MEDICAL MUTUAL®

Drug Policy

Policy:	Topical Diclofenac Sodium 3% gel	Annual Review Date: 05/18/2023 Last Revised Date: 05/18/2023

OVERVIEW

Diclofenac sodium 3% gel is a topical nonsteroidal anti-inflammatory drug (NSAID) indicated for the topical treatment of actinic keratoses (AK). It is also noted in the labeling that sun avoidance is indicated during therapy. The mechanism of action of diclofenac sodium in the treatment of AK is unknown or not completely understood; however, it is hypothesized that diclofenac sodium may clear AK lesions via cell signaling mechanisms and possibly may play a part in the reduction of angiogenesis and induction of apoptosis (either directly or through a cytotoxic independent pathway).

There are other topical NSAIDs commercially available in the US: Voltaren Gel (diclofenac sodium topical 1% gel; generics) which is indicated for the relief of the pain of osteoarthritis (OA) of joints amenable to topical treatment, such as the knees and those of the hands; Flector Patch (diclofenac epolamine 1.3% topical patch) which is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions; and Pennsaid (diclofenac sodium 2% w/w topical solution) which is indicated for the treatment of signs and symptoms of OA of the knee(s).

POLICY STATEMENT

This policy involves the use of topical diclofenac sodium 3% gel. Prior authorization is recommended for pharmacy benefit coverage of topical diclofenac sodium 3% gel. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

Automation: When available, ICD-10 codes for actinic keratosis (ICD-10: L57.0) will be used for automation to allow approval of the requested medication for patients 18 years or older.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of topical diclofenac sodium 3% gel is recommended in those who meet the following criteria:

1. <u>Actinic Keratosis (AK)</u>
Criteria. *Patient must meet the following criteria*

A. The patient is 18 years of age or older

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 3 months
B) *Extended Approval:* 3 months

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Topical diclofenac sodium 3% gel has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Osteoarthritis (OA).** There has been one small, randomized, placebo-controlled study assessing the efficacy of a topical diclofenac 3%/sodium hyaluronate 2.5% gel (Canadian formulation) applied as 2 grams four times daily (QID) to one joint for 2 weeks in patients (n = 119) with uncontrolled OA pain despite chronic (≥ 1 month) oral NSAID use. The effect of topical diclofenac 3%/sodium hyaluronate 2.5% gel in patients who continued their chronic oral NSAID therapy demonstrated only marginally significantly greater analgesic effect than placebo gel: the mean change from baseline in overall pain from OA (using a 5-point scale) was -0.7 vs. -0.4 for topical diclofenac and placebo, respectively (P = 0.0568). Additional data are needed to define the place in therapy of diclofenac sodium 3% gel for the treatment of OA. Other topical agents are indicated for this use.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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3. Voltaren® Gel [prescribing information]. Princeton, NJ: Sandoz; April 2016.
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5. Pennsaid® topical solution [prescribing information]. Lake Forest, IL: Horizon Pharma; May 2016.
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10. Diclofenac Sodium. In: DRUGDEX (online database). Truven Health Analytics; Greenwood Village, CO. Last updated 10 May 2022. Accessed on 17 May 2022.