



Policy:	Branded Nonsteroidal Anti-Inflammatory Drugs (NSAIDS)	Annual Review Date: 02/15/2024
Impacted Drugs:		Last Revised Date: 02/15/2024

OVERVIEW

Nonsteroidal anti-inflammatory drugs (NSAIDs) exhibit anti-inflammatory, analgesic and antipyretic activities and are used for a variety of conditions. The mechanism of action of NSAIDs is related to prostaglandin synthetase inhibition. NSAIDs inhibit both cyclooxygenase (COX)-1, and COX-2 isoenzymes at therapeutic doses. In Arthrotec, diclofenac sodium is combined with misoprostol, a gastrointestinal (GI) mucosal protective prostaglandin E1 analog. The individual components of the combination products are available separately. Zorvolex (diclofenac capsules) and Vivlodex (meloxicam capsules) are not interchangeable with other diclofenac and meloxicam products.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of two preferred products prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of two preferred drugs within the 130-day look-back period are excluded from step therapy.

Preferred Medications

- diclofenac potassium
- diclofenac sodium (IR and ER)
- diclofenac sodium and misoprostol
- diclofenac sodium topical solution 1.5%*
- etodolac (IR and ER)
- flurbiprofen
- ibuprofen
- indomethacin (IR and ER)
- ketoprofen IR 50 mg and 75 mg
- ketorolac (tablets)
- meloxicam tablets
- nabumetone
- naproxen**
- oxaprozin

This document is subject to the disclaimer found at https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx to change. https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx



Policy Prug

- piroxicam
- sulindac
- tolmetin**

Non-Preferred Medications

- Anaprox DS
- Arthrotec
- Cataflam
- Daypro
- diclofenac sodium 1% topical gel*
- diclofenac sodium 2% topical solution*
- Feldene
- Fenoprofen (brand), fenoprofen 600 mg
- Fenortho
- Indocin
- ketoprofen ER 200 mg
- ketoprofen IR 25 mg
- Licart*
- Lodine
- meloxicam capsules
- meloxicam suspension
- Mobic
- Motrin
- Nalfon
- Naprelan and generics
- Naprosyn, EC-Naprosyn, and generic suspension
- Pennsaid 2%*
- Omiiz
- Relafen
- Sprix
- Tivorbex
- tolmetin 400 mg, 600 mg
- Vivlodex
- Voltaren Gel 1%*
- Voltaren XR
- Zipsor
- Zorvolex

IR – Immediate-release; ER – Extended-release

* Denotes topical product

This document is subject to the disclaimer found at https://www.medmutual.com/For-Providers/Policies-and-Standards/Policies-





** Some generic naproxen and tolmetin products are non-preferred

PREFERRED STEP THERAPY CRITERIA

- 1. If the patient has tried two different prescription-strength generic preferred medications for the current condition, then authorization for a non-preferred branded medication may be given. Note: over the counter (OTC) NSAIDs count when the patient has used prescription-strength doses.
- 2. If the patient has tried generic diclofenac sodium topical solution 1.5% and the patient has difficulty swallowing or cannot swallow, authorization may be given for Pennsaid 2%, Klofensaid II, diclofenac sodium 1% topical gel, Licart topical system, or Voltaren gel if the patient has tried generic diclofenac sodium topical solution 1.5%, diclofenac sodium topical solution 2%.
- 3. If the patient has tried generic diclofenac sodium topical solution 1.5% and has a chronic musculoskeletal pain condition (e.g. Osteoarthritis [OA]) who are at risk of NSAID-associated toxicity (e.g. patients with a previous GI bleed, history of peptic ulcer disease, impaired renal function, CV disease, hypertension, heart failure, elderly patients with impaired hepatic function or taking concomitant anticoagulants), authorization for Pennsaid 2%, Klofensaid II, diclofenac sodium 1% topical gel, or Voltaren gel may be given if the patient has tried generic diclofenac sodium topical 1.5% solution, diclofenac sodium topical solution 2%.
- **4.** For patients with hand or knee OA, authorization may be given for Pennsaid 2%, Klofensaid II, diclofenac sodium 1% topical gel, Licart topical system, or Voltaren gel if the patient has tried generic diclofenac sodium topical solution 1.5%, diclofenac sodium topical solution 2%.

Approval Duration: 365 days (1 year)

Step Therapy Exception Criteria

Approve for 1 year if the patient meets the following (A, B, or C):

- A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
- B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
- C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
 - 1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period

This document is subject to the disclaimer found at https://www.medmutual.com/For-Providers/Policies-and-Standards/Polic

© 2024 Medical Mutual of Ohio Page 3 of 5



Policy Prug

- AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
- 2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When <u>documentation</u> is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

- 1. Facts and Comparisons Online[®]. Wolters Kluwer Health, Inc.; Last updated January 30, 2020. Available at: http://fco.factsandcomparisons.com/action/home. Accessed on February 11, 2020. Search term: Nonsteroidal anti-inflammatory agents.
- 2. Cambia® oral solution [prescribing information]. Newark, CA: Depomed; March 2017.
- 3. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.
- Food and Drug Administration. FDA Drug Safety Communication: FDA strengthens warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) can cause heart attack or stroke. July 9, 2015. Available at: www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-strengthens-warning-non-aspirin-nonsteroidal-anti-inflammatory. Accessed on February 11, 2020.
- 5. Lanza FL, Chan FKL, Quigley EMM, and the Practice Parameters Committee of the American College of Gastroenterology. Guidelines for prevention of NSAID-related ulcer complications. *Am J Gastroenterol.* 2009;104:728-738.
- 6. Diclofenac sodium topical solution 1.5% [prescribing information]. Baton Rouge, LA: Sola Pharmaceuticals; October 2019.
- 7. Flector® [prescribing information]. New York, NY: Pfizer/Alpharma; March 2019.
- 8. Licart™ topical system [prescribing information]. Lugano, Switzerland: IBSA Institut Biochimique SA; December 2018.
- 9. Pennsaid® 2% topical solution [prescribing information]. Lake Forest, IL: Horizon Pharma; May 2016.

This document is subject to the disclaimer found at https://www.medmutual.com/For-Providers/Policies-and-Standards/Policies-



Policy Prug

- 10. Voltaren[®] Gel [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc.; February 2018.
- 11. McPhereson ML, Cimino MN. Topical NSAID formulations. Pain Med. 2013;14(Suppl 1):S35-S39.
- 12. Honvo G, Leclercq V, Geernick A, et al. Safety of topical non-steroidal anti-inflammatory drugs in osteoarthritis: outcomes of a systematic review and meta-analysis. *Drugs and Aging*. 2019;36(Suppl 1):S45-S64.
- 13. Sprix[®] nasal spray [prescribing information]. Wayne, PA: Egalet US; January 2018.
- 14. Kolasinki SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the management of osteoarthritis of the hand, hip, and knee. *Arthritis Rheumatol.* 2020;72(2):220–233.
- 15. Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res.* 2012;64:465-474.
- 16. Kloppenburg M, Kroon F, Blanco FJ, et al. 2018 update of the EULAR recommendations for the management of hand osteoarthritis. *Ann Rheum Dis.* 2019;78:16-24.
- 17. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI recommendations for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage*. 2014;22:363-388.
- 18. Chou R, McDonagh MS, Nakamoto E, Griffin J. Analgesics for osteoarthritis: an update of the 2006 comparative effectiveness review. Rockville (MD): Agency for Healthcare Research and Quality (US); 2011 Oct. Report No.: 11(12):EHC076-EF. Available at: http://www.ncbi.nlm.nih.gov/books/NBK65646/pdf/TOC.pdf. Accessed on January 13, 2020.
- 19. Bannuru RR, Osani MC, Vaysbrot EE, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. *Osteoarthritis Cartilage*. 2019;27(11):1578-1589.
- 20. The American Geriatric Society 2019 Beers Criteria Update Expert Panel. American Geriatric Society 2019 Updated Beers Criteria for potentially inappropriate medication use in older adults. *J Am Geriatr Soc.* 2019;67:674-594.

This document is subject to the disclaimer found at https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx to change. https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx