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5.70.082

Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	July 3, 2020
Subject:	Elyxyb	**Page:**	1 of 4

Last Review Date: December 12, 2025

Elyxyb

Description

Elyxyb (celecoxib) oral solution

Background
Elyxyb (celecoxib) is a nonsteroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory, and antipyretic properties. The mechanism of action by which Elyxyb exerts therapeutic effects in migraine patients is not fully understood but may involve inhibition of prostaglandin synthesis, primarily via inhibition of COX-2 (1).

Regulatory Status
FDA-approved indication: Elyxyb is indicated for the acute treatment of migraine with or without aura in adults (1).

Limitations of Use: Elyxyb is not indicated for the preventative treatment of migraine (1).

Elyxyb has a boxed warning regarding the risk of serious cardiovascular and gastrointestinal (GI) events. NSAIDs cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. Elyxyb is contraindicated in the setting of coronary artery bypass graft (CABG) surgery. NSAIDs also cause an increased risk of serious GI adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal (1).

The recommended dose of Elyxyb is 120 mg taken orally, with or without food. The maximum dosage in a 24-hour period is 120 mg. The safety and effectiveness of a second dose in a 24—

hour period have not been established. Elyxyb should be used for the fewest number of days per month, as needed (1).

The safety and effectiveness of Elyxyb in pediatric patients less than 18 years of age have not been established (1).

Related policies
5-HT1 Agonists, Butalbital analgesics, Dihydroergotamine Nasal Sprays, Maxalt, Migraine CGRP Antagonists IV, Migraine CGRP Antagonists Nasal, Migraine CGRP Antagonists Oral, Migraine CGRP Antagonists SC, Migraine 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.

Elyxyb may be considered **medically necessary** if the conditions indicated below are met.

Elyxyb may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

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

1. Migraine, with aura (classic)
2. Migraine, without aura (common)

AND ALL of the following:

a. Inadequate treatment response, intolerance, or contraindication to at least **TWO** triptan agents
b. Patient has **NOT** had CABG surgery within the last 14 days
c. Prescriber agrees to monitor for cardiovascular and gastrointestinal events
d. **NO** dual therapy with a triptan agent at prior authorization quantities

Prior-Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

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

1. Migraine, with aura (classic)
2. Migraine, without aura (common)

AND ALL of the following:

a. Patient has **NOT** had CABG surgery within the last 14 days
b. Prescriber agrees to monitor for cardiovascular and gastrointestinal events
c. **NO** dual therapy with a triptan agent at prior authorization quantities

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 27 bottles (120 mg/4.8 mL) per 90 days

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Elyxyb (celecoxib) is a nonsteroidal anti-inflammatory drug with analgesic, anti-inflammatory, and antipyretic properties. The mechanism of action by which Elyxyb exerts therapeutic effects in migraine patients is not fully understood but may involve inhibition of prostaglandin synthesis, primarily via inhibition of COX-2. The safety and effectiveness of Elyxyb in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Elyxyb [package insert]. Raleigh, NC: BioDelivery Sciences International, Inc.; September 2021.

Policy History

Date	Action
July 2020	Addition to PA
September 2020	Annual review
March 2021	Annual review
September 2021	Annual review
March 2023	Annual review. Changed policy number to 5.70.082
September 2023	Annual review and reference update
March 2024	Annual review
December 2024	Annual review
December 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.