Clinical Policy: Celecoxib (Celebrex)

Reference Number: PA.CP.PMN.122
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
Celecoxib (Celebrex®) is a nonsteroidal anti-inflammatory drug (NSAID).

FDA approved indication
Celebrex is indicated:

- For the treatment of osteoarthritis (OA)
- For the treatment of rheumatoid arthritis (RA)
- For the treatment of juvenile rheumatoid arthritis (JRA) in patients 2 years and older
- For the treatment of ankylosing spondylitis (AS)
- For the treatment of acute pain (AP)
- For the treatment of primary dysmenorrhea (PD)

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness ® that Celebrex is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. All Indications (must meet all)**:**

1. Age ≥ 2 years;
2. Member must meet (a or b):
   a. Member has one of the following (i,ii,iii,iv):
      i. Age > 65 years;
      ii. Current use of corticosteroid;
      iii. Current use of an anticoagulant (aspirin, warfarin, low molecular weight heparin, direct thrombin inhibitors, factor Xa inhibitors, and clopidogrel);
      iv. Prior gastrointestinal bleed or active peptic ulcer disease (not gastroesophageal reflux disease (GERD));
   b. Member meets both of the following (i and ii):
      i. Failure of a ≥ 4 week trial of meloxicam at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
      ii. Failure of a ≥ 4 week trial of one additional generic NSAID at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed 800 mg (2 capsules/day)

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not 800 mg per day (2 capsules/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
AP: acute pain
AS: ankylosing spondylitis
FDA: Food and Drug Administration
GERD: gastroesophageal reflux disease
JRA: juvenile rheumatoid arthritis
NSAID: nonsteroidal anti-inflammatory drug
OA: osteoarthritis
PD: primary dysmenorrhea
PDL: preferred drug list
RA: rheumatoid arthritis

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Osteoarthritis	200 mg once daily or 100 mg twice daily	800 mg/day
Rheumatoid arthritis	100 to 200 mg twice daily	800 mg/day
Juvenile rheumatoid arthritis	50 mg twice daily in patients 10–25 kg	800 mg/day

	100 mg twice daily in patients more than 25 kg	
Ankylosing spondylitis	200 mg once daily single dose or 100 mg twice daily. If no effect is observed after 6 weeks, a trial of 400 mg (single or divided doses) may be of benefit	800 mg/day
Acute Pain	400 mg initially, followed by 200 mg dose if needed on first day. On subsequent days, 200 mg twice daily as needed	800 mg/day
Primary dysmenorrhea	400 mg initially, followed by 200 mg dose if needed on first day. On subsequent days, 200 mg twice daily as needed	800 mg/day

VI. Product Availability

Capsules: 50 mg, 100 mg, 200 mg, and 400 mg

VII. References

1. Celecoxib Drug Monograph. Clinical Pharmacology. Accessed December 2017. http://www.clinicalpharmacology-ip.com.
2. Celebrex Prescribing Information. New York, NY: G.D. Searle, LLC; May 2016. Available at: http://www.celebrex.com/. Accessed December 20, 2017.
3. Lanza FL, Chan FK, Quigley EM et al. Guidelines for prevention of NSAID-related ulcer complications. Am J Gastroenterol. 2009 Mar;104(3):728-38. doi: 10.1038/ajg.2009.115. Epub 2009 Feb 24.
4. Hochberg MC, Altman RD, April KT et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. Arthritis Care Res (Hoboken). 2012 Apr;64(4):465-74.
5. Ringold S, Weiss PF, Beukelman T et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum. 2013 Oct;65(10):2499-512. doi: 10.1002/art.38092.
6. Ware MM, Deodhar A, Akl EA et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2016 Feb;68(2):282-98. doi: 10.1002/art.39298.
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8. Silverstein, et al. Gastrointestinal toxicity with celecoxib vs. nonsteroidal antiinflammatory drugs for osteoarthritis and rheumatoid arthritis (CLASS Study). JAMA 2000;284:1247-1255.
9. Mukherjee, et al. Risk of cardiovascular events associated with selective COX-2 inhibitors. JAMA 2001;286:954-959.
10.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2018 annual review: Added age and max dose; increased approval duration from 3/12 to 12/12; decreased trials from 3 (meloxicam & 2 NSAIDs) to 2 (meloxicam & 1 NSAID); references reviewed and updated.	2.20.18	