## Prior Authorization Review Panel

**CHC-MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

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|---|---|---|
| **Plan: PA Health & Wellness** | **Submission Date**: **6/1/2018** | |
| **Policy Number: PA.CP.PPA.01** | **Effective Date: 01/2018**<br>**Revision Date: 04/18/2018** | |
| **Policy Name: Celecoxib (Celebrex)** | **HC Approval Date:** | |

**Type of Submission – Check all that apply:**

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

**Please provide any changes or clarifying information for the policy below:**

This policy is being retired and replaced by the following policy:

- **PA.CP.PMN.122 Celecoxib (Celebrex)**

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| **Name of Authorized Individual (Please type or print):**<br><br>**Francis G. Grillo, MD** | **Signature of Authorized Individual:** |

## CLINICAL POLICY
**Celecoxib**
Clinical Policy: Celecoxib (Celebrex)
Reference Number: PA.CP.PPA.01
Effective Date: 01/18
Last Review Date: 05/17
Line of Business: Medicaid

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. 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 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<br>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. 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 |
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