MEDICAL MUTUAL®

Drug Policy

Policy:	**Cyclooxygenase-2 (COX-2) Inhibitor Step Therapy** **Preferred Step Therapy Policy**	**Annual Review Date: 10/19/2023** **Last Revised Date: 10/19/2023**

OVERVIEW

Celebrex is a nonsteroidal anti-inflammatory drug (NSAID) that works primarily by inhibiting prostaglandin synthesis by way of cyclooxygenase-2 (COX-2) [termed a COX-2 inhibitor] and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.[1] Celebrex is indicated for the following conditions: osteoarthritis (OA); rheumatoid arthritis (RA); juvenile rheumatoid arthritis (JRA) in patients aged ≥ 2 years; ankylosing spondylitis; acute pain in adults; and for the treatment of primary dysmenorrhea.[1] Overall, it appears that Celebrex and NSAIDs have similar clinical efficacy at equipotent doses for the management of acute and chronic pain and other conditions associated with pain; however, individual responses to NSAIDs vary among patients for reasons that are not well understood.

POLICY STATEMENT

A step therapy program has been developed to encourage the use of two Step 1 products (oral NSAIDs) prior to the use of the Step 2 product (generic celecoxib), unless the patient meets exceptions. Approval for a Step 3 product (brand Celebrex) may be authorized if the patient has tried two Step 1 products (oral NSAIDS) and has tried the Step 2 product (generic celecoxib). If the step therapy rule is not met for the Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 12 months in duration except for use in the preoperative/perioperative/postoperative period where authorization is provided for up to 30 days for the Step 2 product (generic celecoxib).

Automation:

- **Step 2 (generic celecoxib):** A patient with a history of two Step 1 Products (oral NSAIDS) within the 130-day look-back period can receive the Step 2 Product (generic celecoxib). Alternatively, a patient with a history of one of the following within the 130-day look-back period: warfarin, clopidogrel, prasugrel, Brilinta™ (ticagrelor tablets), Xarelto® (rivaroxaban tablets and oral suspension), Pradaxa® (dabigatran capsules), Eliquis® (apixaban tablets), or Savaysa™ (edoxaban tablets) can receive the Step 2 Product (generic celecoxib).
- **Step 3 (brand Celebrex):** A patient with a history of two Step 1 Products (oral NSAIDS) and the Step 2 Product (generic celecoxib) within the 130-day look-back period can receive the Step 3 Product (brand Celebrex). Alternatively, a patient with the history of the Step 2 Product (generic celecoxib) and of one of the following, both within the 130-day look-back period: warfarin, clopidogrel, prasugrel, Brilinta™ (ticagrelor tablets), Xarelto® (rivaroxaban tablets and oral suspension), Pradaxa® (dabigatran capsules), Eliquis® (apixaban tablets), or Savaysa™ (edoxaban tablets) can receive the Step 3 Product (brand Celebrex).

**Some generic naproxen and tolmetin products are not Step 1 products

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Step 1: Cataflam, diclofenac potassium, diclofenac sodium (IR and ER), ficlofenac sodium and misoprostol, etodolac, fenoprofen, flurbiprofen, ibuprofen, infomethacin (IR and ER), ketoprofen IR 50mg and 75mg, ketorolac (tablets), meclofenamate, mefenamic acid, meloxicam, nabumetone, naproxen**, oxaprozin, piroxicam, sulindac, tolmetin**

Step 2: generic celecoxib

Step 3: brand Celebrex

Criteria

1. Approve the Step 2 product (generic celecoxib) for 1 year if the patient meets one of the following (A, B, C, D, or E):
- **A)** Patient has tried two Step 1 products (oral NSAIDs), either as prescription products or as over-the-counter (OTC) products, at prescription-strength doses for the current condition; OR
- **B)** Patient is currently taking chronic systemic corticosteroid therapy (e.g., prednisone), warfarin, clopidogrel, prasugrel, Brilinta™ (ticagrelor tablets), Xarelto® (rivaroxaban tablets and oral suspension), Pradaxa® (dabigatran capsules), Eliquis® (apixaban tablets), Savaysa™ (edoxaban tablets), chronic aspirin therapy, fondaparinux injection or a low molecular weight heparin product (i.e., enoxaparin injection, Fragmin® [dalteparin injection]); OR
- **C)** Patient has reduced platelet counts or other coagulation disorders; OR
- **D)** Patient is > 75 years of age and is using celecoxib for a chronic condition; OR
- **E)** Patient has had a documented upper gastrointestinal bleed from a duodenal or gastric ulcer.

1. Approve the Step 2 product (generic celecoxib) for 30 days if the patient is using the agent during the preoperative/perioperative/postoperative period.

2. Approve the Step 3 product (brand Celebrex) for 1 year if the patient meets the following (A and B):
- **A)** The patient has tried two Step 1 products (oral NSAIDs,) either as prescription products or as over-the-counter (OTC) products at prescription-strength doses, for the current condition; AND
- **B)** The patient has tried the Step 2 product (generic celecoxib).

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year (365 days)
B) *Extended Approval:* 1 year (365 days)

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):
- A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
- B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**

C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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