

Policies Repository



Policy Title Tramadol Extended-Release (ER) (Ultram ER®)

Policy Number FS.CLIN.9

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Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Tramadol extended-release (ER) (Ultram ER)** is indicated for the management of moderate to moderately severe chronic pain in adults who require continuous pain relief for an extended period of time.

The use of the brand name Ultram ER® requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Tramadol extended-release (ER) (Ultram ER®) is a centrally acting synthetic opioid analgesic. Although its mode of action is not completely understood, at least two complementary mechanisms appear to be applicable during animal testing: binding of parent and M1 metabolites to μ -opioid receptors and weak inhibition of reuptake of norepinephrine and serotonin. In four 12-week, randomized, double-blind, placebo-controlled trials, tramadol ER (Ultram ER®) was studied in individuals with moderate to moderately severe chronic pain due to osteoarthritis and/or lower back pain. All four trials concluded that tramadol ER (Ultram ER®) was significantly better than the placebo in alleviating chronic pain. No trials have been conducted to compare tramadol ER (Ultram ER®) with other analgesic agents.

Policy Guideline Inclusion

Tramadol extended-release (ER) (Ultram ER®) is approved when the following inclusion criteria is met:

- Documentation of a trial and failure of or intolerance to generic tramadol extended release

Policy Guideline Exclusion

Tramadol extended-release (ER) (Ultram ER®) is denied when the following exclusion criteria is present:

- No documentation of a trial and failure of or intolerance to generic

tramadol extended release

Policy List of Applicable Drugs

Brand Name	Generic Name
Ultram ER	tramadol ER

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

Facts and Comparisons. Ultram ER® (tramadol). [Facts and Comparisons Web site]. Available at: <http://www.factsandcomparisons.com/efacts.asp> [via subscription only]. Accessed March 19, 2010.

Tramadol extended-release. In: *DrugPoints* [online through STAT! Ref]. Greenwood Village, CO: Thompson Micromedex. Available at: <http://www.thomsonhc.com> [via subscription only]. Accessed March 19, 2010.

Ultram ER® [prescribing information]. Raritan, NJ: Ortho-McNeil; 2007. Also available online at: <http://www.ultram-er.com/ultram-er/shared/pi/ultram-er.pdf#zoom=100>. Accessed March 19, 2010.

Policy Link to Related Policies**Printed**

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