Clinical Policy: Celecoxib (Celebrex)
Reference Number: CP.PPA.01
Effective Date: 01/07
Last Review Date: 05/17
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® that Celebrex is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Dose does not exceed 800 mg (2 capsules/day)
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 two additional PDL generic NSAIDs at up to maximally indicated doses, each trialed for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;

Approval duration: 3 months

B. Other diagnoses/indications
1. Refer to 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 Centene benefit or member has previously met initial approval criteria;
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 Centene benefit and documentation supports positive response to therapy; or
2. Refer to 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 – 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 100 mg twice daily in patients more than 25 kg	800 mg/day

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. Workflow Document

Celebrex WF.docx

VIII. References

1. Celecoxib Drug Monograph. Clinical Pharmacology. Accessed January 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 January 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Removed FAP indication from the "FDA Labeled Indications" section Updated reference section to reflect current literature search.	02/12	02/12
Added the following to the "Special Instructions" section: "Celebrex® can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal and can occur without warning even without known prior sulfa allergy. Discontinue use at first appearance of rash or skin reactions. Added "severe hepatic impairment (Child-Pugh Class C) to section D in the "Criteria for Approval" section. Added age requirement of 2 years and older to JRA in the "FDA l abeled Indications"	02/13	02/13

Reviews, Revisions, and Approvals	Date	P&T Approval Date
section. Updated reference section to reflect current literature search.		
Updated reference section to reflect current literature search	02/14	02/14
Updated reference section to reflect current literature search.	02/15	02/15
Converted to new template Removed criteria C: No reported allergy to sulfonamides, or ASA or other NSAIDs (e.g., asthma, urticaria or other allergic reaction) Removed Criteria D: Patient does not have severe renal insufficiency – an eGFR (estimated glomerular filtration rate) below 30 OR severe hepatic impairment (Child-Pugh Class C) as safety criteria will be programmed as a safety edit Initial approval time for all indications adjusted to 3 months for patients without risk for GI toxicity.	08/15	08/15
Updated references to reflect current literature search and updated formatting; Removed requirement that request does not exceed 2 capsules/day and changed to a general statement to exceed FDA and plan limits.	04/16	05/16
- Converted to new template - Added quantity and dosage limit - Removed age criteria as age is not an absolute contraindication - Updated references	03/17	05/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the

coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.