



Drug Quantity Management – Per Days Topical Non-Steroidal Anti-Inflammatory Drugs – Diclofenac

Table of Contents

National Formulary Medical Necessity	1
Conditions Not Covered.....	2
Background.....	2
References	3
Revision History.....	4

Product Identifier(s)

Effective 1/1/23 to 2/6/23: 109016
Effective 2/7/23: 54645

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.

National Formulary Medical Necessity

Drugs Affected

- Diclofenac sodium 1.5% topical solution (generic only)
- Pennsaid® (diclofenac sodium 2% topical solution – generic)
- Solaraze® (diclofenac sodium 3% topical gel – generic)
- Voltaren® (diclofenac sodium 1% topical gel – generic)

This Drug Quantity Management program has been developed to prevent stockpiling, misuse, and/or overuse of the topical diclofenac products. If the Drug Quantity Management rule is not met at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Package Size/Dose Form	Retail Maximum Quantity per 28 Days	Home Delivery Quantity per 84 Days
Voltaren® (diclofenac sodium 1% topical gel, generic)	100 gram tube	5 tubes (500 grams)	15 tubes (1,500 grams)
Diclofenac sodium 1.5% topical solution (generic only)	150 mL bottle	1 bottle (150 mL)	3 bottles (450 mL)
Pennsaid® (diclofenac sodium 2% topical solution, generic)	112 gram bottle	1 bottle (112 grams)	3 bottles (336 grams)
Solaraze® (diclofenac sodium 3% topical gel, generic)	100 gram tube	1 tube (100 grams)	3 tubes (300 grams)

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Diclofenac sodium 1% topical gel (Voltaren, generic)

1. If the individual is treating the pain of osteoarthritis in multiple joints and requires more than 16 grams per day, approve the requested quantity not to exceed 9 tubes (900 grams) per 28 days at retail and 27 tubes (2,700 grams) per 84 days at home delivery.

Diclofenac sodium 1.5% topical solution (generic only)

1. If the individual is treating signs and symptoms of osteoarthritis in both knees, approve the requested quantity not to exceed 2 bottles (300 mL) per 28 days at retail and 6 bottles (900 mL) per 84 days at home delivery.

Diclofenac sodium 2% topical solution (Pennsaid, generic)

1. If the individual is treating the pain of osteoarthritis in both knees, approve the requested quantity, not to exceed 2 bottles (224 grams) per 28 days at retail and 6 bottles (672 grams) per 84 days at home delivery.

Diclofenac sodium 3% topical gel (Solaraze, generic)

1. If the individual is treating more than three 5 cm x 5 cm actinic keratosis lesions, approve 1 tube (100 grams) per 28 days at retail and 3 tubes (300 grams) per 84 days at home delivery for every three 5 cm x 5 cm actinic keratosis lesions being treated.
Note: Round up to the nearest multiple of three to determine the override quantity. For example, if the individual is treating a total of eight 5 cm x 5 cm actinic keratosis lesions, round up to nine lesions, and approve 3 tubes (300 grams) per 28 days at retail and 9 tubes (900 grams) per 84 days at home delivery.

Conditions Not Covered

Any other exception is considered not medically necessary, including the following:

1. No overrides are recommended for use in compounded formulations.

Background

Overview

Diclofenac sodium 1% topical gel (Voltaren, generic) is indicated for the relief of pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands.¹ It has not been evaluated for use on the spine, hip, or shoulder.

Diclofenac sodium 1.5% topical solution is indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s).²

Diclofenac sodium 2% topical solution (Pennsaid, generic) is indicated for the treatment of the pain of osteoarthritis of the knee(s).³

Diclofenac sodium 3% topical gel (Solaraze, generic) is indicated for the topical treatment of actinic keratoses.⁴ Sun avoidance is indicated during therapy.

Dosing

Diclofenac sodium 1% topical gel (Voltaren, generic)

For the treatment of the lower extremities, apply 4 grams of gel to the affected foot, ankle, or knee four times daily.¹ Do not apply more than 16 grams daily to any single joint of the lower extremities. For the treatment of the upper extremities, apply 2 grams of gel to the affected hand, wrist, or elbow four times daily. Do not apply more than 8 grams daily to any single joint of the upper extremities. The total dose should not exceed 32 grams per day, over all affected joints. A total of 448 grams of gel would be needed for an application of 16 grams per day for 28 days and 896 grams of gel would be needed for the maximum dose of 32 grams per day.

For each use, the proper amount of diclofenac sodium 1% topical gel should be measured using a dosing card that is supplied in the drug product carton.¹ The gel should be applied within the rectangular area of the dosing card up to the 2 gram or 4 gram line (2 grams for each elbow, wrist, or hand, and 4 grams for each knee, ankle, or foot). The 2 gram line is 2.25 inches long and the 4 gram line is 4.5 inches long. The dosing card can then be used to apply the gel.

Diclofenac sodium 1.5% topical solution

The recommended dose is 40 drops (approximately 1.2 mL) per knee applied to clean, dry skin four times daily for the relief of the signs and symptoms of osteoarthritis of the knee(s).² Application of diclofenac sodium topical solution in an amount that is more or less than the recommended dose has not been studied and is therefore not recommended. A total of approximately 135 mL of solution is needed to treat one knee for 28 days, while approximately 270 mL would be needed to treat two knees.

Diclofenac sodium 2% topical solution (Pennsaid, generic)

The recommended dose is 40 mg (2 pump actuations), applied to each painful knee, twice daily for the relief of the pain of osteoarthritis of the knee(s).³ Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals. Each gram of solution contains 20 mg of diclofenac. Therefore, 112 grams of the 2% topical solution would be needed to treat one knee for 28 days, while approximately 224 grams would be needed to treat two knees.

Diclofenac sodium 3% topical gel (Solaraze, generic)

Diclofenac sodium 3% topical gel should be applied to lesion areas twice daily.⁴ The amount needed varies based on the size of the lesion site. Normally, 0.5 grams of gel is used on each 5 cm x 5 cm lesion site and the recommended duration of therapy is from 60 days to 90 days. Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy. Approximately 84 grams of gel would be needed to treat three 5 cm x 5 cm lesion sites twice daily for 28 days.

Availability

Diclofenac sodium 1% topical gel (Voltaren, generic) is supplied in 100 gram tubes.¹ Diclofenac sodium 1.5% topical solution is available as 150 mL bottles.² Diclofenac sodium 2% topical solution (Pennsaid, generic) is available as 112 gram bottles.³ Diclofenac sodium 3% topical gel (Solaraze, generic) is available as 100 gram tubes.⁴

References

1. Diclofenac sodium 1% topical gel [prescribing information]. Durham, NC: Encube Ethicals; February 2020.
2. Diclofenac sodium 1.5% topical solution [prescribing information]. Baton Rouge, LA: Sola; June 2021.
3. Pennsaid® 2% topical solution [prescribing information]. Deerfield, IL: Horizon Medicines; January 2022.
4. Solaraze® 3% topical gel [prescribing information]. Melville, NY: Fougera; April 2016.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	<p>Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.</p> <p>Diclofenac sodium 1% topical gel (Voltaren, generic): For a patient who is treating the pain of osteoarthritis in multiple joints and requires more than 16 grams per day, the override quantity was changed from 10 tubes per 28 days to 9 tubes per 28 days at retail and 27 tubes per 84 days at home delivery.</p> <p>Diclofenac sodium 3% topical gel (Solaraze, generic): Override criteria for a patient treating more than three 5 cm x 5 cm actinic keratosis lesions were clarified to approve 1 tube per 28 days at retail and 3 tubes per 84 days at home delivery for every three lesions being treated. Previously, criteria approved these quantities for each additional lesion being treated.</p>	08/31/2022

“Cigna Companies” refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc. and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2023 Cigna.