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5.75.012

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	December 6, 2013
Subject:	Tizanidine powder	**Page:**	1 of 4

Last Review Date: December 13, 2024

Tizanidine powder

Description

Tizanidine powder

Background
Tizanidine is a skeletal muscle relaxant that for the management of spasticity, muscle spasms related to neurological conditions such as spinal cord injury and multiple sclerosis (1).

Zanaflex (tizanidine) tablets are available in two strengths as white uncoated tablets containing tizanidine hydrochloride 2 mg or 4 mg. The capsules are available in three strengths as two-piece hard gelatin capsules containing tizanidine hydrochloride 2 mg, 4mg, or 6 mg (1).

Regulatory Status
FDA-approved indication: Tizanidine is a short-acting drug for the management of spasticity. Because of the short duration of effect, treatment with tizanidine should be reserved for those daily activities and times when relief of spasticity is most important (1).

There is a potential interaction with ciprofloxacin or fluvoxamine. In a pharmacokinetic study, tizanidine serum concentrations were significantly increased AUC 33-fold when taken with fluvoxamine and AUC 10-fold when concomitantly taken with ciprofloxacin. Clinically significant hypotension (decreases in both systolic and diastolic pressure) has been reported with concomitant administration of either fluvoxamine or ciprofloxacin and single doses of 4 mg of tizanidine. Therefore, concomitant use of tizanidine with fluvoxamine or with ciprofloxacin, potent inhibitors of CYP1A2, is contraindicated (1).

There are no adequate and well-controlled studies to document the safety and efficacy of tizanidine in children (1).

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

Related policies
Baclofen powder, Cyclobenzaprine 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.

Tizanidine powder may be considered **medically necessary** if the conditions indicated below are met.

Tizanidine powder may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

Spasticity

AND ALL of the following:

1. The requested **ORAL** dose does not exceed 6mg/unit
2. The requested strength is not commercially available
3. **NO** concurrent therapy with either ciprofloxacin or fluvoxamine

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

Rationale

Summary

Tizanidine is a short-acting drug for the oral administration for the management of spasticity. Because of the short duration of effect, treatment with tizanidine should be reserved for those daily activities and times when relief of spasticity is most important. There are no adequate and well-controlled studies to document the safety and efficacy of tizanidine in children (1).

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

References

1. Zanaflex [package insert]. Zug, Switzerland: Covis Pharma; December 2020.

Policy History

Date	Action
October 2013	New addition to PA
December 2013	Editorial review by PMPC
December 2014	Annual editorial review and reference update
September 2016	Annual editorial review and reference update Policy number change from 5.06.16 to 5.75.12
September 2017	Annual review
September 2018	Annual review
September 2019	Annual review
September 2020	Annual review

December 2021	Annual review and reference update
December 2022	Annual review. Changed policy number to 5.75.012
December 2023	Annual review
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.