



RATIONALE FOR INCLUSION IN PA PROGRAM

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.

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