Effective Date **1/1/2024**
Next Review Date **1/1/2025**
Coverage Policy Number **IP0021**

Topical Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

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Related Coverage Resources

Quantity Limitations – (1201)

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 formulary exceptions to the following non-covered Topical Non-Steroidal Anti-Inflammatory Drugs (NSAIDs):

- **diclofenac sodium** 2% topical solution
- **diclofenac sodium** 1.5% topical solution
- **Flector®** (diclofenac epolamine) 1.3% topical patch
- **Licart™** (diclofenac epolamine) 1.3% topical patch
- **Pennsaid®** (diclofenac sodium) 2% topical solution
- **Voltaren®** (diclofenac sodium) 1% 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 2% topical solution	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to the following (A): A. diclofenac sodium 1% gel
diclofenac sodium 1.5% topical solution	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to the following (A): A. diclofenac sodium 1% gel
Flector (diclofenac epolamine) 1.3% topical patch	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to the following (A): A. diclofenac sodium 1% gel
Licart (diclofenac epolamine) 1.3% topical patch	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to the following (A): A. diclofenac sodium 1% gel
Pennsaid (diclofenac sodium) 2% topical solution	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to the following (A): A. diclofenac sodium 1% gel
Voltaren (diclofenac sodium) 1% gel	There is documentation the individual has tried **diclofenac sodium 1% gel** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.

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 Non-Steroidal Anti-Inflammatory Drugs is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial and reauthorization approval duration is up to 12 months.

Background

OVERVIEW
Diclofenac 1% gel, diclofenac 1.5% solution, Flector, Licart, and Pennsaid 2% are all topical nonsteroidal anti-inflammatory drugs (NSAIDs) containing diclofenac as the active ingredient.[1-5] Additionally, diclofenac 1% gel is available over-the-counter (OTC) as Voltaren Arthritis Pain (previously marketed for prescription use as Voltaren Gel).[7] Labeled uses for the prescription topical NSAIDs are as follows:

A. Diclofenac 1% gel is indicated for the relief of the pain of osteoarthritis (OA) of joints amenable to topical treatment, such as the knees and those of the hands.[5] Diclofenac 1% gel was not assessed for use on joints of the spine, hip, or shoulder.

B. Diclofenac 1.5% solution is indicated for the treatment of signs and symptoms of OA of the knee(s).[1]

C. Flector patch is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions in patients ≥ 6 years of age.[2]

D. Licart topical system shares the same indication as Flector but is indicated only for adults.[3]

E. Pennsaid 2% is indicated for the treatment of pain of OA of the knee(s).[4]

Another diclofenac prescription topical product is Solaraze gel (diclofenac 3% gel, generic), which is indicated for the topical treatment of actinic keratoses and is not further detailed in this document.[6]

References

1. Diclofenac sodium 1.5% solution [prescribing information]. Baton Rouge, LA: Sola Pharmaceuticals; December 2020.
2. Flector [prescribing information]. New York, NY: Pfizer/Alpharma; April 2021.
3. Licart topical system [prescribing information]. Lugano, Switzerland: IBSA Institut Biochimique SA; April 2021.
4. Pennsaid 2% topical solution [prescribing information]. Lake Forest, IL: Horizon Pharma; April 2021.
5. Voltaren Gel [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc.; February 2018.
6. Solaraze Gel [prescribing information]. Melville, NY: PharmaDerm/Fougera; April 2021.
7. FDA approve GSK's Voltaren Arthritis Pain for over-the-counter use in the United States [press release]. Warren, NJ: GlaxoSmithKline; February 17, 2020. Available at: https://us.gsk.com/en-us/media/press-releases/fda-approves-gsk-s-voltaren-arthritis-pain-for-over-the-counter-use-in-the-united-states/. Accessed on July 9, 2021.