

<b>Bibliographic Data</b>	
Authors	Chou R, Deyo R, et al
Title	Systemic Pharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline
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Other information if relevant	

<b>Methods</b>	
Aim of study	To review the current evidence on systemic pharmacologic treatments of acute or chronic low back pain
Design	Systematic review of randomized clinical trials

<b>Reasons not to cite as evidence</b>
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- Although numerous topics were discussed in the review, the only topic related to the chronic pain guideline was the authors' suggestion that there is evidence to support duloxetine for chronic low back pain
- The evidence supporting duloxetine was drawn from three studies whose first author was Skljarevski, published in 2009 and 2010
- Each of these trials compared duloxetine with placebo, but only one (Skljarevski, Desai et al 2010) was registered with an online protocol
- This latter study was reviewed for the Division's Chronic Pain Guideline in 2010, but was not cited as supporting evidence of the effectiveness of duloxetine due to concerns that investigators did not have access to the complete database, which remained in the custody of the corporate sponsor; the analysis of the data was complex, and the statistical analysts were not blinded to the group assignments, as well as the fact that concealment of allocation was not clearly reported
- The authors of the systematic review rated the studies on several quality criteria, including randomization, allocation concealment, baseline similarity of treatment groups, blinding, and avoiding cointervention bias; however, one significant threat to study validity, namely selective outcome reporting, was not among the quality criteria, and it is this criterion which is affected by non-registration of clinical trials
- Only the Skljarevski 2009 study had clear "yes" criteria for randomization, allocation concealment, and baseline similarity of treatment groups, and this study, which appeared to have the lowest risk of bias of the three published studies, did not find a difference between duloxetine and placebo at the 13 week which was the timing of the primary endpoint
- Therefore, the statement that duloxetine is more effective than placebo does not meet the Division's criteria for being cited as evidence

#### **Additional references or comments if relevant**

- Skljarevski V, Ossanna M, L et al. A double-blind, randomized trial of duloxetine versus placebo in the management of chronic low back pain. *Eur J Neurol.* 2009;16:1041-8.
- Skljarevski V, Zhang S, et al. Duloxetine versus placebo in patients with chronic low back pain: a 12-week, fixed-dose, randomized, double-blind trial. *J Pain.* 2010;11:1282-90.
- Skljarevski V, Desai D, et al. Efficacy and safety of duloxetine in patients with chronic low back pain. *Spine* 2010;35:E578-85.