Drug Coverage Policy

Effective Date.....12/15/2025
Coverage Policy Number.....IP0282
Policy Title..Diclofenac Sodium 3% Gel

Topical Diclofenac Sodium 3% Gel

- diclofenac sodium 3% gel (generic only)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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 2.2025 – February 7, 2025) cite topical diclofenac (formulation is not specified, although the 3% gel is referenced) as an 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 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, retinoids (topical preferred over systemic), and topical 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.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for 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.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information.

Diclofenac sodium 3% gel is considered medically necessary when ONE of the following is met:

FDA Approved Indication

1. **Actinic Keratoses.** Approve for 6 months when the following criteria is met:
   A. Preferred product criteria are met for the products listed in the below table(s)

Other Uses with Supportive Evidence

2. **Actinic Cheilitis (Actinic Keratoses of the Lip[s]).** Approve for 6 months when the following criteria is met:
   A. Preferred product criteria are met for the products listed in the below table(s)

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 **[documentation required]**.
   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.

Employer Plans:

Product	Criteria
diclofenac sodium 3% topical gel	1. **Actinic Keratoses.** Patient has tried **BOTH** of the following (A and B) **[documentation required]**: A. 5-fluorouracil cream or solution (2% or 5%) B. imiquimod 5% cream 2. **Actinic Cheilitis.** Patient has tried **BOTH** of the following (A and B) **[documentation required]**: A. 5-fluorouracil cream or solution (2% or 5%) B. imiquimod 5% cream

Individual and Family Plans:

Product	Criteria
diclofenac sodium 3% topical gel	1. **Actinic Keratoses.** Patient has tried **BOTH** of the following (A and B) **[documentation required]**: A. 5-fluorouracil cream or solution (2% or 5%) B. imiquimod 5% cream 2. **Actinic Cheilitis.** Patient has tried **BOTH** of the following (A and B) **[documentation required]**: A. 5-fluorouracil cream or solution (2% or 5%) B. imiquimod 5% cream

Conditions Not Covered

Topical diclofenac sodium 3% gel for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.

References

1. Diclofenac® gel [prescribing information]. Mahwah, NJ: Glenmark; November 2024.
2. The NCCN Squamous Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – February 7, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 5, 2025.
3. Le C, Bedocs PM. Disseminated Superficial Actinic Porokeratosis. 2025 Apr 6. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 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.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	**Actinic Keratoses.** **Updated from** Documentation of failure, contraindication, or intolerance to **ONE** of the following: 5-fluorouracil cream, 5-fluorouracil solution (2% or 5%), imiquimod 5% cream **to** "Documentation of failure, contraindication, or intolerance to **BOTH** of the following: 5-fluorouracil cream or solution (2% or 5%), imiquimod 5% cream" **Actinic Cheilitis.** **Updated from** Documentation of failure, contraindication, or intolerance to **ONE** of the following: 5-fluorouracil cream, 5-fluorouracil solution (2% or 5%), imiquimod 5% cream **to** "Documentation of failure, contraindication, or intolerance to **BOTH** of the following: 5-fluorouracil cream or solution (2% or 5%), imiquimod 5% cream" **Disseminated Superficial Actinic Porokeratosis.** **Updated from** Documentation of failure, contraindication, or intolerance to **ONE** of the following: 5-fluorouracil cream, 5-fluorouracil solution (2% or 5%), imiquimod 5% cream **to** "Documentation of failure, contraindication, or intolerance to **BOTH** of the following: 5-fluorouracil cream or solution (2% or 5%), imiquimod 5% cream"	12/15/2024
Annual Revision	**Added** FDA Approved Indications for "Actinic Keratosis," "Actinic Cheilitis," and "Disseminated Superfiical Actinic Porokeratosis" to policy. **Updated** Preferred Product Table to show standard format and updated language, and split them into Employer Plans and Individual and Family Plans. **Removed** "Disseminated Superficial Actinic Porokeratosis" criteria **from** Preferred Product Tables.	12/15/2025

The policy effective date is in force until updated or retired.