CENTENE Corporation

PRIOR AUTHORIZATION GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** celecoxib (Celebrex®)
PAGE: 1 of 5	**REFERENCE NUMBER:** NH.PPA.01
EFFECTIVE DATE: 01/07	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 02/14, 02/15, 6/16, 3/17
PRODUCT TYPE: Medicaid	**REVISED:** 02/10, 02/11, 02/12, 02/13

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. 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.

Description: Celecoxib is a nonsteroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic and antipyretic activities in animal models. The mechanism of action is believed to result from inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2). At therapeutic levels in humans celecoxib does not inhibit the COX-1 isoenzyme.

Brand: celecoxib (Celebrex®): 50mg, 100mg, 200mg, 400mg caps

FDA Labeled Indications:

1. Osteoarthritis/Rheumatoid arthritis
2. Ankylosing Spondylitis
3. Acute pain in adults
4. Primary dysmenorrhea
5. Juvenile rheumatoid arthritis/Juvenile idiopathic

Centene Medical Policy Statements represent technical documents developed by the Medical Management Staff. Questions regarding interpretation of these policies for the purposes of benefit coverage should be directed to a Medical Management Staff person.

CENTENE Corporation

PRIOR AUTHORIZATION GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** celecoxib (Celebrex®)
PAGE: 2 of 5	**REFERENCE NUMBER:** NH.PPA.01
EFFECTIVE DATE: 01/07	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 02/14, 02/15, 6/16, 3/17
PRODUCT TYPE: Medicaid	**REVISED:** 02/10, 02/11, 02/12, 02/13

arthritis (JIA) in patients 2 years and older

Criteria for Approval:

A. Patient has **one** of the following risk factors:
   i. Current anticoagulant use (Note: needs close monitoring of INR)
   ii. Previous documented history of complicated GI event (GI bleed, gastric perforation, symptomatic ulcer).
   iii. Patient is on chronic systemic corticosteroid therapy

or

B. Trial and failure of, or contraindication to, three Preferred Drug List (PDL) NSAIDs one of which must be meloxicam, dosed at maximum prescription strength and used adherently for four weeks,

and

C. No reported allergy to sulfonamides, or ASA or other NSAIDs (e.g., asthma, urticaria or other allergic reaction)

and

D. Patient does not have severe renal insufficiency - an eGFR (estimated glomerular filtration rate) below 30 OR severe hepatic impairment (Child-Pugh Class C).

NOTE: Trials and adherent use of PDL agents must be visible in the prescription history or documented in the progress notes submitted for prior authorization.

Approval:

Initial Approval: 12 months for chronic pain and inflammation. 1 month for acute pain.
Continued Approval: 12 months for chronic pain/inflammation if documentation shows efficacy, no adverse events, and drug therapy adherence.

CENTENE Corporation

PRIOR AUTHORIZATION GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** celecoxib (Celebrex®)
PAGE: 3 of 5	**REFERENCE NUMBER:** NH.PPA.01
EFFECTIVE DATE: 01/07	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 02/14, 02/15, 6/16, 3/17
PRODUCT TYPE: Medicaid	**REVISED:** 02/10, 02/11, 02/12, 02/13

NOTE: Quantity limits of one month supplies are applied consistent with FDA approved labeling. Quantity limits of 10 day supplies per month apply to a diagnosis of dysmenorrhea.

Special Instructions

- Celebrex®, and all NSAID's, may cause an **increased risk** of serious cardiovascular thrombotic events, MI, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for it may be at higher risk for these possibly fatal complications.
- NSAID's, including Celebrex® cause an increased risk of serious GI adverse reactions, including bleeding, ulceration, and perforation of the stomach or intestines. This can be fatal, particularly in the elderly or infirmed. These reactions can occur at any time during use and without warning symptoms.
- Celebrex® is contraindicated in treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.
- 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.
- Pregnancy Category C risk, Category D beyond 30 weeks gestation.
- Please see prescribing information for dosing, warnings, precautions.

References:

1. Celebrex Drug Monograph. Clinical Pharmacology. Accessed Feburary 2016. http://www.clinicalpharmacology-ip.com
2. Solomon DH. Overview of selective COX-2 inhibitor. Furst DE (Ed), UpToDate. Waltham MA. Accessed Feburary 2016.
3. Celebrex Prescribing Information. New York, NY: G.D. Searle,

PRIOR AUTHORIZATION GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** celecoxib (Celebrex®)
PAGE: 4 of 5	**REFERENCE NUMBER:** NH.PPA.01
EFFECTIVE DATE: 01/07	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 02/14, 02/15, 6/16, 3/17
PRODUCT TYPE: Medicaid	**REVISED:** 02/10, 02/11, 02/12, 02/13

LLC.; June 2015. Available at: http://www.celebrex.com/. Accessed Feburary 2016.

Revision Log	
Revision	**Date**
Added a new indication in the "FDA Labeled Indications" section.	02/10
Updated criteria points in the "Criteria for Approval" section.	02/10
Updated reference section to reflect current literature search.	02/10
Added requirement for use of meloxicam as one of the previously trialed NSAIDs. References updated.	02/11
Removed FAP indication from the "FDA Labeled Indications" section.	02/12
Updated reference section to reflect current literature search.	02/12
Added age requirement of 2 years and older to JRA in the "FDA Labeled Indications" section.	02/13
Added "severe hepatic impairment (Child-Pugh Class C) to section D in the "Criteria for Approval" section.	02/13
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.	02/13
Updated reference section to reflect current literature search.	02/13
Updated reference section to reflect current literature search.	02/14
Updated reference section to reflect current literature search.	02/15
Removed age related risk factor from "Criteria for Approval" section: i. Age over 65yrs	05/15
Updated references to reflect current literature search.	6/16
Annual Review, No Changes	03/17

PRIOR AUTHORIZATION GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** celecoxib (Celebrex®)
PAGE: 5 of 5	**REFERENCE NUMBER:** NH.PPA.01
EFFECTIVE DATE: 01/07	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 02/14, 02/15, 6/16, 3/17
PRODUCT TYPE: Medicaid	**REVISED:** 02/10, 02/11, 02/12, 02/13

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file