

Title: celecoxib (Celebrex)

Origination: 01/21/99	Revised: 05/25/11	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Celebrex is a non-steroid anti-inflammatory medication (NSAID) that is a selective inhibitor of cyclooxygenase-2 (COX-2) and exhibits non-steroidal anti-inflammatory, analgesic, and antipyretic activities.
- Celebrex is indicated for the:
 - Relief of the signs and symptoms of osteoarthritis (OA), rheumatoid arthritis (RA), juvenile rheumatoid arthritis (JRA), and ankylosing spondylitis (AS);
 - Management of acute pain in adults Members;
 - Treatment of primary dysmenorrhea;
 - Reduction in the number of adenomatous colorectal polyps in Members with familial adenomatous polyposis.

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Member who has experienced asthma, urticaria, hives or other allergic-type reactions after taking aspirin, Celebrex, or other NSAIDs.
- Members with a history of NSAID-induced gastrointestinal event while being administered a PPI.
- Member with sulfonamide allergy.
- Member less than two (2) years of age.
- For treatment of peri-operative pain in the setting of coronary artery bypass graft surgery.

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Procedure:

- 1.0 Request for *initial therapy* with Celebrex requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **one** (1) of the following:
- 1.1 Member with acute or chronic pain **and** at increased risk of developing NSAID-induced ulcer as defined by **one** (1) of the following:
- 1.1.1 Age over 65 years; **OR**
- 1.1.1 On chronic (more than 60 days) concurrent therapy with warfarin or oral corticosteroids (prednisone);
- OR**
- 1.2 Inadequate response to a trial of adequate doses of or is not a candidate for at least two (2) of the following prescription strength NSAIDs (not all inclusive list):
- 1.2.1 Diclofenac (with or without misoprostol);
- 1.2.2 Etodolac (Lodine);
- 1.2.3 Ibuprofen (Motrin);
- 1.2.4 Indomethacin (Indocin);
- 1.2.5 Ketoprofen (Oruvail);
- 1.2.6 Meloxicam (Mobic);
- 1.2.7 Nabumetone (Relafen);
- 1.2.8 Naproxen (Anaprox or Naprosyn);
- 1.2.9 Oxaprozin (Daypro);
- 1.2.10 Piroxicam (Feldene);
- 1.2.11 Sulindac (Clinoril);
- OR**
- 1.2 Diagnosis of familial multiple polyposis syndrome (FAP);
- OR**
- 1.2 Documented history of a complicated gastrointestinal (GI) event as defined as **one** (1) of the following:
- 1.2.1 Peptic, duodenal, or gastric ulcer; **OR**
- 1.2.1 GI hemorrhage or bleed;
- 1.3 If all criteria are met, may approve Celebrex for up to one (1) year using lowest possible dose and quantity necessary and not exceeding the manufacturer recommended dosing for the requested indication.

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Procedure, continued:

- 2.0 Request for *continuation of therapy* with Celebrex requires documentation from the Member's medical records maintained by the requesting independent practitioner indicating the Member is responding to therapy with no adverse events:
- 2.1 If all criteria are met, may approve Celebrex for up to one (1) year using lowest possible dose and quantity necessary and not exceeding the manufacturer recommended dosing for the requested indication.

References:

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5. Chen, JT et al. Celecoxib versus a non-selective NSAID plus proton-pump inhibitor: what are the considerations? [J Pain Palliat Care Pharmacother](#). 2006;20(4):11-32.
6. Chan, FK et al. Combination of a cyclo-oxygenase-2 inhibitor and a proton-pump inhibitor for prevention of recurrent ulcer bleeding in patients at very high risk: a double-blind, randomised trial. [Lancet](#). 2007 May 12;369(9573):1621-6.
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8. DiPiro, J et al. Pharmacotherapy: A Pathophysiologic Approach, 7th edition <http://www.accesspharmacy.com/content.aspx?aID=3200434>.
9. Michigan Quality Improvement Consortium. Medical management of adults with osteoarthritis. Southfield (MI): Michigan Quality Improvement Consortium; 2007 Aug. 1 p.



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Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.