



CYCLOBENZAPRINE POWDER (cyclobenzaprine)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Cyclobenzaprine is a muscle relaxant which relieves muscle spasm of local origin without interfering with muscle function. Cyclobenzaprine acts primarily at the brain stem (and to a lesser extent at spinal cord level) to relieve skeletal muscle spasms (1).

Cyclobenzaprine is commercially available as 5mg, 7.5mg, and 10mg immediate release tablets and 15mg and 30mg extended release capsules (2).

Regulatory Status

FDA-approved indication: Cyclobenzaprine is a muscle relaxant indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions (1-2).

Limitations of Use:

Cyclobenzaprine should be used only for short periods (up to 2 or 3 weeks). Cyclobenzaprine has not been found effective in the treatment of spasticity or cerebral palsy (1-2).

Off-label (non-FDA approved) compounded topical preparations of cyclobenzaprine have not been proven to be safe or effective.

Safety and efficacy in patients younger than 18 years of age have not been established (1).

Summary

Cyclobenzaprine is a muscle relaxant indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. There are no clinically controlled studies confirming that topical application of cyclobenzaprine is safe and effective (1-2).

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

References

1. Amrix [package insert]. Vandalia, OH: Adare Pharmaceuticals, Inc.; May 2020.
2. Cyclobenzaprine [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; August 2020.