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

Effective: October 19, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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

- Celecoxib capsule (Celebrex) is indicated for osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis in patients 2 years and older, ankylosing spondylitis, acute pain, and primary dysmenorrhea.
- 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. The recommended dose of Flector for adults and pediatric patients 6 years of age and older is one topical system to the most painful area twice daily. Flector patch is available generically.
- Diclofenac epolamine topical patch (Licart) is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions. The recommended dose of Licart is one topical system applied to the most painful area once daily.
- Diclofenac sodium 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 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:
   - Age 65 or greater
   - Diagnosis of Rheumatoid Arthritis and 50 years of age or older

- Previous or active GI bleeding or hemorrhage
- History of Gastroesophageal Reflux Disease (GERD)
- History of peptic ulcer disease (PUD) (e.g., peptic ulcer, gastric ulcer, duodenal ulcer)
- 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.)
- 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)
- 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
- 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 tried and failed therapy with diclofenac 1% gel (Voltaren)

AND

3. **Licart only:** Member has tried and failed therapy with generic Flector patch

Mefenamic acid:

1. The Member is at least 14 years of age

AND

2. One of the following conditions:
    a) The Member tried and failed therapy with 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 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 (diclofenac 1.3%) patch approval 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. Lexi-Comp Online™: Ketorolac [cited July 12, 2012]. Hudson, Ohio: Lexi-Comp, Inc. Available from: online.lexi.com/crlsql/servlet/crlonline.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically.
3. Voltaren Gel 1% (diclofenac) [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc.; February 2018.
4. Celebrex (celecoxib) [prescribing information]. New York, NY: Pfizer Inc; May 2019.

5. Flector (diclofenac epolamine) [prescribing information]. New York, NY: Pfizer; March 2019.
6. Licart (diclofenac epolamine) [prescribing information]. Lugano, Switzerland: IBSA Institut Biochimique; December 2018.
7. Pennsaid 1.5% (diclofenac sodium) [prescribing information]. Mississauga, Ontario: Nuvo Research Inc; May 2016.
8. Pennsaid 2% (diclofenac sodium) [prescribing information]. Lake Forest, IL: Horizon Pharma; May 2016.
9. Sprix (ketorolac) [prescribing information]. Shirley, NY: American Regent; January 2018.
10. Ponstel (mefenamic acid) [prescribing information]. Mason, OH: Prasco Laboratories; May 2016.
11. Lanza FL, Chan FK, Quigley EM. Guidelines for prevention of NSAID-related ulcer complications. Am J Gastroenterology. 2009;104(3):728.

APPROVAL HISTORY

October 7, 2014: Reviewed by Pharmacy & Therapeutics Committee. Incorporated individual drug-criteria into a comprehensive NSAID guideline.

Subsequent endorsement date(s) and changes made:
1. October 6, 2015: No changes.
2. January 1, 2016: Administrative change to rebranded template.
3. October 18, 2016: No changes.
4. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
5. November 14, 2017: No changes.
6. December 11, 2018: Administrative changes made to template.
7. November 12, 2019: No changes.
8. April 14, 2020: Effective 4/20/20, celecoxib and diclofenac 1% sodium gel (Voltaren) are removed from the MNG, as they are covered. Effective 7/1/2020, added quantity limit of 200 grams per 30 days for diclofenac sodium 1% gel.
9. October 13, 2020: Added criteria for Licart to the MNG.

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.