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 indication: 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 in patients with pheochromocytoma or for the prevention or treatment of dermal necrosis and sloughing following intravenous administration of extravasation of norepinephrine and if the conditions indicated below are met.

Phentolamine powder is considered investigational in patients for all other indications.

**Prior-Approval Requirements**

**Diagnoses**

Patient must have ONE of the following:

1. Pheochromocytoma

   AND ONE of the following:
   a. Use for the prevention of or control of hypertensive episodes as a result of stress or manipulation during preoperative preparation and surgical excision.
   b. Used in the diagnosis of pheochromocytoma by the phentolamine blocking test
      i. 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
Duration 12 months

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

Policy History

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<tr>
<td>December 2013</td>
<td>New Addition to PA</td>
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<tr>
<td>March 2014</td>
<td>Annual review</td>
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<td>March 2015</td>
<td>Annual editorial review and reference update</td>
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<td>September 2016</td>
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<tr>
<td></td>
<td>Policy number change from 5.06.18 to 5.40.24</td>
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<td>September 2017</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective October 1, 2019.