

## 5.70.06

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2021
<b>Subsection:</b>	Analgesics and Anesthetics	<b>Original Policy Date:</b>	September 8, 2011
<b>Subject:</b>	Celebrex	<b>Page:</b>	1 of 6

---

**Last Review Date:** March 12, 2021

---

## Celebrex

### Description

#### Celebrex (celecoxib)

#### Background

Celebrex is commonly referred to as a COX-2 selective inhibitor. The mechanism of action of Celebrex is believed to be inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2). It is classified as a NSAID, which have become synonymous with the management of acute musculoskeletal injuries. NSAIDs reduce pain through their inhibition of the enzyme cyclooxygenase (COX), leading to a significant decrease in prostaglandin production. COX exists as two isoenzymes, COX-1 and COX-2 (1). COX-1 enzyme exists in many body tissues, including the stomach. Most frequent side effects on the gastrointestinal tract are a result of the COX-1 inhibition, the most common being gastritis and upper gastrointestinal ulcer and bleeding. COX-2 enzyme is associated with inflammation in the joints. Selective inhibition of COX-2 should lead to decreased inflammation in musculoskeletal tissues and, by sparing COX-1, to a decrease in the incidence of GI mucosal injury (2-3).

#### Regulatory Status

FDA-approved indication: Celebrex is a nonsteroidal anti-inflammatory drug FDA indicated for Osteoarthritis (OA), Rheumatoid Arthritis (RA), Juvenile Rheumatoid Arthritis (JRA) in patients 2 years and older, Ankylosing Spondylitis (AS), Acute Pain (AP), Primary Dysmenorrhea (PD) (1).

Celebrex has a boxed warning regarding the gastrointestinal, cardiovascular, bleeding and renal risk. Celebrex can cause peptic ulcers, GI bleeding, and/or perforation of the stomach or intestines, which can be fatal. NSAIDs may cause an increased risk of serious CV thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with

# 5.70.06

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2021
<b>Subsection:</b>	Analgesics and Anesthetics	<b>Original Policy Date:</b>	September 8, 2011
<b>Subject:</b>	Celebrex	<b>Page:</b>	2 of 6

---

duration of use. Patients with CV disease or risk factors for CV disease may be at greater risk. Celebrex is contraindicated for treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery. Celebrex is contraindicated in patients with peptic ulcer disease or history of GI bleeding. Celebrex is contraindicated in patients with advanced renal impairment and in patients at risk for renal failure due to volume depletion (1).

Principal risk factors for serious GI events and hospitalization were age, smoking, use of alcohol, a history of prior NSAID-related ulceration and its complications, corticosteroid or anticoagulant use, and debilitating disorders such as cardiovascular disease. The use of low-dose aspirin alone, in the absence of other risk factors is associated with an increased risk for both GI bleeding and death from GI complications (3).

NSAIDs should be prescribed with extreme caution in patients with a prior history of ulcer disease or gastrointestinal bleeding. To minimize the potential risk for an adverse GI event, the lowest effective dose should be used for the shortest duration consistent with individual patient treatment goals. Physicians and patients should remain alert for signs and symptoms of GI ulceration and bleeding during Celebrex therapy and promptly initiate additional evaluation and treatment if a serious GI adverse event is suspected. For high-risk patients, alternate therapies that do not involve NSAIDs should be considered. Celebrex is contraindicated in patients with active GI bleeding (1).

The safety and effectiveness of Celebrex have not been established in pediatric patients under the age of 2 years, in patients with body weight less than 10kg (22 lbs), and in patients with active systemic features (1).

## **Related policies**

Anti-Inflammatory Pain Powders

## **Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Celebrex may be considered **medically necessary** in patients 2 years of age or older for the treatment of acute pain, osteoarthritis, rheumatoid arthritis, ankylosing spondylitis or primary dysmenorrhea.

Celebrex may be considered **investigational** for patients below 2 years of age and for all other indications.

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2021
<b>Subsection:</b>	Analgesics and Anesthetics	<b>Original Policy Date:</b>	September 8, 2011
<b>Subject:</b>	Celebrex	<b>Page:</b>	3 of 6

---

## Prior-Approval Requirements

**Age** 2 years of age or older

### Diagnoses

Patient must have **ONE** of the following:

1. Acute Pain\*
  - a. Location of pain
2. Rheumatoid Arthritis
3. Osteoarthritis
4. Juvenile rheumatoid arthritis (JRA)
5. Ankylosing Spondylitis
6. Primary Dysmenorrhea

## Prior – Approval *Renewal* Requirements

**Age** 2 years of age or older

### Diagnoses

Patient must have **ONE** of the following:

1. Acute Pain\*
  - a. Location of pain
  - b. **NOT** continuous therapy for same location as previously treated
2. Rheumatoid Arthritis
3. Osteoarthritis
4. Juvenile rheumatoid arthritis (JRA)
5. Ankylosing Spondylitis
6. Primary Dysmenorrhea

## [Policy Guidelines](#)

### Pre - PA Allowance

**Age** 2 years of age or older

# 5.70.06

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2021
<b>Subsection:</b>	Analgesics and Anesthetics	<b>Original Policy Date:</b>	September 8, 2011
<b>Subject:</b>	Celebrex	<b>Page:</b>	4 of 6

---

## Quantity

50 mg	360 capsules per 365 days <b>OR</b>
100 mg	360 capsules per 365 days <b>OR</b>
200 mg	180 capsules per 365 days <b>OR</b>
400 mg	180 capsules per 365 days

**Duration** 365 days

## Prior - Approval Limits

### Quantity

50 mg	960 capsules per 90 days <b>OR</b>
100 mg	480 capsules per 90 days <b>OR</b>
200 mg	240 capsules per 90 days <b>OR</b>
400 mg	120 capsules per 90 days

**Maximum daily limit of any combination: 400mg**

**Duration** \*3 months for a diagnosis of acute pain  
12 months for all other diagnoses/conditions

## Prior – Approval *Renewal* Limits

Same as above

## Rationale

### Summary

NSAIDs have become synonymous with the management of acute musculoskeletal injuries. They are some of the most widely used medications, and are reliable and effective when used appropriately for pain relief and to reduce inflammation. NSAIDs reduce pain through their inhibition of the enzyme cyclooxygenase (COX), leading to a significant decrease in prostaglandin production. COX exists as two isoenzymes, COX-1 and COX-2. COX-2 inhibitors are associated with a significantly lower incidence of gastric and duodenal ulcers when compared to traditional NSAIDs. Celebrex is contraindicated in patients with active GI bleeding. The mechanism of action of Celebrex is believed to be inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2). It does not inhibit the cyclooxygenase-1 (COX-1). Celebrex is commonly referred to as a COX-2 selective inhibitor (1).

# 5.70.06

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2021
<b>Subsection:</b>	Analgesics and Anesthetics	<b>Original Policy Date:</b>	September 8, 2011
<b>Subject:</b>	Celebrex	<b>Page:</b>	5 of 6

---

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Celebrex while maintaining optimal therapeutic outcomes.

## References

1. Celebrex [package insert]. New York, NY: Searle & Co and Pfizer Inc.; May 2019.
2. Farkouh ME, Greenberg BP. An Evidence-Based Review of the Cardiovascular Risks of Nonsteroidal Anti-inflammatory Drugs. *Am J Cardiol* 2009; 103:1227-1237.
3. Lanza FL, Chan FKL, Quigley EMM, et al. Guidelines for Prevention of NSAID-Related Ulcer Complications. *Am J Gastroenterol* 2009; 104:728-738.

## Policy History

Date	Action	Reason
May 2007	In order to be consistent with current benefit design, we recommend that Celebrex 50mg capsules be included in the overall current upfront COX-2 standard allowance of 90 days' supply per year.	
September 2008	The Prior Approval Limits were increased by a 30 day supply (1/3 increase) to allow for members to fill up to 90-day supply at mail order after a starter quantity is filled at retail.	
May 2012	Comprehensive criteria review and update. FAP deleted (no longer FDA-approved)	
March 2013	Annual editorial review and reference update. Minimum age 2 years.	
June 2014	Annual review and addition of contraindication: active GI bleeding	
June 2015	Annual review	
March 2016	Annual review and reference update Policy number changed from 5.02.06 to 5.70.06	
March 2017	Annual editorial review and reference update Addition requirements for acute pain and location of pain and no continuous use for same location in renewal	
June 2017	Removal of at risk for adverse GI events, at risk for bleeding, at risk for cardiovascular events, at risk for renal impairment	
September 2017	Annual review	
March 2018	Annual editorial review	
November 2018	Annual review. Changed Pre-PA allowance to double the quantities allowed per 365 days and Pre-PA age requirement from 55 years to 2 years of age	
March 2019	Annual review	
March 2020	Annual review and reference update	

## 5.70.06

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2021
<b>Subsection:</b>	Analgesics and Anesthetics	<b>Original Policy Date:</b>	September 8, 2011
<b>Subject:</b>	Celebrex	<b>Page:</b>	6 of 6

---

March 2021      Annual review

### Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.**