Reference number(s)
787-C

Initial Prior Authorization With Quantity Limit
Pennsaid PA

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**
diclofenac sodium topical solution 1.5% (all other brands)	diclofenac sodium topical solution 1.5%
Pennsaid	diclofenac sodium topical solution 2%

Indications

FDA-approved Indications

Diclofenac Sodium Topical Solution 1.5%

Diclofenac sodium is indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s).

Pennsaid

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

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Coverage Criteria

Osteoarthritis Pain of the Knee(s)

Authorization may be granted when the patient has osteoarthritis pain of the knee(s) when ONE of the following criteria are met:

- Treatment with the requested drug is necessary due to a concern about intolerance to oral nonsteroidal anti-inflammatory drugs (NSAIDs)
- Treatment with the requested drug is necessary due to a contraindication to oral NSAIDs

Continuation of Therapy

Osteoarthritis Pain of the Knee(s)

Authorization may be granted when the patient has osteoarthritis pain of the knee(s) when ALL of the following criteria are met:

- The patient has achieved or maintained a positive clinical response to the requested drug
- The patient has been re-evaluated periodically to determine if treatment is still necessary

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
(diclofenac sodium topical solution 1.5%)	300 mL (2 bottles, 150 mL each) / 21 days	900 mL (6 bottles, 150 mL each) / 63 days
Pennsaid (diclofenac sodium topical solution 2%)	224gm (2 bottles, 112 gm each) / 21 days	672 gm (6 bottles, 112gm each) / 63 days

Duration of Approval (DOA)

- 787-C: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months

Reference number(s)
787-C

References

1. Pennsaid [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; January 2022.
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.; 2023. https://online.lexi.com. Accessed April 25, 2023.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 04/25/2023).
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.