Drug/Drug Class: Epinephrine Self-Injectable Agents PDL Edit
First Implementation Date: April 14, 2010
Revised Date: July 9, 2020
Prepared For: MO HealthNet
Prepared By: MO HealthNet/Conduent
Criteria Status: ☑ Existing Criteria
      ☐ Revision of Existing Criteria
      ☐ New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Anaphylaxis is an acute systemic, severe, type I hypersensitivity allergic reaction in humans and other mammals. Minute amounts of allergens may cause a life-threatening anaphylactic reaction. Anaphylaxis may occur after ingestion, skin contact, injection or inhalation of an allergen. Anaphylactic shock, the most severe type of anaphylaxis, occurs when an allergic response triggers a quick release of large quantities of immunological mediators (histamines, prostaglandins, and leukotrienes) from mast cells and basophils, leading to systemic vasodilation (associated with a sudden drop in blood pressure) and edema of bronchial mucosa, resulting in bronchoconstriction causing difficulty breathing. Anaphylactic shock can lead to death in a matter of minutes if left untreated. The primary treatment for anaphylaxis is administration of epinephrine, which prevents worsening of the airway constriction by acting on Beta-2 adrenergic receptors in the lung as a powerful bronchodilator, stimulates the heart to continue beating, causes vasoconstriction in order to increase blood pressure, and may be life-saving.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

<table>
<thead>
<tr>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Epinephrine Inj (gen Adrenaclick® and EpiPen®)</td>
<td>• EpiPen®</td>
</tr>
<tr>
<td>• Epinephrine Inj (gen Adrenaclick® and EpiPen Jr.®)</td>
<td>• EpiPen Jr.®</td>
</tr>
<tr>
<td>• Symjepi™</td>
<td></td>
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</tbody>
</table>

Type of Criteria: ☑ Increased risk of ADE
      ☐ Appropriate Indications

Data Sources: ☑ Only Administrative Databases
      ☐ Databases + Prescriber-Supplied

MO HealthNet ~ Net
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☐ Increased risk of ADE
☐ Appropriate Indications
☐ Only Administrative Databases
☒ Preferred Drug List
☐ Clinical Edit
☒ Databases + Prescriber-Supplied

SmartPA PDL Proposal Form
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Setting & Population

- Drug class for review: Epinephrine Self-Injectable Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 1 preferred agent
  - Documented trial period of preferred agents
  - Documented ADE/ADR to preferred agents

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met

Required Documentation

Laboratory Results: ____________  Progress Notes: ____________
MedWatch Form: ____________  Other: ____________

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

4. USPDI, Micromedex; 2020.
5. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.