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

Last Review Date: September 6, 2024

Phentolamine Powder

Description

Phentolamine Powder

Background
Phentolamine is a vasodilator, which acts by producing an alpha-adrenergic blockade which causes the vessels to expand for a short duration. This mechanism of action allows phentolamine to be used clinically in various hypertensive crisis, dermal necrosis and sloughing following intravenous administration or extravasation of norepinephrine and aiding in the diagnosis of pheochromocytoma (1).

Regulatory Status
FDA-approved indications: Phentolamine powder is indicated for the prevention or control of hypertensive episodes that may occur in a patient with pheochromocytoma as a result of stress or manipulation during preoperative preparation and surgical excision. Phentolamine is also indicated in the prevention or treatment of dermal necrosis and sloughing following intravenous administration of extravasation of norepinephrine and used in the diagnosis of pheochromocytoma by the phentolamine blocking test (1).

The phentolamine blocking test is most reliable in detecting pheochromocytoma in patients with sustained hypertension and least reliable in those with paroxysmal hypertension. False-positive tests may occur in patients with hypertension without pheochromocytoma (1).

Phentolamine is contraindicated in myocardial infarction, history of myocardial infarction, coronary insufficiency, angina, or other evidence suggestive of coronary artery disease; hypersensitivity to phentolamine or related compounds (1).

Off-Label Use:
Off-label (non-FDA approved) compounded topical preparations of phentolamine have not been proven safe or effective.
Phentolamine for treatment of erectile dysfunction (ED) is excluded from coverage.

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

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

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

Prior-Approval Requirements

Diagnoses

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

1. Pheochromocytoma
   a. Patient has **ONE** of the following:
      i. Used for the prevention of or control of hypertensive episodes as a result of stress or manipulation during preoperative preparation and surgical excision
      ii. Used in the diagnosis of pheochromocytoma by the phentolamine blocking test
         1) Preferred urinary assays and other biochemical assays have been attempted
2. Prevention or treatment of dermal necrosis and sloughing following intravenous administration or extravasation of norepinephrine

AND ALL of the following:

1. The powder will be compounded into an injection
2. The concentration of the injection solution does not exceed 5 mg/ml
3. The requested concentration is not commercially available
4. **NOT** used as an intracavernosal injection

AND NONE of the following:

1. History of myocardial infarction
2. Coronary insufficiency
3. Angina
4. Evidence suggestive of coronary artery disease

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

Phentolamine is a vasodilator, which acts by producing an alpha-adrenergic blockade which causes the vessels to expand for a short duration. This mechanism of action allows phentolamine to be used clinically in various hypertensive crisis, dermal necrosis and sloughing following intravenous administration or extravasation of norepinephrine, and the diagnosis of pheochromocytoma. The phentolamine blocking test is not the procedure of choice and should be reserved for cases in which additional confirmatory evidence is necessary and the relative risks involved in conducting the test have been considered. Phentolamine is contraindicated in

myocardial infarction, history of myocardial infarction, coronary insufficiency, angina, or other evidence suggestive of coronary artery disease; hypersensitivity to phentolamine or related compounds (1).

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

References

1. Phentolamine mesylate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; March 2024.

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 and reference update Policy number change from 5.06.18 to 5.40.24
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.