



PRIOR AUTHORIZATION POLICY

POLICY: Migraine – Elyxyb Prior Authorization Policy

- Elyxyb™ (celecoxib oral solution – BioDelivery Sciences)

REVIEW DATE: 04/03/2024

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 NATIONAL FORMULARY COVERAGE:

OVERVIEW

Elyxyb, a nonsteroidal anti-inflammatory drug, is indicated for the **acute treatment of migraine with or without aura** in adults¹ 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 Ubrelvy[®] [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.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Elyxyb. All approvals are provided for the duration noted below.

- **Elyxyb[™] (celecoxib oral solution – BioDelivery Sciences)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. Migraine, Acute Treatment. Approve for 1 year if the patient meets the following (A and B):

A) Patient is \geq 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.

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.

CONDITIONS NOT COVERED

- **Elyxyb[™] (celecoxib oral solution – BioDelivery Sciences)**

is(are) considered experimental, investigational, or unproven for ANY other use(s) 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.
- 2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria.** Criteria will be updated as new published data are available.

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria change.	03/22/2023
Annual Revision	No criteria change.	04/03/2024

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