Celecoxib

Override(s)	Approval Duration
Prior Authorization	1 year
Quantity Limit	

Medications	Quantity Limit
Celebrex (celecoxib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for celecoxib may be approved if the following criteria is met:

I. Individual has had a trial (medication samples/ coupons/ discount cards are excluded from consideration as a trial) and inadequate response or intolerance to two preferred single agent oral Non-Steroidal Anti-Inflammatory Drugs (NSAIDs);

Preferred Agents: Generic prescription oral NSAIDs.

OR

- II. Individual has history of a gastrointestinal disorder (including, ulcer, gastritis); OR
- III. Individual has a diagnosis of Desmoid tumors (aggressive fibromatosis) (NCCN 2A); OR
- IV. The preferred NSAIDs are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and the requested non-preferred agent does.

Requests for **brand** Celebrex must also meet the following criteria, in addition to the above Prior Authorization criteria:

I. Individual has failed an adequate trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one chemically equivalent generic celecoxib agent;

AND

- A. Generic celecoxib had inadequate response; OR
- B. Generic celecoxib caused adverse outcome; OR
- C. The individual has a genuine allergic reaction to an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Key References:

- 1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <u>http://www.clinicalpharmacology.com</u>. Updated periodically.
- 2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 13, 2021.
- 3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

- Lexi-Comp ONLINE[™] with AHFS[™], Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
 The NCCN Drugs & Biologics Compendium (NCCN Compendium[™])[©] 2020 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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