



Drug Coverage Policy

Effective Date.....01/01/2025

Coverage Policy Number.....IP0640

Policy Title..... Elyxyb

Migraine – Elyxyb

- Elyxyb™ (celecoxib oral solution – BioDelivery Sciences)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

OVERVIEW

Elyxyb, a nonsteroidal anti-inflammatory drug, is indicated for the **acute treatment of migraine with or without aura** in adults ¹ Limitations of Use: Elyxyb is not indicated for the preventive treatment of migraine.

Disease Overview

Migraine is a common, ongoing condition marked by paroxysmal, unilateral attacks of moderate to severe throbbing headache which are aggravated by routine physical activity (e.g., walking or climbing stairs) and associated with nausea, vomiting, and/or photophobia and phonophobia.² Migraines have been defined as chronic or episodic. Chronic migraine is described by the International Headache Society as headache occurring on ≥ 15 days/month for more than 3 months,

which has the features of migraine headache on ≥ 8 days/month. Episodic migraine is characterized by headaches that occur < 15 days/month.³

Guidelines

Triptans (e.g., almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, and zolmitriptan) are considered the gold standard for acute treatment of moderate to severe migraine headaches or mild to moderate migraine headaches that respond poorly to over-the-counter analgesics. An assessment of the preventive and acute treatment of migraine by the American Headache Society (2018; updated 2021) reaffirms previous migraine guidelines.^{4,5} Nonsteroidal anti-inflammatory drugs (NSAIDs) as a class are mentioned as an option for acute treatment of mild to moderate migraine attacks; celecoxib is not specifically addressed. The potential for cardiovascular and gastrointestinal adverse events with NSAID use is noted. Other treatment options in the mild to moderate setting include nonopioid analgesics, acetaminophen, or caffeinated analgesic combinations. For moderate to severe attacks or attacks which respond poorly to NSAIDs or caffeinated combinations, the update lists the triptans, dihydroergotamine, the oral gepants (Nurtec[®] ODT [rimegepant orally disintegrating tablets,] and Ubrovelvy[®] [ubrogepant tablets]), and Reyvow[™] (lasmiditan tablet) as effective treatments. The recommendation remains that clinicians must consider medication efficacy and potential medication-related adverse events when prescribing acute medications for migraine.

Medical Necessity Criteria

Elyxyb is considered medically necessary when the following criteria are met:

FDA-Approved Indication

- 1. Migraine, Acute Treatment.** Approve for 1 year if the patient meets the following (A, B, and C):
 - A.** Patient is ≥ 18 years of age; AND
 - B.** Patient meets ONE of the following (i or ii):
 - i.** Patient has tried at least one triptan therapy; OR
 - ii.** Patient has a contraindication to triptan(s) according to the prescriber; AND
Note: Examples of contraindications to triptans include a history of coronary artery disease; cardiac accessory conduction pathway disorders; history of stroke, transient ischemic attack, or hemiplegic or basilar migraine; peripheral vascular disease; ischemic bowel disease; uncontrolled hypertension; or severe hepatic impairment.
 - C.** Preferred product criteria is met for the product as listed in the below table(s)

Employer Plans:

Product	Criteria
Elyxyb (celecoxib oral solution)	According to the prescriber, there is a significant clinical concern such that the individual is unable to use celecoxib capsules

Individual and Family Plans:

Product	Criteria
Elyxyb (celecoxib oral solution)	According to the prescriber, there is a significant clinical concern such that the individual is unable to use celecoxib capsules

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based

literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Management of Acute Pain Unrelated to Migraine Headache.** Celecoxib is also available as a capsule (Celebrex®, generic).⁶ Celecoxib capsules are indicated for the management of the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis in adults and juvenile rheumatoid arthritis in patients ≥ 2 years of age; acute pain in adults; and primary dysmenorrhea in adults. For patients who have difficulty swallowing capsules, the contents of a celecoxib capsule can be added to applesauce. There are no published studies with Elyxyb in acute pain.

References

1. Elyxyb™ oral solution [prescribing information]. Palo Alto, CA: Scilex; June 2023.
2. Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders: 3rd edition. *Cephalalgia*. 2018;38(1):1-211.
3. Lipton RB, Silberstein SD. Episodic and chronic migraine headache: breaking down barriers to optimal treatment and prevention. *Headache*. 2015;52:103-122.
4. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.
5. Ailani J, Burch RC, Robbins MS, on behalf of the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021;61(7):1021-1039.
6. Celebrex® capsules [prescribing information]. New York, NY: Pfizer; April 2021.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	01/01/2025

The policy effective date is in force until updated or retired.

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