



**BlueCross
BlueShield**

Federal Employee Program.
Federal Employee Program®
1310 G Street, N.W.
Washington, D.C. 20005
202.942.1000
Fax 202.942.1125

5.75.08

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Neuromuscular Drugs	Original Policy Date:	December 6, 2013
Subject:	Cyclobenzaprine Powder	Page:	1 of 3

Last Review Date: March 12, 2021

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).

5.75.08

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Neuromuscular Drugs	Original Policy Date:	December 6, 2013
Subject:	Cyclobenzaprine Powder	Page:	2 of 3

Related policies

Baclofen powder, Tizanidine powder

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

Same as above

5.75.08

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Neuromuscular Drugs	Original Policy Date:	December 6, 2013
Subject:	Cyclobenzaprine Powder	Page:	3 of 3

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

1. Amrix [package insert]. Vandalia, OH: Adare Pharmaceuticals, Inc.; May 2019.
2. Cyclobenzaprine [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; January 2019.

Policy History

Date	Action
October 2013	New addition to PA
December 2013	Annual review
December 2014	Annual editorial review and reference update
December 2015	Annual review
September 2016	Annual review and reference update Policy number changed from 5.06.12 to 5.75.08
September 2017	Annual editorial review and reference update
September 2018	Annual review
September 2019	Annual review and reference update
September 2020	Annual review
March 2021	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.