Pharmacy Medical Necessity Guidelines: Celebrex® (celecoxib)

Effective: May 14, 2018

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

This pharmacy medical necessity guideline applies to the following:

Tufts Health Plan Commercial Plans

☒ Tufts Health Plan Commercial Plans – large group plans

☒ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans

☒ Tufts Health Direct – Health Connector

☐ Tufts Health Together – A MassHealth Plan

☐ Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products

☒ Tufts Health Freedom Plan - large group plans

☒ Tufts Health Freedom Plan - small group plans

Fax Numbers:

RXUM: 617.673.0988

Note: This pharmacy medical necessity guideline applies to commercial products. For Tufts Health Plan Medicare Preferred members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Celebrex (celecoxib) is indicated for the management of the signs and symptoms of osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, and ankylosing spondylitis, and for the management of acute pain in adults and primary dysmenorrhea.

Celebrex (celecoxib), a cyclooxygenase-2 (COX-2) inhibitor, helps alleviate pain through the inhibition of COX-2, a substance produced as part of the inflammatory process. The mechanism of action of Celebrex (celecoxib) is similar to the nonsteroidal anti-inflammatory drugs (NSAIDS) (e.g., ibuprofen or naproxen), but may produce less gastric irritation than existing NSAIDS.

COVERAGE GUIDELINES

The plan may authorize coverage for brand Celebrex for members meeting one or more of the following clinical criteria:

1. Age 65 or greater
2. Diagnosis of rheumatoid arthritis and 50 years of age or older
3. Previous or active gastrointestinal bleeding or hemorrhage
4. History of gastroesophageal reflux disease (GERD)
5. History of peptic ulcer disease (PUD) (e.g., peptic ulcer, gastric ulcer, duodenal ulcer)
6. Demonstrated lack of effectiveness in relief of symptoms with a fair trial of at least 2 prescription non-COX-2 inhibitor NSAIDS (e.g., diclofenac, etodolac, ibuprofen, nabumetone, naproxen)
7. Inability to tolerate other agents in the NSAID class as evidenced by significant symptoms of gastrointestinal intolerance (e.g., dyspepsia, gastritis, abdominal or stomach pain, heartburn)
8. Bleeding diathesis or other medical condition(s) that would constitute a significant predisposition to bleeding such as:
   a) Coagulopathy
   b) Hemophilia
   c) Low platelet count
   d) A surgical procedure booked within 5 days of starting the COX-2 drug
9. Member is currently taking any of the following medications:
   a) Anticoagulant therapy (e.g., Coumadin®, warfarin, heparin, Lovenox®, Fragmin®, Innohep®, Pradaxa®, Xarelto®, Eliquis®)
   b) Methotrexate, Imuran® or other metabolites
   c) Oral corticosteroids (e.g., prednisone, dexamethasone, etc.)
   d) Proton pump inhibitors (PPIs) (e.g., Prilosec®, Protonix®, Prevacid®, Nexium®)
   e) H_2 antagonists (e.g., ranitidine, cimetidine)
   f) Arthrotec® (diclofenac Na/misoprostol) or Cytotec® (misoprostol)

LIMITATIONS

The Medical Necessity Guidelines apply only to brand Celebrex

CODES

None

REFERENCES

1. Walsh, P. ed. 2001 Physician's Desk Reference. New Jersey: Medical Economics Company.
2. McEvoy, G. ed. 2001 AHFS Drug Information. Maryland: American Society of Health-System Pharmacists.
3. Fotsch, E. ed. 2010 Physician's Desk Reference. New Jersey: PDR Network, LLC.
4. Celebrex (celecoxib) [package insert]. New York, NY: G.D. Searle LLC; October 2017.
5. Strand V, Simon LS, Dougados M, Sands GH, Bhadra P, Breazna A, Immitt J. Treatment of osteoarthritis with continuous versus intermittent celecoxib. J Rheumatol. 2011 Dec;38(12):2625-34. Epub 2011 Nov 1.

APPROVAL HISTORY

July 1999: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- April 12, 2005: Delete Bextra® (valdecoxib) as one of the covered COX-2 Inhibitors from the criteria
- February 14, 2006: No changes
- January 9, 2007: No changes
- March 4, 2008: No changes
- March 10, 2009: No changes
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred)
- March 9, 2010: No changes
- March 8, 2011: Removal of the criteria; History or diagnosis of familial adenomatous polyposis (FAP) (Celebrex only)
- February 14, 2012: No changes
- February 12, 2013: No changes
- October 15, 2013: Added Pradaxa, Xarelto, and Eliquis as examples of anticoagulant therapy
- October 7, 2014: No changes
- October 6, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- October 18, 2016: No changes
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- October 17, 2017: No changes
- May 8, 2018: Effective May 14, 2018, generic celecoxib is removed from the MNG. The criteria only apply to brand Celebrex.
- October 16, 2018: Criteria retired. Effective October 1, 2018 criteria no longer applies to brand medication, as brand is non-covered for all Commercial business lines.

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. They are used in conjunction with a member's benefit document and in coordination with the member's physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan members or to certain delegated service arrangements. Unless otherwise noted in the member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured

member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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