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

Celecoxib (Celebrex®); Diclofenac, topical (diclofenac 1% gel, Pennsaid, Flector®; Mefenamic Acid (Ponstel); Ketorolac (Sprix®)

Effective: 10/17/14

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OVERVIEW

FDA-APPROVED INDICATIONS

Non-steroidal anti-inflammatory agents (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 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 topical patch (Flector) is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions.
- 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).
- 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

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan – Network Health may authorize coverage of non-preferred NSAIDs for members when the following criteria for a particular regimen are met and limitations do not apply:

For celecoxib and for diclofenac topical gel and transdermal patch, one of the following criterions:

- 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.)
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Proton pump inhibitors (PPIs) (e.g., Prilosec®, Protonix®, Prevacid®, Nexium*)
- H2 antagonists (e.g., ranitidine, cimetidine)
- Arthrotec® (diclofenac Na/misoprostol) or Cytotec® (misoprostol),

For diclofenac patch (Flector), in addition to the above,
- Member has tried and failed therapy with diclofenac 1% gel

For mefenamic acid,
- The member is at least 14 years of age
- One of the following conditions:
  - The member tried and failed therapy with two preferred NSAIDs, or the provider indicates clinical inappropriateness of therapy with two preferred NSAIDs
  - The member is stable on mefenamic acid and is currently on an anticoagulant agent

For ketorolac intranasal spray,
- The provider indicates oral NSAIDs are clinically inappropriate for the member

Preferred NSAIDs covered without restriction include: over-the-counter (OTC) aspirin, ibuprofen, naproxen and prescription-strength ibuprofen, indomethacin, naproxen, piroxicam, meloxicam, ketoprofen, etc.

LIMITATIONS
- Ketorolac nasal spray (Sprix) approval will be limited to one course of therapy; five single-day nasal sprays.
- Diclofenac 1% gel total daily dose should not exceed 32 gm.
- Diclofenac 1.3% transdermal (Flector patch) approval is limited to two patches per day for 3 months duration.
- Requests for brand-name products, which have AB-rated generic products, will be reviewed according to Brand Name criteria.

CODES
None

REFERENCES
5. Flector (diclofenac epolamine) [prescribing information]. Bristol, TN: King Pharmaceuticals; July 2009.
6. Pennsaid 1.5% (diclofenac sodium) [prescribing information]. Hazelwood, MO: Mallinckrodt Brand Pharmaceuticals; October 2013.
7. Sprix (ketorolac) [prescribing information]. Shirley, NY: American Regent; April 2014.

APPROVAL HISTORY
- 10/7/14: Reviewed by the Pharmacy and Therapeutics Committee. Incorporated individual drug-criteria into a comprehensive NSAID guideline.

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION
Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by
national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan – Network Health offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable product formulary in the Pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

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.