PRIOR AUTHORIZATION POLICY

POLICY: Topical Diclofenac Sodium 3% Gel Prior Authorization Policy
- diclofenac sodium 3% gel (generic only)

REVIEW DATE: 08/03/2022

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 2.2022 – May 2, 2022) 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 treatement options are: surgical vermillionectomy, lip shave, electrodessication, 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 D_3 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

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 D_3 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 (Solaraze) 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

1. Solaraze® gel [prescribing information]. Melville, NY: PharmaDerm; April 2016.
2. The NCCN Squamous Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – May 2, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 25, 2022.
3. Le C, Bedocs PM. Disseminated Superficial Actinic Porokeratosis. 2021 Aug 11. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan–. PMID: 29083728.
4. Marks S, Varma R, Cantrell W, et al. Diclofenac sodium 3% gel as a potential treatment for disseminated superficial actinic porokeratosis. *J Eur Acad Dermatol Venereol.* 2009;23(1):42-45.
5. 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.