Pharmacy Policy Bulletin

Title:	Diclofenac Products
Policy #:	Rx.01.155

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, quantity, or formulary restrictions (ie limits on non-preferred drugs). 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:

The intent of this policy is to communicate the medical necessity criteria for **diclofenac epolamine 1.3% (Flector®/Licart® Patch), diclofenac sodium 2% solution, and diclofenac sodium (Pennsaid®)** as provided under the member's prescription drug benefit.

Description:

Diclofenac epolamine 1.3% (Flector®/Licart® Patch) is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions in adults and pediatric patients 6 years or older.

Generic diclofenac epolamine patch is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions in adults

Diclofenac sodium 1.5% and 2% solution (Pennsaid) is indicated for the treatment of the pain of osteoarthritis of the knee(s).

Diclofenac reversibly inhibit cyclooxygenase 1 and 2 (COX-1 and COX-2) enzymes, which results in decreased formation of prostaglandin precursors. Diclofenac also has antipyretic, analgesic, and anti-inflammatory properties.

Policy:

INITIAL CRITERIA: diclofenac epolamine (Flector®/Licart®) patch, diclofenac sodium 2% solution or Pennsaid® is approved when BOTH of the following are met:

1. Diagnosis of pain; and
2. ONE of the following:
    a. BOTH of the following:
        i. Inadequate response or inability to tolerate TWO of the following:
            1. Meloxicam
            2. Celecoxib
            3. Other oral NSAID; and
        ii. Inadequate response or inability to tolerate ONE of the following:
            1. Generic topical diclofenac gel 1%
            2. Generic topical diclofenac solution 1.5%; or
    b. BOTH of the following:
        i. Member is 65 years of age or older; and
        ii. Inadequate response or inability to tolerate ONE of the following
            1. Generic topical diclofenac gel 1%
            2. Generic topical diclofenac solution 1.5%

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: diclofenac epolamine (Flector®/Licart®) patch, diclofenac sodium 2% solution or Pennsaid® is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

Diclofenac

Cardiovascular risk: Nonsteroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction (MI), and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

Diclofenac is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.

GI risk: NSAIDs cause an increased risk of serious GI adverse events, including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These reactions can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious GI events.

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 prescription drug 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:

Galer BS, Rowbotham M, Perander J, et al. Topical diclofenac patch relieves minor sports injury pain: results of a multicenter controlled clinical trial. J Pain Symptom Manage. 2000 Apr;19(4):287-94.

Flector patch (diclofenac epolamine patch) [product information]. New York, NY: Pfizer, Inc. April 2021. Available at: http://labeling.pfizer.com/ShowLabeling.aspx?id=829. Accessed April 19, 2023.

Licart™ (diclofenac epolamine) topical system [prescribing information]. Parsippany, NJ: IBSA Pharma Inc.: April 2021. Available from: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=851c8b39-6056-4bbc-812e-b9b13977c1ac. Accessed April 19, 2023.

Pennsaid (diclofenac sodium topical solution) Lake Forest, IL. Horizon Pharma USA Inc. [product information]. January 2022. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=802cd382-443d-48e3-9c9d-fd946c73c79f&type=display. Accessed April 19, 2023.

Diclofenac epolamine patch prescribing information. North Wales, PA. Teva Pharmaceuticals USA, Inc. December 2019. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bda1c346-56ff-4197-9a19-7f0cc7f9ebad. Accessed April 19, 2023.

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
Flector®/Licart® Patch	Diclofenac epolamine 1.3% patch
Pennsaid® Solution	Diclofenac sodium 1.5%, 2% solution

Cross References:

Off-Label Use Rx.01.33

Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit Rx.01.76

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Next Required Review Date:	March 16, 2024