

Reference number(s)
5457-C

This document applies to the following:

Formulary	Applies
Advanced Control (ACF)	<input type="checkbox"/>
Advanced Control Formulary Chart (ACFC)	<input type="checkbox"/>
Advanced Control – Choice (ACCF)	<input type="checkbox"/>
Basic Control (BC)	<input type="checkbox"/>
Basic Control Chart (BCC)	<input type="checkbox"/>
Standard Control (SF)	<input type="checkbox"/>
Standard Control Formulary Chart (SFC)	<input type="checkbox"/>
Standard Control – Choice (SCCF)	<input type="checkbox"/>
Value (VF)	<input type="checkbox"/>
Value Formulary Chart (VFC)	<input type="checkbox"/>

Formulary	Applies
Managed Medicaid Template (MMT)	<input type="checkbox"/>
Marketplace (MF)	<input type="checkbox"/>
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	<input checked="" type="checkbox"/>
Aetna Individual Lives (IVL)	<input checked="" type="checkbox"/>
Aetna Fully Insured Advanced Control Formulary (Aetna FI ACF)	<input type="checkbox"/>
Aetna Fully Insured Advanced Control Formulary Chart (Aetna FI ACFC)	<input type="checkbox"/>
Aetna Fully Insured Standard Opt-Out (Aetna FI SOO)	<input type="checkbox"/>

# Medical Necessity Criteria

## Pennsaid

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Pennsaid	diclofenac sodium	topical solution 2%

## Indications

### FDA-approved Indications

Pennsaid is indicated for the treatment of the pain of osteoarthritis of the knee(s).

## Coverage Criteria

### Osteoarthritis of the Knee(s)

Authorization may be granted when the requested drug is being prescribed for the treatment of the pain of osteoarthritis of the knee(s) when ALL of the following criteria are met:

- The patient cannot be treated with a preferred product. (Available Formulary Alternative: diclofenac 1 percent gel).
- The patient has experienced an inadequate treatment response, intolerance to, or has a clinical reason to avoid the preferred product: diclofenac 1 percent gel. [ACTION REQUIRED: Documentation is required for approval.]
- The patient meets ONE of the following:
  - The patient has experienced an inadequate treatment response to TWO oral nonsteroidal anti-inflammatory drugs (NSAIDs). [ACTION REQUIRED: Documentation is required for approval.]
  - Treatment with the requested drug is necessary due to concern about intolerance to oral NSAIDs. [ACTION REQUIRED: Documentation is required for approval.]
  - Treatment with the requested drug is necessary due to a contraindication to oral NSAIDs. [ACTION REQUIRED: Documentation is required for approval.]

## Quantity Limits Apply

### Quantity Limit

The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.

Drug	4 Week Limit	12 Week Limit
Pennsaid (diclofenac sodium topical solution 2%)	224 gm (2 bottles, 112 gm each) / 21 days	672 gm (6 bottles, 112 gm each) / 63 days

## Duration of Approval (DOA)

- 5457-C: DOA 12 months

## References

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1. Pennsaid [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; November 2024.
2. Diclofenac Sodium Topical Solution 1.5% [package insert]. Baton Rouge, LA: SOLA Pharmaceuticals, LLC; June 2021.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed May 13, 2025.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 05/13/2025).
5. Kolasinski SL, Neogi T, Hockberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip and Knee. *Arthritic Care & Research* 2020;72(2):149-162.
6. American Academy of Orthopaedic Surgeons. Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Clinical Practice Guideline (3rd Edition). August 31, 2021.