Policies Repository

Independence Blue Cross

Policy Title	Tramadol Extended-Release (ER) (Ultram ER®)
Policy Number	FS.CLIN.3

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

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 **all** of the following inclusion criteria are met:

- The individual is 18 years of age or more
- Documentation of a trial and failure of or intolerance to tramadol immediate release (Ultram®)

Policy Guideline Exclusion

Tramadol ER (Ultram ER®) is denied when **any** of the following exclusion criteria are present:

- The individual is less than 18 years of age
- No documentation of a trial and failure of or intolerance to tramadol immediate release (Ultram®)

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 July 28, 2009.

Tramadol extended-release. In: *DrugPoints* [online through STAT! Ref]. Greenwood Village, CO: Thompson Micromedex. Available at: http://www.thomsonhc.com [via subscription only]. Accessed July 28, 2009.

Ultram ER® [prescribing information]. Raritan, NJ: Ortho-McNeil; 2007. Also available online at: http://www.ultram-er.com/ultram-er/shared/pi/ultramer.pdf#zoom=100. Accessed July 28, 2009.

Policy Link to Related Policies

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