

PRIOR AUTHORIZATION POLICY

POLICY: Topical Diclofenac Sodium 3% Gel Prior Authorization Policy

- diclofenac sodium 3% gel (generic only)

REVIEW DATE: 08/14/2024

OVERVIEW

Diclofenac sodium 3% gel, a nonsteroidal anti-inflammatory drug, is indicated for the topical treatment of **actinic keratoses**.¹ It is also noted in the labeling that sun avoidance is indicated during therapy.

Guidelines

The National Comprehensive Cancer Network (NCCN) Squamous Cell Skin Cancer guidelines (version 1.2024 – November 9, 2023) cite topical diclofenac (formulation is not specified) as a treatment option for the treatment of actinic keratoses.² The guidelines also note diclofenac as a (potential) treatment option for the treatment of actinic keratosis on the lips (actinic cheilitis); other treatment options are: surgical vermilionectomy, lip shave, electrodesiccation, laser vermilion ablation, laser resurfacing, 5-fluorouracil, laser + 5-fluorouracil, trichloroacetic acid chemical peel, photodynamic therapy, and photodynamic therapy plus imiquimod.

Other Uses

Disseminated Superficial Actinic Porokeratosis (DSAP)

Diclofenac gel is noted as a treatment that may be effective for DSAP.³ Pharmacologic treatment options for DSAP include topical 5-fluorouracil, topical vitamin D₃ analogs, topical imiquimod, topical tacrolimus, oral retinoids (e.g., isotretinoin, acitretin) and topical retinoids (tretinoin, tazarotene), and diclofenac. Diclofenac was studied in an open-label study where patients (n = 17) received 12 weeks of therapy with diclofenac sodium 3% gel and at the end of 12 weeks, treatment could be extended for an additional 12 weeks.⁴ At Week 12, the target area lesions (treated lesions) had a mean reduction of 4% vs. a 12% mean increase in the total body lesions (global). Ten patients received 24 weeks of treatment and there was a mean increase of 10% in lesions in the target area vs. a 19% increase in global lesions.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of diclofenac sodium 3% gel. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Actinic Keratoses.** Approve for 6 months.

Other Uses with Supportive Evidence

08/14/2024

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- 2. Actinic Cheilitis (Actinic Keratoses of the Lip[s]).** Approve for 6 months.
- 3. Disseminated Superficial Actinic Porokeratosis.** Approve for 6 months if the patient has tried at least two other therapies used for the management of disseminated superficial actinic porokeratosis.
Note: Examples of therapies for management of disseminated superficial actinic porokeratosis include topical 5-fluorouracil (5-FU), imiquimod, topical corticosteroids, topical vitamin D₃ analogs, topical or oral retinoids, cryotherapy, photodynamic therapy, and laser.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of diclofenac sodium 3% gel is not recommended in the following situations:

- 1. Osteoarthritis (OA).** The benefit of topical diclofenac gel 3% in osteoarthritis is uncertain. 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 to one joint for 2 weeks in patients (n = 119) with uncontrolled OA pain despite chronic (≥ 1 month) oral nonsteroidal anti-inflammatory drug (NSAID) use.⁵ The addition of topical diclofenac 3%/sodium hyaluronate to oral NSAID therapy resulted in only marginally greater analgesic effect than NSAID alone. 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.

REFERENCES

- Diclofenac[®] gel [prescribing information]. Mahwah, NJ: Glenmark; July 2023.
- The NCCN Squamous Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 1.2024 – November 9, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 12, 2024.
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- Roth SH. A controlled clinical investigation of 3% diclofenac/2.5% sodium hyaluronate topical gel in the treatment of uncontrolled pain in chronic oral NSAID users with osteoarthritis. *Int J Tissue React.* 1995;17(4):129-132.