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Coverage Policy Number **IP0282**

Topical Diclofenac Sodium 3% Gel

Table of Contents

Overview 1
Medical Necessity Criteria 1
Reauthorization Criteria 2
Authorization Duration 2
Conditions Not Covered 2
Background 2
References 3

Related Coverage Resources

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. 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

This policy supports medical necessity review for topical diclofenac sodium 3% gel.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Non-Covered Product	Criteria
diclofenac sodium 3% topical gel	**1. Actinic Keratoses.** Documentation of failure, contraindication, or intolerance to **ONE** of the following: A. 5-fluorouracil cream B. 5-fluorouracil solution (2% or 5%) C. imiquimod 5% cream

Non-Covered Product	Criteria
	2. **Actinic Cheilitis.** Documentation of failure, contraindication, or intolerance to **ONE** of the following: A. 5-fluorouracil cream B. 5-fluorouracil solution (2% or 5%) C. imiquimod 5% cream 3. **Disseminated Superficial Actinic Porokeratosis.** Documentation of failure, contraindication, or intolerance to **ONE** of the following: A. 5-fluorouracil cream B. 5-fluorouracil solution (2% or 5%) C. imiquimod 5% cream

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of topical diclofenac sodium 3% gel is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 6 months
Reauthorization approval duration: up to 6 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

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.

Background

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 1.2023 – March 10, 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 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.

References

1. Diclofenac® gel [prescribing information]. Mahwah, NJ: Glenmark; May 2022.
2. The NCCN Squamous Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – March 10, 2023). ©2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 1, 2023.
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.