Cyclobenzaprine Powder

Description

Cyclobenzaprine Powder

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).
Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cyclobenzaprine powder may be considered medically necessary for oral administration in patients for the treatment of muscle spasm associated with acute, painful musculoskeletal condition(s) and if the conditions indicated below are met.

Cyclobenzaprine powder is considered investigational in patients for all other indications.

Prior-Approval Requirements

Diagnosis

Muscle spasm associated with acute, painful musculoskeletal condition(s)

AND ALL of the following:
1. The immediate release requested oral dose does not exceed 10mg/unit
2. The extended release requested oral dose does not exceed 30mg/unit
3. The requested strength is not commercially available

Prior – Approval Renewal Requirements

Same as above

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
Duration 12 months
Rationale

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

Policy History

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<td>October 2013</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.