal cord stimulation devices have been FDA approved as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral and bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

Particular technical expertise is required to perform this procedure and is available in some neurosurgical, rehabilitation, and anesthesiology training programs and fellowships. Physicians performing this procedure must be trained in neurostimulation implantation and participate in ongoing training workshops on this subject, such as those sponsored by the Spine Intervention Society (SIS), North American Neuromodulation Society (NANS), or as sponsored by implant manufacturers. Permanent electrical lead and IPG placement should be performed by surgeons (orthopedic or neurosurgery) with fellowship training in

spine based surgical interventions or other physicians who have completed an Accreditation Council for Graduate Medical Education (ACGME) accredited pain medicine fellowship and have completed the required number of supervised implantations during fellowship.

b. Complications: Serious, less common complications include spinal cord compression, paraplegia, epidural hematoma, epidural hemorrhage, undesirable change in stimulation, seroma, CSF leakage, infection, erosion, and allergic response. Other complications consist of dural puncture, hardware malfunction or equipment migration, pain at implantation site, loss of pain relief, chest wall stimulation, and other surgical risks. In recent studies, device complication rates have been reported to be 25% at 6 months, 32% at 12 months, and 45% at 24 months. The most frequent complications are reported to be electrode migration (14%) and loss of paresthesia (12%), up to 24% required additional surgery. In a recent review of spinal stimulation, 34.6% of all patients reported a complication, most of them being technical equipment-related issues or undesirable stimulation.

c. Surgical Indications: Patients with established CRPS I or II or a failed spinal surgery with persistent functionally limiting radicular pain greater than axial pain who have failed conservative therapy including active and/or passive therapy, pre-stimulator trial psychiatric evaluation and treatment, medication management, and therapeutic injections. Traditional SCS is ***not recommended*** for patients with the major limiting factor of persistent axial spine pain. High frequency stimulators may be used for patients with predominantly axial back pain. Traditional or other SCS may be indicated in a subset of patients who have a clear neuropathic radicular pain (radiculitis) with or without previous surgery. The extremity pain should account for at least 50% or greater of the overall back and leg pain experienced by the patient. Prior authorization is required. Habituation to opioid analgesics in the absence of a history of addictive behavior does not preclude the use of SCS. Patients with severe psychiatric disorders, issues of secondary gain, and one or more primary risk factors are not candidates for the procedure. The prognosis worsens as the number of secondary risk factors increases. Approximately, one third to one half of patients who qualify for SCS can expect a substantial long-lasting pain relief; however, it may not influence allodynia and hypesthesia. Patients' expectations need to be realistic, and therefore, patients should understand that the SCS intervention is not a cure for their pain but rather a masking of their symptomatology which might regress over time. There appears to be a likely benefit of up to 3 years, although some practitioners have seen benefits persist for longer periods.

Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work, as well as possible complications. The patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

Informed decision making should be documented for all invasive procedures. This must include a thorough discussion of the pros and cons of the procedure and the possible complications as well as the natural history of the identified diagnosis. Since many patients with the most common conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment.

Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician. If a treating physician recommends a specific smoking cessation program peri-operatively, this should be covered by the insurer. Typically the patient should show some progress toward cessation at about 6 weeks. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels. The surgeon will make the final determination as to whether smoking cessation is required prior to surgery. Patients with demonstrated success may continue the program up to 3 months or longer if needed based on the operative procedure. Smoking cessation should continue throughout the post-operative period. Refer to Section G.10.j, Smoking Cessation Medications and Treatment, for further details.

Patients must meet the following criteria in order to be considered for neurostimulation:

i. Traditional or other SCS may be indicated in a subset of patients who have a clear neuropathic radicular pain (radiculitis); are not candidates for surgical intervention on the spine; have burning pain in a distribution amenable to stimulation coverage and have pain at night not relieved by position. The extremity pain should account for at least 50% or greater of the overall leg and back pain experienced by the patient. High frequency stimulators may be used for patients with predominantly axial back pain.

ii. *Prior* to the stimulator trial, a comprehensive psychiatric or psychological evaluation, for a chronic pain evaluation. Refer to Section F.2, Personality/Psychological Evaluation for Pain Management, for more information. This evaluation should include a standardized detailed personality inventory with validity scales (e.g., MMPI-2, MMPI-2-RF, or PAI); pain inventory with validity measures (e.g., BHI 2, MBMD); clinical interview and complete review of the medical records. The psychologist or psychiatrist performing these evaluations should not be an employee of the physician performing the implantation. This evaluation must be completed, with favorable findings, before the screening trial is scheduled. Before proceeding to a spinal stimulator trial, the evaluation should find the following:

- No indication of falsifying information.
- No indication of invalid results on testing; and
- No primary psychiatric risk factors or “red flags” (e.g., psychosis, active suicidality, severe depression, or addiction). (Note that tolerance and dependence to opioid analgesics are not addictive behaviors and do not preclude implantation); and
- A level of secondary risk actors or “yellow flags” (e.g., moderate depression, job dissatisfaction, dysfunctional pain conditions) judged to be below the threshold for compromising the patient’s ability to benefit from neurostimulation.
- The patient is cognitively capable of understanding and operating the neurostimulation control device; and

- The patient is cognitively capable of understanding and appreciating the risks and benefits of the procedure; and
- The patient is familiar with the implications of having an implant, can accept the complications, potential disfigurement, and effort it takes to maintain the device; and
- The patient is cognitively capable of understanding the course of injury both with and without neurostimulation; and
- The patient has demonstrated a history of motivation in and adherence to prescribed treatments; and
- The patient understands the work related restrictions that may occur with placement of the stimulator. All reasonable surgical and non-surgical treatment has been exhausted; and
- The topography of pain and its underlying pathophysiology are amenable to stimulation coverage (the entire painful area has been covered); and
- A successful neurostimulation screening test of at least 5 to 7 days.

iii. For a spinal cord neurostimulation screening test, a temporary lead is implanted at the level of pain and attached to an external source to validate therapy effectiveness. A screening test is considered successful if the patient meets both of the following criteria: (a) experiences a 50% decrease radicular or CRPS in pain, which may be confirmed by visual analogue scale (VAS) or Numerical Rating Scale (NRS), and (b) demonstrates objective functional gains or decreased utilization of pain medications.

Objective, measurable, functional gains must be evaluated by an independent occupational therapist, not affiliated with the physician performing the screening or the implant of the stimulator, and/or physical therapist and the primary treating physician prior to and before discontinuation of the trial. Functional gains may include: standing, walking, positional tolerance, upper extremity activities, increased social participation, or decreased medication use.

d. Contraindications:

- Unsuccessful SCS test: inability to obtain objective, documented, functional improvement, or reduction of pain.
- Those with cardiac pacemakers should be evaluated on an individual basis as some may qualify for surgery.
- Patients who are unable to properly operate the system.
- Patients who are anti-coagulated and cannot be without anticoagulation for a few days (e.g., patients with artificial heart valves).

- Patients with frequent severe infections.

- Patients for whom a future MRI is planned unless the manufacturer has approval for the body part that will be the subject of the MRI.

e. Operative Treatment: Implantation of stimulating leads connected by extensions to either an implanted neurostimulator or an implanted receiver powered by an external transmitter. The procedure may be performed either as an open or a percutaneous procedure, depending on the presence of epidural fibrosis and the anatomical placement required for optimal efficacy. During the final procedure for non-high frequency devices, the patient must be awakened to establish full coverage from the placement of the lead. One of the most common failures is misplaced leads. Functional improvement is anticipated for up to 3 years or longer when objective functional improvement has been observed during the time of neurostimulation screening exam.

f. Post-operative Considerations:

- MRI may be contraindicated depending on the model and implant location.

- Work restrictions postplacement include no driving when active paresthesias are present. This does not apply to high frequency stimulators as no paresthesia is present. Thus, use of potentially dangerous or heavy equipment while the simulator is active is prohibited. The physician may also limit heavy physical labor.

g. Post-operative Therapy: Active and/or passive therapy should be employed to improve function. Implantable stimulators will require frequent monitoring such as adjustment of the unit and replacement of batteries. Estimated battery life of SCS implantable devices is usually 5 – 10 years depending on the manufacturer.

Evidence Statements Regarding Neurostimulation		
Some Evidence	Evidence Statement	Design
	SCS is superior to reoperation in the setting of persistent radicular pain after lumbosacral spine surgery. Success was defined as achieving 50% or more pain relief.	Randomized clinical trial
	SCS is superior to conventional medical management in the setting of persistent radicular pain after lumbosacral spine surgery. Success was defined as achieving 50% or more pain relief. However, the study could not demonstrate increased return to work.	Randomized clinical trial

Evidence Statements Regarding Neurostimulation		
Some Evidence, Continued	A high-frequency, 10 KHz spinal cord stimulator is more effective than a traditional low frequency 50 Hz stimulator in reducing both back pain and leg pain in patients who have had a successful trial of an external stimulator. Two-thirds of the patients had radiculopathy and one-half had predominant back pain. The high frequency device appears to lead to greater patient satisfaction than the low frequency device, which is likely to be related to the fact that the high frequency device does not produce paresthesias in order to produce a pain response. In contrast to the low frequency stimulator, which requires recharging about twice per month, the high frequency stimulator is recommended for daily recharging for 30 to 45 minutes.	Randomized controlled trial The study was designed as a non-inferiority study for the experimental SCS system, and testing for superiority was done if the non-inferiority margins were met for the outcomes under consideration.
	SCS is superior to re-operation and conventional medical management for severely disabled patients who have failed conventional treatment and have CRPS I or failed back surgery with persistent radicular neuropathic pain.	Randomized clinical trials

2. DORSAL ROOT GANGLION STIMULATOR

There are currently no studies qualifying for evidence regarding chronic pain patients. Please refer to the Division's CRPS Medical Treatment Guideline for more information.

3. PERIPHERAL NERVE STIMULATION

There are no randomized controlled studies for this treatment. This modality should only be employed with a clear nerve injury or when the majority of pain is clearly in a nerve distribution in patients who have completed 6 months of other appropriate therapy including the same pre-trial psychosocial evaluation and treatment as are recommended for spinal cord stimulation. A screening trial should take place over 3 to 7 days and is considered successful if the patient meets both of the following criteria: (a) experiences a 50% decrease in pain, which may be confirmed by Visual Analogue Scale (VAS) or Numerical Rating Scale (NRS) and (b) demonstrates objective functional gains or decreased utilization of pain medications. Objective, measurable, functional gains must be evaluated by an independent occupational therapist and/or physical therapist and the primary treating physician prior to and before discontinuation of the trial. The primary treating doctor is not the doctor who placed the nerve stimulator. It may be used for proven occipital, ulnar, median, and other isolated nerve injuries.

4. INTRATHECAL DRUG DELIVERY

Not generally recommended. Requires prior authorization. Due to conflicting studies in this population and complication rate for long-term use, it may be considered only in very rare occasions when dystonia and spasticity are dominant features or when pain is not able to be managed using any other non-operative treatment. Specific brands of infusion systems have been FDA approved for the following: chronic intraspinal (epidural and intrathecal) infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, chronic infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intrathecal infusion of baclofen

for the management of severe spasticity.

Due to lack of proven efficacy and safety, the following medications are ***not recommended***: magnesium, benzodiazepines, neostigmine, tramadol, and ketamine.

a. Description: This mode of therapy delivers small doses of medications directly into the cerebrospinal fluid.

b. Complications: Intrathecal delivery is associated with significant complications, such as infection, catheter disconnects, CSF leak, arachnoiditis, pump failure, nerve injury, and paralysis.

Typical adverse events reported with opioids (i.e., respiratory depression, tolerance, and dependence) or spinal catheter-tip granulomas that might arise during intrathecal morphine or hydromorphone treatment have not currently been recorded for ziconotide. The most common presentation of an intraspinal mass is a sudden increase in dosage required for pain relief, with new neurologic defects secondary to a mass effect. Technical errors can lead to drug overdose which can be life-threatening.

Surveys have shown technical problems requiring surgical correction in 18% to 40% of patients. CSF leakage may occur with multiple dural punctures. Since the needle is larger than the spinal catheter, there may be incomplete tissue sealing around the catheter. The function of the pump depends on its electronic power source, which may be disrupted by the magnet of an MRI; therefore, after the patient has an MRI, the pump should be checked to ensure that it does not need to be restarted. The delivery rate can be affected by atmospheric pressure and body temperature.

c. Indications: Clinical studies are conflicting, regarding long-term, effective pain relief in patients with non-malignant pain. The Division does not generally recommend the use of intrathecal drug delivery systems in injured workers with chronic pain. Due to the complication rate for long-term use, it may be considered only in very rare occasions when dystonia and spasticity are dominant features or when pain is not able to be managed using any other non-operative treatment. This treatment must be prior authorized and have the recommendation of at least one physician experienced in chronic pain management in consultation with the primary treating physician. The procedure should be performed by physicians with documented experience.

Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work, as well as possible complications. The patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

Informed decision making should be documented for all invasive procedures. This must include a thorough discussion of the pros and cons of the procedure and the possible complications as well as the natural history of the identified diagnosis. Since many patients with the most common conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment.

Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician. If a treating physician recommends a specific smoking cessation program peri-operatively, this should be covered by the insurer. Typically the patient should show some progress toward cessation at about 6 weeks. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels. The surgeon will make the final determination as to whether smoking cessation is required prior to surgery. Patients with demonstrated success may continue the program up to 3 months or longer if needed based on the operative procedure. Refer to Section G.10.j, Smoking Cessation Medications and Treatment, for further details.

This small eligible sub-group of patients must meet all of the following indications:

i. A diagnosis of a specific physical condition known to be chronically painful has been made on the basis of objective findings; and

ii. All reasonable surgical and non-surgical treatment has been exhausted including failure of conservative therapy including active and/or passive therapy, medication management, or therapeutic injections; and

iii. Pre-trial psychiatric or psychological evaluation has been performed (same as for SCS); and

iv. There is no evidence of current addictive behavior. (Tolerance and dependence to opioid analgesics are not addictive behaviors and do not preclude implantation); and

v. It is recommended that most patients be tapered off of opioids before the trial; and

vi. A successful trial of continuous infusion by a percutaneous spinal infusion pump for a minimum of 24 hours or by bolus infusion. A screening test is considered successful if the patient (a) experiences a 50% decrease in pain, which may be confirmed by VAS, and (b) demonstrates objective functional gains or decreased utilization of pain medications. Functional gains should be evaluated by an occupational therapist and/or physical therapist prior to and before discontinuation of the trial.

d. Contraindications: Infection, body size insufficient to support the size and weight of the implanted device. Patients with other implanted programmable devices should be given these pumps with caution since interference between devices may cause unintended changes in infusion rates.

5. NEUROABLATION WITH RHIZOTOMY AS THE EXCEPTION

Neuroablation or neuro-destructive procedures are not commonly used in the management of non-malignant pain. These techniques require specific expertise to perform, have erratic results, and high rates of complication. Therefore, the use of neuroablative procedures is **not recommended**, except medial branch nerve rhizotomy, for injured workers with chronic pain.

6. DORSAL NERVE ROOT RESECTION

This procedure is ***not recommended***. There exists the possibility of complications including unintended extensive nerve damage causing significant motor or sensibility changes from larger than anticipated lesioning of the ganglia at the dorsal ganglia level. For radio-frequency ablation refer to Section G.8.d, Radio Frequency Ablation - Dorsal Nerve Root Ganglion.

I. MAINTENANCE MANAGEMENT

Successful management of chronic pain conditions results in fewer relapses requiring intense medical care. Failure to address long-term management as part of the overall treatment program may lead to higher costs and greater dependence on the health care system. Management of CPD continues after the patient has met the definition of maximum medical improvement (MMI). MMI is declared when a patient's condition has plateaued and an authorized treating physician believes no further medical intervention is likely to result in improved function. When the patient has reached MMI, a physician must describe in detail the maintenance treatment.

Maintenance care in CPD requires a close working relationship between the carrier, the providers, and the patient. Providers and patients have an obligation to design a cost-effective, medically appropriate program that is predictable and allows the carrier to set aside appropriate reserves. Carriers and adjusters have an obligation to assure that medical providers can design medically appropriate programs. Designating a primary physician for maintenance management is strongly recommended.

Maintenance care will be based on principles of patient self-management. When developing a maintenance plan of care, the patient, physician, and insurer should attempt to meet the following goals:

- Maximal independence will be achieved through the use of home exercise programs or exercise programs requiring special facilities (e.g., pool, health club) and educational programs;
- Modalities will emphasize self-management and self-applied treatment;
- Management of pain or injury exacerbations will emphasize initiation of active therapy techniques and may occasionally require anesthetic injection blocks.
- Dependence on treatment provided by practitioners other than an authorized treating physician will be minimized;
- Reassessment of the patient's function must occur regularly to maintain daily living activities and work function;
- Patients will understand that failure to comply with the elements of the self-management program or therapeutic plan of care may affect consideration of other interventions.

It is recommended that valid functional tests are used with treatments to track efficacy. The following are Specific Maintenance Interventions and Parameters:

1. **HOME EXERCISE PROGRAMS AND EXERCISE EQUIPMENT**: Most patients have the ability to participate in a home exercise program after completion of a supervised exercise rehabilitation program. Programs should incorporate an exercise prescription including the continuation of an age-adjusted and diagnosis-specific program for aerobic conditioning, flexibility, stabilization, and strength. Many patients will benefit from several booster sessions per year, which may include motivational interviewing and graded activity.

Some patients may benefit from the purchase or rental of equipment to maintain a home exercise program. Determination for the need of home equipment should be based on

medical necessity to maintain MMI, compliance with an independent exercise program, and reasonable cost. Before the purchase or long-term rental of equipment, the patient should be able to demonstrate the proper use and effectiveness of the equipment. Effectiveness of equipment should be evaluated on its ability to improve or maintain functional areas related to activities of daily living or work activity. Home exercise programs are most effective when done 3 to 5 times a week. Prior to purchasing the equipment a therapist and/or exercise specialist who has treated the patient should visit a facility with the patient to assure proper use of the equipment. Occasionally, compliance evaluations may be made through a 4 week membership at a facility offering similar equipment.

2. **EXERCISE PROGRAMS REQUIRING SPECIAL FACILITIES**: Some patients may have higher compliance with an independent exercise program at a health club versus participation in a home program. All exercise programs completed through a health club facility should focus on the same parameters of an age-adjusted and diagnosis-specific program for aerobic conditioning, flexibility, stabilization, and strength. Prior to purchasing a membership, a therapist and/or exercise specialist who has treated the patient should visit a facility with the patient to assure proper use of the equipment. Selection of health club facilities should be limited to those able to track attendance and utilization, and provide records available for physician and insurer review.

Time Frames for Exercise Programs Requiring Special Facilities	
Frequency	2 to 3 times per week.
Maximum Maintenance Duration	3 months. Continuation beyond 3 months should be based on functional benefit and patient compliance. Health club membership should not extend beyond 3 months if attendance drops below 2 times per week on a regular basis.

3. **PATIENT EDUCATION MANAGEMENT**: Educational classes, sessions, or programs may be necessary to reinforce self-management techniques. This may be performed as formal or informal programs, either group or individual.

Time Frames for Patient Education Management	
Maintenance Duration	2 to 6 educational visits during one 12 month period.

4. **PSYCHOLOGICAL MANAGEMENT**: An ideal maintenance program will emphasize management options implemented in the following order: (a) individual self-management (pain control, relaxation, and stress management, etc.), (b) group counseling, (c) individual counseling by a psychologist or psychiatrist, and (d) inpatient treatment. Exacerbation of the injury may require psychological treatment to restore the patient to baseline. In those cases, use treatments and time frame parameters listed in the Biofeedback and Psychological Evaluation or Intervention sections.

Time Frames for Psychological Management	
Maintenance Duration	6 to 10 visits during the first year and 4 to 6 visits per year thereafter. In cases of significant exacerbation or complexity, refer to Section G.15, on psychological treatment.

5. **NON OPIOID MEDICATION MANAGEMENT**: In some cases, self-management of pain and injury exacerbations can be handled with medications, such as those listed in the Medication section. Physicians must follow patients who are on any chronic medication or prescription regimen for efficacy and side effects. Laboratory or other testing may be appropriate to monitor medication effects on organ function.

Time Frames for Non Opioid Medication Management	
Maintenance Duration	Usually, 4 medication reviews within a 12 month period. Frequency depends on the medications prescribed. Laboratory and other monitoring as appropriate.

6. **OPIOID MEDICATION MANAGEMENT**: In very selective cases, scheduled opioids may prove to be the most cost effective means of ensuring the highest function and quality of life; however, inappropriate selection of these patients may result in a high degree of iatrogenic illness including addiction and drug overdose. A patient should have met the criteria in the opioids section of this guideline before beginning maintenance opioids. Laboratory or other testing may be appropriate to monitor medication effects on organ function. The following management is suggested for maintenance opioids:

- The medications should be clearly linked to improvement of function, not just pain control. All follow-up visits should document the patient's ability to perform routine functions satisfactorily. Examples include the abilities to perform: work tasks, drive safely, pay bills or perform basic math operations, remain alert and upright for 10 hours per day, or participate in normal family and social activities. If the patient is not maintaining reasonable levels of activity the patient should usually be tapered from the opioid and tried on a different long-acting opioid.

- A lower risk opioid medication regimen is defined as less than 50 MME per day. This may minimally increase or decrease over time. Dosages will need to be adjusted based on side effects of the medication and objective function of the patient. A patient may frequently be maintained on non-opioid medications to control side effects, treat mood disorders, or control neuropathic pain; however, only one long-acting opioid and one short-acting opioid for rescue use should be prescribed. Buccally absorbed opioids other than buprenorphine are not appropriate for these non-malignant pain patients. Transdermal opioid medications are ***not recommended,*** other than buprenorphine.

- All patients on chronic opioid medication dosages need to sign an appropriate opioid contract with their physician for prescribing the opioids.

- The patient must understand that continuation of the medication is contingent on their cooperation with the maintenance program. Use of non-prescribed drugs may result in tapering of the medication. The clinician should order random drug testing at least annually and when deemed appropriate to monitor medication compliance.

- Patients on chronic opioid medication dosages must receive them through one prescribing physician.

Time Frames for Opioid Medication Management	
Maintenance Duration	12 visits within a 12 month period to review the opioid plan. Laboratory and other monitoring, as appropriate.

7. **THERAPY MANAGEMENT**: Some treatment may be helpful on a continued basis during maintenance care if the therapy maintains objective function and decreases medication use. With good management, exacerbations should be uncommon; not exceeding 2 times per year and using minimal or no treatment modality beyond self-management. On occasion, exacerbated conditions may warrant durations of treatment beyond those listed below. Having specific goals with objectively measured functional improvement during treatment can support extended durations of care. It is recommended that if after 6 to 8 visits no treatment effect is observed, alternative treatment interventions should be pursued.

Time Frames for Therapy Management	
Maintenance Duration	Active therapy, acupuncture, or manipulation: 10 visits [for each treatment] during the first year and then decreased to 5 visits per year thereafter.

8. **INJECTION THERAPY**:

a. Trigger Point Injections and Dry Needling: These injections or dry needling may occasionally be necessary to maintain function in those with myofascial problems.

Time Frames for Injection Therapy: Trigger Point Injections and Dry Needling	
Maintenance Duration	Not more than 4 injections per session not to exceed 4 sessions per 12 month period.

b. Epidural and Selective Nerve Root Injections: Patients who have experienced functional benefits from these injections in the past may require injection for exacerbations of the condition. Recall that the total steroid injections at all sites, including extremities, should be limited to 4 per year to avoid side effects from steroids.

Time Frames for Epidural and Selective Nerve Root Injections	
Maintenance Duration	2 to 4 injections per 12 month period. For chronic radiculopathy, injections may be repeated only when a functional documented response lasts for 3 months. A positive result would include a return to baseline function as established at MMI, return to increased work duties, and measurable improvement in physical activity goals including return to baseline after an exacerbation. Injections may only be repeated when these functional and time goals are met and verified by the designated primary physician. Patient completed functional questionnaires such as those recommended by the Division as part of QPOP and/or the Patient Specific Functional Scale can provide useful additional confirmation.

Time Frames for Zygapophyseal (Facet) Injections	
Maintenance Duration	2 injections per year and limited to 3 joint levels either unilaterally or bilaterally. Injections may be repeated only when a functional documented response lasts for 3 months. A positive result would include a return to baseline function as established at MMI, return to increased work duties, and a measurable improvement in physical activity goals including return to baseline after an exacerbation. Injections may only be repeated when these functional and time goals are met and verified by the designated primary physician. Patient completed functional questionnaires such as those recommended by the Division as part of QPOP and/or the Patient Specific Functional Scale can provide useful additional confirmation.

Time Frames for Sacro-iliac Joint Injections	
Maintenance Duration	2 per year injections may be repeated only if a functional documented response lasts for 3 months. A positive result would include a return to baseline function as established at MMI, return to increased work duties, and a measurable improvement in physical activity goals including return to baseline after an exacerbation. Injections may only be repeated when these functional and time goals are met and verified by the designated primary physician. Patient completed functional questionnaires such as those recommended by the Division as part of QPOP and/or the Patient Specific Functional Scale can provide useful additional confirmation.

Time Frames for Radiofrequency Medial Branch Neurotomy/ Facet Rhizotomy	
Maintenance Duration:	1 time per year not exceeding 3 levels, up to 12 total in a lifetime. The patient must meet the criteria as described in Section G.8.f, Radio Frequency Denervation. The initial indications including repeat blocks and limitations apply. The long-term effects of repeat rhizotomies, especially on younger patients are unknown. There is a possibility that repeated denervation could result in premature degenerative changes. In addition the patient should always reconsider all of the possible permanent complications before consenting to a repeat procedure. There are no studies addressing the total number of RF neurotomies that should be done for a patient. Patient should receive at least 6 to 18 months minimum improvement in order to qualify for repeat procedures.
Optimum/Maximum Maintenance Duration	Twice in the first year after the initial rhizotomy and once a year after up to 12 total.

9. **PURCHASE OR RENTAL OF DURABLE MEDICAL EQUIPMENT (DME)**: It is recognized that some patients may require ongoing use of self-directed modalities for the purpose of maintaining function and/or analgesic effect. Purchase or rental of modality based equipment should be done only if the assessment by the physician and/or physical/occupational therapist has determined the effectiveness, compliance, and improved or maintained function by its application. It is generally felt that large expense purchases such as spas, whirlpools, and special mattresses are not necessary to maintain function.

Refer to Rule 18-6(H) for DME rental time frames.

APPENDIX: DESCRIPTION OF TESTS OF PSYCHOLOGICAL FUNCTIONING

Refer to Section F.2.c, Tests of Psychological Functioning, for more information. Examples of frequently used psychometric tests performed include, but are not limited to, the following:

1. Comprehensive Inventories for Medical Patients:

a. Battery for Health Improvement, 2nd Edition (BHI™ -2).

What it measures – Depression, anxiety, and hostility; violent and suicidal ideation; borderline, dependency, chronic maladjustment, substance abuse, conflicts with work, family and physician, pain preoccupation, somatization, perception of functioning, catastrophizing and kinesiophobia, and risk assessment for surgery, physical rehabilitation, and abuse of prescription medication.

Benefits – When used as a part of a comprehensive evaluation, can contribute substantially to the design of interventions and to the understanding of psychosocial factors underlying pain reports, perceived disability, and somatic preoccupation. Serial administrations can track changes in a broad range of variables during the course of treatment and assess outcome.

Characteristics – Standardized test normalized on patients with chronic pain or injury and on community members, with reference groups for six other subcategories of injured patients.

b. Millon™ Behavioral Medical Diagnostic (MBMD™).

What it measures – Updated version of the Millon Behavioral Health Inventory (MBHI). Provides information on coping styles (introversive, inhibited, dejected, cooperative, sociable, etc.), health habits (smoking, drinking, eating, etc.), psychiatric indications (anxiety, depression, etc.), stress moderators (illness apprehension vs. illness tolerance, etc.), treatment prognostics (interventional fragility vs. interventional resilience, medication abuse vs. medication competence, etc.), and other factors.

Benefits – When used as a part of a comprehensive evaluation, can contribute substantially to the understanding of psychosocial factors affecting medical patients. Understanding risk factors and patient personality type can help to optimize treatment protocols for a particular patient.

Characteristics – Standardized test normalized on medical patients with various diseases, and bariatric population. Chronic pain/presurgical analysis cites a chronic pain reference group but the analysis is based on a general medical population.

2. Comprehensive Psychological Inventories:

These tests are designed for detecting various psychiatric syndromes but in general are more prone to false positive findings when administered to medical patients.

a. Millon® Clinical Multiaxial Inventory®, (MCMI®-IV).

What it measures – Has scales to assess 15 types of maladaptive personality types, and 10 clinical syndromes including bipolar spectrum, depression, anxiety, drug/alcohol abuse, somatic symptom, post-traumatic stress and psychosis.

Benefits – When used as a part of a comprehensive evaluation, can screen for a broad range of ICD psychiatric diagnoses.

Characteristics – Standardized test normalized on psychiatric patients.

b. Minnesota Multiphasic Personality Inventory®, 2nd Edition (MMPI®-2).

What it measures – Original scale constructs, such as hysteria and psychasthenia are archaic but continue to be useful. Newer content scales include depression, anxiety, health concerns, bizarre mentation, social discomfort, low self-esteem, and almost 100 others.

Benefits – When used as a part of a comprehensive evaluation, measure a number of factors that have been associated with poor treatment outcome.

Characteristics – Standardized test normalized on community members

c. Minnesota Multiphasic Personality Inventory®, 2nd Edition Revised Form (MMPI®-2).

What it measures – 50 scales assess a wide range of psychiatric disorders and personality traits, plus 8 validity scales, critical items.

Benefits – new version of MMPI-2 has undergone extensive revision to correct perceived MMPI-2 deficiencies. Has advantages over the original MMPI-2 in psychiatric assessment, but may be less capable when assessing patients with chronic pain.

Characteristics – Standardized test normalized on community members, with multiple other reference groups including chronic pain and spine surgery candidate.

d. Personality Assessment Inventory™ (PAI®).

What it measures – A measure of general psychopathology that assesses depression, anxiety, somatic complaints, stress, alcohol and drug use reports, mania, paranoia, schizophrenia, borderline, antisocial, suicidal ideation, and more than 30 others.

Benefits – When used as a part of a comprehensive evaluation, can contribute substantially to the identification of a wide variety of risk factors that could potentially affect the medical patient.

Characteristics – Standardized test normalized on community members.

3. Brief Multidimensional Screens for Medical Patients:

Treating providers may use brief instruments to assess a variety of psychological and medical conditions, including depression, pain, disability, and others. These instruments may also be employed as repeated measures to track progress in treatment or as one test in a more comprehensive evaluation. Brief instruments are valuable in that the test may be administered in the office setting and hand scored by the physician. Results of these tests should help providers distinguish which patients should be referred for a specific type of comprehensive evaluation.

a. Brief Battery for Health Improvement, 2nd Edition (BBHI™ -2).

What it measures – Depression, anxiety, somatization, pain, function, and defensiveness.

Benefits – Can identify patients needing treatment for depression and anxiety and identify patients prone to somatization, pain magnification, and self-perception of disability. Can compare the level of factors above to other pain patients and community members. Serial administrations can track changes in measured variables during the course of treatment and assess outcome.

Characteristics – Standardized test normalized on patients with chronic pain or injury and on community members, with reference groups for six subcategories of injured patients.

b. Pain Patient Profile (P-3®).

What it measures – Assesses depression, anxiety, and somatization.

Benefits – Can identify patients needing treatment for depression and anxiety and patients prone to somatization. Can compare the level of depression, anxiety, and somatization to other pain patients and community members. Serial administrations can track changes in measured variables during the course of treatment and assess outcome.

Characteristics – Standardized test normalized on patients with chronic pain and on community members.

c. SF-36®.

What it measures – A survey of general health, well-being, and functional states.

Benefits – Assesses a broad spectrum of patient disability reports. Serial administrations could be used to track patient perceived functional changes during the course of treatment and assess outcome.

Characteristics – Non-standardized test without norms.

d. Sickness Impact Profile (SIP).

What it measures – Perceived disability in the areas of sleep, eating, home management, recreation, mobility, body care, social interaction, emotional behavior, and communication.

Benefits – Assesses a broad spectrum of patient disability reports. Serial

administrations could be used to track patient perceived functional changes during the course of treatment and assess outcome.

Characteristics – Non-standardized test without norms.

e. McGill Pain Questionnaire (MPQ).

What it measures – Cognitive, emotional, and sensory aspects of pain.

Benefits – Can identify patients prone to pain magnification. Repeated administrations can track progress in treatment for pain.

Characteristics – Non-standardized test without norms.

f. McGill Pain Questionnaire – Short Form (MPQ-SF).

What it measures – Emotional and sensory aspects of pain.

Benefits – Can identify patients prone to pain magnification. Repeated administrations can track progress in treatment for pain.

Characteristics – Non-standardized test without norms.

g. Oswestry Disability Questionnaire (ODQ).

What it measures – Disability secondary to low back pain.

Benefits – Can measure patient's self-perceptions of disability. Serial administrations could be used to track changes in self-perceptions of functional ability during the course of treatment and assess outcome.

Characteristics – Non-standardized test without norms.

h. Visual Analog Scales (VAS).

What it measures – Graphical measure of patient's pain report, in which the patient makes a mark on a line to represent pain level.

Benefits – Quantifies the patient's pain report, most-commonly using a 10 centimeter horizontal line. Serial administrations could be used to track changes in pain reports during the course of treatment and assess outcome.

Characteristics – Non-standardized test without norms. Some patients may have difficulty with this conceptual test format, depending on perceptual, visuomotor, cultural orientation, or other factors.

i. Numerical Rating Scales (NRS).

What it measures – Numerical report of patient's pain.

Benefits – Quantifies the patient's pain report, typically on a 0-10 scale. Serial administrations could be used to track changes in pain reports during the course of treatment and assess outcome.

Characteristics – Recommended by the Joint Commission on Accreditation of

Healthcare Organizations (JCAHO). Non-standardized test without norms. May be more easily understood than the VAS.

j. Chronic Pain Grade Scale (CPGS):

What it measures - The CPGS is a multidimensional measure that assesses two dimensions of overall chronic pain severity: pain intensity and pain-related disability.

Benefits – Among patients with moderate to severe chronic musculoskeletal pain, the CPGS has been shown to be modestly responsive to change.

Characteristics – Non-standardized test without norms.

k. Brief Multidimensional Screens for Psychiatric Patients:

These tests are designed for detecting various psychiatric syndromes but in general are more prone to false positive findings when administered to medical patients.

l. Brief Symptom Inventory (BSI®).

What it measures: Somatization, obsessive-compulsive, depression, anxiety, phobic anxiety, hostility, paranoia, psychoticism, and interpersonal sensitivity.

Benefits: Can identify patients needing treatment for depression and anxiety and patients prone to somatization. Can compare the level of depression, anxiety, and somatization to community members. Serial administrations could be used to track changes in measured variables during the course of treatment and assess outcome.

Characteristics – Standardized test normalized on community members.

m. Brief Symptom Inventory – 18 (BSI®-18).

What it Measures: Depression, anxiety, and somatization.

Benefits: Can identify patients needing treatment for depression and anxiety and patients prone to somatization. Can compare the level of depression, anxiety, and somatization to community members. Serial administrations could be used to track patient perceived functional changes during the course of treatment and assess outcome.

Characteristics – Standardized test normalized on patients with chronic pain associated with cancer.

n. Symptom Check List – 90 Revised (SCL-90R®).

What it measures: Somatization, obsessive-compulsive, depression, anxiety, phobic anxiety, hostility, paranoia, psychoticism, and interpersonal sensitivity.

Benefits: Can identify patients needing treatment for depression and anxiety and patients prone to somatization. Can compare the level of depression, anxiety, and somatization to community members. Serial administrations could be used to track changes in measured variables during the course of treatment and assess

outcome.

Characteristics – Standardized test normalized on community members.

4. Brief Specialized Psychiatric Screening Measures:

a. Beck Depression Inventory® (BDI®).

What it measures: Depression.

Benefits: Can identify patients needing referral for further assessment and treatment for depression and anxiety and identify patients prone to somatization. Repeated administrations can track progress in treatment for depression, anxiety, and somatic preoccupation. Requires a professional evaluation to verify diagnosis.

Characteristics – Standardized test without norms, uses cutoff scores.

b. Center of Epidemiologic Studies – Depression Questionnaire (CES-D).

What it measures: Depression.

Benefits: Brief self-administered screening test. Requires a professional evaluation to verify diagnosis.

Characteristics – Non-standardized test without norms.

Note: Designed for assessment of psychiatric patients, not pain patients, which can bias results, and this should be a consideration when using.

c. Brief Patient Health Questionnaire from PRIME - MD®. (The PHQ-9 may also be used as a depression screen.)

What it measures: Depression, panic disorder.

Benefits: Brief self-administered screening test. Requires a professional evaluation to verify diagnosis.

Characteristics – Non-standardized test without norms, keyed to diagnostic criteria, uses cutoff scores.

d. Zung Depression Questionnaire.

What it measures: Depression.

Benefits: Brief self-administered screening test. Requires a professional evaluation to verify diagnosis.

Characteristics – Non-standardized test without norms.

Note: The Zung Depression Scale must be distinguished from the Modified Zung Depression scale used by the DRAM (a QPOP measure). The Zung Depression Scale has different items and a different scoring system than the Modified Zung Depression scale, making the cutoff scores markedly different. The cutoff scores for one measure cannot be used for the other.