

**ELYXYB
(celecoxib oral solution)****RATIONALE FOR INCLUSION IN PA PROGRAM****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).

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,



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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.