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.
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 for oral or injectable administration for the treatment of cerebral and peripheral ischemia associated with arterial spasm and myocardial ischemia complicated by arrhythmias.

Papaverine is considered investigational in patients who do not have cerebral and peripheral ischemia associated with arterial spasm or myocardial ischemia complicated by arrhythmias; if the oral dose exceeds 150mg/unit; if the injectable solution exceeds 30mg/ml; or if administered via intracavernosal injection or topically.

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:

1. The requested ORAL dose does not exceed 150mg/unit
2. The requested INJECTABLE solution does not exceed 30mg/ml.
3. The requested strength is not commercially available
4. NOT administered via intracavernosal injection
5. NOT administered topically
Prior – Approval **Renewal Requirements**  
Same as above

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## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Duration**  
12 months

### Prior – Approval **Renewal Limits**

**Duration**  
12 months

### 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.

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

Section: Prescription Drugs

Subsection: Central Nervous System Drugs

Subject: Papaverine Powder

Effective Date: April 1, 2014

Original Policy Date: January 1, 2014

Date
Action
December 2013
New addition to PA
March 2014
Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 13th, 2014 and is effective April 1, 2014.

Signature on File

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