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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Cardiovascular Agent	**Original Policy Date:**	January 1, 2014
Subject:	Papaverine Powder	**Page:**	1 of 4

Last Review Date: September 6, 2024

Papaverine Powder

Description

Papaverine Powder

Background
Papaverine relaxes the smooth musculature of the larger blood vessels, including the coronary, cerebral, peripheral, and pulmonary arteries. This provides the basis for the clinical use of papaverine in peripheral or pulmonary arterial embolism (1).

Papaverine is commercially available as a 150mg extended release capsule and a 30mg/ml solution for injection (1).

Regulatory Status
FDA-approved indication: Papaverine is indicated for relief of cerebral and peripheral ischemia associated with arterial spasm and myocardial ischemia complicated by arrhythmias (1).

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

Papaverine for treatment of erectile dysfunction (ED) is **excluded** from coverage.

Related policies
Baclofen powder, Cyclobenzaprine 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.

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

Papaverine may be considered **investigational** for all other indications.

Papaverine for treatment of erectile dysfunction (ED) is **excluded** from coverage.

Prior-Approval Requirements

Diagnoses

Patients must have **ONE** of the following:

1. Cerebral and peripheral ischemia associated with arterial spasm
2. Myocardial ischemia complicated by arrhythmias

AND ALL of the following:

a. The requested **ORAL** dose does not exceed 150mg/unit
b. The requested **INJECTABLE** solution does not exceed 30mg/ml.
c. The requested strength is not commercially available
d. **NOT** administered via intracavernosal injection
e. **NOT** administered topically

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

Papaverine is indicated for relief of cerebral and peripheral ischemia associated with arterial spasm and myocardial ischemia complicated by arrhythmias. Off-label (non-FDA approved) compounded topical preparations of Papaverine have not been proven to be safe or effective (1).

Papaverine for treatment of erectile dysfunction (ED) is **excluded** from coverage.

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

References

1. Papaverine Hydrochloride Injection [package insert]. Shirley, NY: American Regent, Inc; November 2023.

Policy History

Date	Action
December 2013	New addition to PA
March 2014	Annual review
March 2015	Annual editorial review and reference update
September 2016	Annual editorial review Policy number change from 5.06.19 to 5.40.25
September 2017	Annual review
September 2018	Annual review and reference update
September 2019	Annual review and reference update
September 2020	Annual review

September 2021	Annual review
September 2022	Annual review
September 2023	Annual review
September 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.