Pharmacy Medical Necessity Guidelines:
Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

Effective: May 12, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Non-steroidal anti-inflammatory drugs (NSAIDs) are indicated for multiple inflammatory and pain-associated conditions including, but not limited to, mild-to-moderate pain, fever, dysmenorrhea, tendonitis, osteoarthritis, acute gout, Inflammatory diseases and rheumatoid disorders

- **Diclofenac sodium 1% gel (Voltaren)** is indicated for relief of osteoarthritis pain in joints amenable to topical therapy. Voltaren® Gel was not evaluated for use on joints of the spine, hip or shoulder.
- **Diclofenac epolamine topical patch (Flector)** is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions in adults and pediatric patients 6 years of age and older.
- **Diclofenac epolamine topical patch (Licart)** is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions. Safety and effectiveness of Licart in pediatric patients have not been established.
- **Diclofenac topical solution (Pennsaid)** is indicated for the treatment of pain of osteoarthritis of the knee(s).
- **Mefenamic acid (Ponstel)** is indicated for relief of mild to moderate pain in patients ≥ 14 years of age, when therapy will not exceed one week (7 days). Mefenamic acid is also approved for the treatment of primary dysmenorrhea.
- **Ketorolac nasal Spray (Sprix)** is indicated in adult patients for the short term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the opioid level.

Preferred NSAIDs covered without restriction include: over-the counter (OTC) aspirin, ibuprofen, naproxen and prescription-strength ibuprofen, indomethacin, naproxen, piroxicam, meloxicam, ketoprofen, celecoxib, and over-the-counter diclofenac sodium 1% gel.

COVERAGE GUIDELINES

The plan may authorize coverage of non-preferred NSAIDs for a Tufts Health Together Member when the following criteria for a particular regimen are met and limitations do not apply:

Flector, Licart, Pennsaid:

1. Member has one of the following:
   a) Age 65 or greater
   b) Diagnosis of Rheumatoid Arthritis and 50 years of age or older
   c) Previous or active GI bleeding or hemorrhage
   d) History of Gastroesophageal Reflux Disease (GERD)
   e) History of peptic ulcer disease (PUD) (e.g., peptic ulcer, gastric ulcer, duodenal ulcer)
   f) Demonstrated lack of effectiveness in relief of symptoms with a fair trial of at least 2 prescription non-COX-2 inhibitor NSAIDS (e.g., ibuprofen, naproxen, diclofenac, Relafen®, Lodine®, Motrin®, etc.)
   g) Inability to tolerate other agents in the NSAID class as evidenced by significant symptoms of GI (gastrointestinal) intolerance (e.g., dyspepsia, gastritis, abdominal or stomach pain, heartburn)
   h) Bleeding diathesis or other medical condition(s) that would constitute a significant predisposition to bleeding such as:
      - Coagulopathy

- Hemophilia
- Low platelet count
- A surgical procedure booked within 5 days of starting the COX-2 drug

i) Member is currently taking any of the following medications:
- Anticoagulant therapy (e.g., Coumadin®, warfarin, heparin, Lovenox®, Fragmin®, Innohep®, Pradaxa®, Xarelto®, Eliquis®)
- Methotrexate, Imuran® or other metabolites
- Oral corticosteroids (e.g., prednisone, dexamethasone, etc.)
- Proton pump inhibitors (PPIs) (e.g., Prilosec®, Protonix®, Prevacid®, Nexium®)
- H2 antagonists (e.g., ranitidine, cimetidine)
- Arthrotec® (diclofenac Na/misoprostol) or Cytotec® (misoprostol)

AND

2. Member has had an inadequate response, adverse reaction, or contraindication to diclofenac 1% gel (Voltaren)

AND

3. **Licart only:** Member has had an inadequate response, adverse reaction, or contraindication to generic Flector patch

Mefenamic acid:

1. The Member meets one of the following conditions:
   a) The Member has had an inadequate response or adverse reaction to two preferred NSAIDs, or the provider indicates clinical inappropriateness of therapy with two preferred NSAIDs

OR

   b) The Member is stable on mefenamic acid and is currently on an anticoagulant agent

Ketorolac intranasal spray (Sprix):

1. The provider indicates that all oral NSAIDs are clinically inappropriate for the Member

LIMITATIONS

1. Ketorolac nasal spray (Sprix) approval will be limited to one course of therapy; five single-day nasal sprays.
2. Diclofenac 1% gel (Voltaren) is limited to 200 grams per 30 days.
3. Diclofenac 1.3% transdermal (Flector patch) approval is limited to two patches per day for 3 months duration.
4. Licart patch is limited to one patch per day for 3 months duration.
5. Requests for brand-name products, which have AB-rated generic products, will be reviewed according to Brand Name criteria

CODES

None

REFERENCES

1. Diclofenac sodium 1.5% [prescribing information]. Baton Rouge, LA: SOLA Pharmaceuticals, LLC; June 2021.
2. Flector (diclofenac epolamine) [prescribing information]. Parsippany, NJ: IBSA Pharmacy Inc; April 2021.
3. Licart (diclofenac epolamine) [prescribing information]. Parsippany, NJ: IBSA Pharmacy Inc; April 2021.
4. Mefenamic acid capsule [prescribing information]. Baltimore, MD: Lupin Pharmaceuticals, Inc; June 2021.
5. Pennsaid 2% (diclofenac sodium) [prescribing information]. Deerfield, IL: Horizon Pharma; January 2022.
6. Sprix (ketorolac) [prescribing information]. Wayne, PA: Zyla Life Sciences US Inc; April 2021.
7. Lanza FL, Chan FK, Quigley EM. Guidelines for prevention of NSAID-related ulcer complications. Am J Gastroenterology. 2009;104(3):728.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. August 8, 2023: No changes.

2. May 14, 2024: Effective August 1, 2024, updated RxUM fax number and updated previous trial language through the MNG.
3. May 13, 2025: No changes
4. May 12, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services