Clinical Policy: Celecoxib (Celebrex, Elyxyb, Vyscoxa)

Reference Number: CP.PMN.122
Effective Date: 01.01.07
Last Review Date: 05.25
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Celecoxib (Celebrex®, Elyxyb™, Vyscoxa™) is a nonsteroidal anti-inflammatory drug (NSAID).

FDA Approved Indication(s)

Celebrex and Vyscoxa are indicated for the treatment of:

- Osteoarthritis (OA)
- Rheumatoid arthritis (RA)
- Ankylosing spondylitis (AS)
- Juvenile rheumatoid arthritis (JRA) in patients 2 years and older

Celebrex is additionally indicated for the treatment of:

- Acute pain
- Primary dysmenorrhea

Elyxyb is indicated for the acute treatment of migraine with or without aura in adults.

Limitation(s) of use:

- Elyxyb is not indicated for the preventive treatment of migraine.
- Vyscoxa must be administered on an empty stomach at least 2 hours before or 1 hour after food. Taking Vyscoxa with food results in plasma exposures of celecoxib up to 50% higher than intended. If patients cannot tolerate Vyscoxa in the fasted state, discontinue use of Vyscoxa.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Celebrex and Elyxyb are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Migraine Treatment (must meet all):

1. Request is for Elyxyb;
2. Diagnosis of migraine;
3. Age ≥ 18 years;
4. Member meets one of the following (a, b, c, d, or e):
   a. Age > 65 years;

b. Current use of a corticosteroid;
c. Current use of an anticoagulant or antiplatelet (e.g., aspirin, warfarin, low molecular weight heparin, direct thrombin inhibitors, factor Xa inhibitors, clopidogrel);
d. Prior gastrointestinal bleed or active peptic ulcer disease (not gastroesophageal reflux disease [GERD]);
e. Failure of a ≥ 4 week trial of both of the following (i and ii), up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced:
   i. Meloxicam;
   ii. One additional generic NSAID;

5. Dose does not exceed 120 mg (4.8 mL) per day.

Approval duration: 12 months

B. Requests for Celebrex for All Other Indications – *FOR MEDICAID and California COMMERCIAL ONLY** (must meet all)**:**

* *Refer to Step Therapy policy CP.CPA.83 for Oregon Commercial*

1. Request is for Celebrex;
2. Age ≥ 2 years;
3. For brand Celebrex requests, member must use generic celecoxib, unless contraindicated or clinically significant adverse effects are experienced;
4. Member meets one of the following (a, b, c, d, or e):
   a. Age > 65 years;
   b. Current use of a corticosteroid;
   c. Current use of an anticoagulant or antiplatelet (e.g., aspirin, warfarin, low molecular weight heparin, direct thrombin inhibitors, factor Xa inhibitors, clopidogrel);
   d. Prior gastrointestinal bleed or active peptic ulcer disease (not gastroesophageal reflux disease [GERD]);
   e. Failure of a ≥ 4 week trial of both of the following (i and ii), up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced:
      i. Meloxicam;
      ii. One additional generic NSAID;
5. Dose does not exceed both of the following (a and b):
   a. 800 mg per day;
   b. 2 capsules per day.

Approval duration: 12 months

C. Requests for Vyscoxa for All Other Indications (must meet all):

1. Request for Vyscoxa;
2. Age ≥ 2 years;
3. Member must use generic celecoxib capsule formulation, unless contraindicated or clinically significant adverse effects are experienced;
4. Member meets one of the following (a, b, c, d, or e):
   a. Age > 65 years;

b. Current use of corticosteroid;
c. Current use of an anticoagulant or antiplatelet (e.g., aspirin, warfarin, low molecular weight heparin, direct thrombin inhibitors, factor Xa inhibitors, clopidogrel);
d. Prior gastrointestinal bleed or active peptic ulcer disease (not GERD);
e. Failure of a ≥ 4 week trial of both of the following (i and ii), up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced:
   i. Meloxicam;
   ii. One additional generic NSAID;

5. Dose does not exceed both of the following (a and b):
   a. 200 mg (20 mL) per dose;
   b. 400 mg (40 mL) per day.

Approval duration: 12 months

D. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Acute Migraine Treatment (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 120 mg (4.8 mL) per day.

Approval duration: 12 months

B. Requests for Celebrex for All Other Indications – *FOR MEDICAID and California COMMERCIAL ONLY** (must meet all)**:**

* *Refer to Step Therapy policy CP.CPA.83 for Oregon Commercial*

1. Member meets one of the following (a or b):

a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 800 mg per day;
   b. 2 capsules per day.

Approval duration: 12 months

C. Requests for Vyscoxa for All other Indications (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 200 mg (20 mL) per dose;
   b. 400 mg (40 mL) per day.

Approval duration: 12 months

D. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AS: ankylosing spondylitis
CABG: coronary artery bypass graft
FDA: Food and Drug Administration
GERD: gastroesophageal reflux disease
JRA: juvenile rheumatoid arthritis
NSAID: nonsteroidal anti-inflammatory drug
OA: osteoarthritis
RA: rheumatoid arthritis

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
naproxen sodium (Anaprox®, Anaprox DS®)	275 – 550 mg PO BID	1,650 mg/day
sulindac	150 – 200 mg PO BID	400 mg/day
salsalate	500 – 750 mg PO TID, titrated up to 3,000 mg/day	3,000 mg/day
piroxicam (Feldene®)	10 – 20 mg PO QD	20 mg/day
indomethacin (Indocin®)	25 – 50 mg PO BID -TID	200 mg/day
indomethacin SR (Indocin® SR)	75 mg PO QD - BID	150 mg/day
meclofenamate	50 – 100 mg PO Q4-6hr	400 mg/day
meloxicam (Mobic®)	7.5 – 15 mg PO QD	15 mg/day
ibuprofen (Motrin®)	400 – 800 mg PO Q6-8hr	3,200 mg/day
fenoprofen (Nalfon®)	200 mg PO Q4-6hr	3,200 mg/day
naproxen (Naprosyn®)	250 – 500 mg PO BID	1,500 mg/day
ketoprofen	25 – 75 mg PO Q6-8hr	300 mg/day
nabumetone (Relafen®)	1000 mg PO QD or 500 mg PO BID	2,000 mg/day
tolmetin (Tolmetin® DS)	400 mg PO TID, titrated up to 1800 mg/day	1,800 mg/day
diclofenac sodium (Voltaren®)	50 mg PO Q6-8hr	200 mg/day
oxaprozin (Daypro®)	600 – 1,200 mg PO QD	1,800 mg/day
etodolac (Lodine®)	400 – 500 mg PO BID	1,200 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to celecoxib or any components of the drug product; history of asthma, urticaria, or other allergic-type reactions to aspirin or other NSAIDs; in the setting of coronary artery bypass graft (CABG) surgery; allergic-type reactions to sulfonamides

- Boxed warning(s): increased risk of serious cardiovascular thrombotic events, including myocardial infarction, and stroke; increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines; in the setting of CABG surgery

Appendix D: General Information

- The risk vs. benefit of COX-II therapy should be individualized based on patient's previous GI history, other co-morbid conditions (e.g., angina, ischemic heart disease, myocardial infarction (MI), coronary artery disease, stroke), age, concurrent medications (e.g., warfarin, oral corticosteroids), duration and dose.
- Celebrex has been associated with an increased risk of serious adverse cardiovascular (CV) events in a long-term placebo-controlled trial. Based on the currently available data, FDA has concluded that an increased risk of serious adverse CV events appears to be a class effect of NSAIDs. FDA has requested that the package insert for all NSAIDs, including Celebrex, be revised to include a boxed warning to highlight the potential increased risk of CV events and the well described risk of serious, and potentially life-threatening, gastrointestinal bleeding.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Celecoxib (Celebrex)	OA	200 mg PO QD or 100 mg PO BID	800 mg/day
	RA	100 to 200 mg PO BID	800 mg/day
	JRA	10-25 kg: 50 mg PO BID > 25 kg: 100 mg PO BID	200 mg/day
	AS	200 mg PO QD or 100 mg PO BID. 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 or primary dysmenorrhea	400 mg PO initially, followed by a 200 mg dose if needed on the first day. On subsequent days, 200 mg PO BID as needed	800 mg/day
Celecoxib (Elyxyb)	Migraine	120 mg PO PRN. Use the fewest number of days per month, as needed.	120 mg/day
Celecoxib (Vyscoxa)*	OA	200 mg PO QD or 100 mg PO BID	200 mg/day
	RA	100 mg to 200 mg PO BID	400 mg/day
	AS	200 mg PO QD or 100 mg PO BID. If no effect is observed after 6 weeks, a trial of 200 mg PO BID may be worthwhile.	400 mg/day
	JRA	10-25 kg: 50 mg PO BID	200 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		> 25 kg: 100 mg PO BID	

**The maximum single dose of Vyscoxa is 200 mg (20 mL). Administering more than 200 mg (20 mL) in a single dose of the Vyscoxa suspension may result in higher than intended plasma concentrations of celecoxib. In patients requiring a single dose greater than 200 mg (20 mL), use a different product.*

VI. Product Availability

Drug Name	Availability
Celecoxib (Celebrex)	Capsules: 50 mg, 100 mg, 200 mg, 400 mg
Celecoxib (Elyxyb)	Oral solution: 120 mg/4.8 mL (25 mg/mL)
Celecoxib (Vyscoxa)	Oral suspension: 10 mg/mL

VII. References

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14. Juni, et al. Are selective COX 2 inhibitors superior to traditional non-steroidal anti-inflammatory drugs. BMJ 2002;324:1287-1288.
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Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2021 annual review: no significant changes; revised HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	03.01.21	05.21
2Q 2022 annual review: no significant changes; added redirection to generic celecoxib for brand Celebrex requests per formulary status; limited use of Elyxyb to its FDA labeled indication; references reviewed and updated.	01.14.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.03.22	
2Q 2023 annual review: no significant changes; added limitation of use for Elyxyb per PI; references reviewed and updated.	01.23.23	05.23
Per May SDC, separated criteria sets for Elyxyb and Celebrex requests; for Celebrex requests added clarification criteria applies to Medicaid and Commercial only, referencing to Step Therapy policy HIM.PA.109 for HIM.	05.24.23	
Added missing approval duration for acute migraine continuation of therapy criteria; revised Commercial approval duration to length of benefit for all requests.	08.03.23	
Added clarification policy applies to California Commercial only; added reference to Step Therapy policy CP.CPA.83 for Oregon Commercial.	09.18.23	
2Q 2024 annual review: for commercial line of business, updated approval duration from “length of benefit” to “12 months”; references reviewed and updated.	03.12.24	05.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Per March SDC: removed HIM line of business; for all indications section, removed reference to Step Therapy policy HIM.PA.109 for HIM.		
2Q 2025 annual review: no significant changes; references reviewed and updated	01.16.25	05.25
RT4: added Vyscoxa, oral suspension formulation, to policy.	08.08.25	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.