Pharmacy Policy Bulletin

Title: Diclofenac potassium (Zipsor™)

Policy #: Rx.01.26

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 restrictions. 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. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. 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.

Intent:

Diclofenac potassium (Zipsor) is indicated for the relief of mild to moderate acute pain.

The use of Diclofenac potassium (Zipsor) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

Description:

Diclofenac potassium (Zipsor) is a nonsteroidal anti-inflammatory drug. The exact mechanism of action is not completely understood but may involve inhibition of the cyclooxygenase (COX-1 and COX-2) pathways.

Policy:

Diclofenac potassium (Zipsor) is approved when **all** of the following inclusion criteria are met:

- Documentation of pain
- Documentation of the trial and failure or contraindication/intolerance to a meloxicam-containing product and one additional oral non-steroidal anti-inflammatory drug (NSAID).

Quantity limit Criteria

Diclofenac potassium (Zipsor) is approved in quantities greater than 120/30days when the following inclusion criteria is met:

- Documentation of a randomized, double blind, active or placebo controlled trial demonstrating the safety and efficacy of the requested dose for the condition submitted, where the results are published in a national peer-reviewed journal.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are

experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Facts and Comparisons website. [Zipsor]. Available at www.factsandcomparisons.com. Accessed April 11, 2011.
Micromedex website [Zipsor]. Available at www.micromedex.com. Accessed April 11, 2011.
Zipsor [package insert]. Xanodyne pharmaceuticals. Newport KY. 2009.
Zipsor website. Available at www.zipsor.com. Accessed April 11, 2011.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Zipsor	Diclofenac potassium

Cross References:

Policy Version Number: 1.00

P&T Approval Date: March 08, 2012

Policy Effective Date: June 01, 2012

Next Required Review Date: March 08, 2013