



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Epinephrine Agents, Self-Injectable PDL Edit
<b>First Implementation Date:</b>	April 14, 2010
<b>Revised Date:</b>	July 1, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> 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:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"><li>• <b>Epinephrine Inj (gen EpiPen®, Mylan Specialty)</b></li><li>• <b>Epinephrine Jr. Inj (gen EpiPen Jr.®, Mylan Specialty)</b></li><li>• <b>EpiPen®</b></li><li>• <b>EpiPen Jr.®</b></li></ul>	<ul style="list-style-type: none"><li>• <b>Epinephrine Inj (gen Adrenaclick®)</b></li><li>• <b>Epinephrine Inj (gen EpiPen®, Teva)</b></li><li>• <b>Epinephrine Jr. Inj (gen Adrenaclick® Jr.)</b></li><li>• <b>Epinephrine Jr. Inj (gen EpiPen Jr®, Teva)</b></li><li>• <b>Symjepi®</b></li></ul>

**Type of Criteria:**  Increased risk of ADE  
 Appropriate Indications  Preferred Drug List  
 Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

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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 2 preferred agents
  - 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 all approval criteria are not met

## Required Documentation

Laboratory Results:  
MedWatch Form:

Progress Notes:  
Other:

## Disposition of Edit

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

Rule Type: PDL

## Default Approval Period

1 year

## References

1. Evidence-Based Medicine Analysis: “Self-Injectable Epinephrine Auto-Injectors”, UMKC-DIC; February 2021.
2. Evidence-Based Medicine and Fiscal Analysis: “Self-Injectable Epinephrine Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; March 2021.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2021.
4. USPDI, Micromedex; 2021.
5. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.

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