

SmartPA Criteria Proposal

Drug/Drug Class:	Epinephrine Self-Injectable Agents PDL Edit
First Implementation Date:	April 14, 2010
Proposed Date:	March 19, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input checked="" type="checkbox"/> Existing Criteria <input 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"> • Epinephrine Inj (gen Adrenaclick® and EpiPen®) • Epinephrine Inj (gen Adrenaclick® and EpiPen Jr.®) • Symjepi™ 	<ul style="list-style-type: none"> • EpiPen® • EpiPen Jr.®

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

Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

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:

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; January 2020.
2. Evidence-Based Medicine and Fiscal Analysis: "Self-Injectable Epinephrine Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; February 2020.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
4. USPDI, Micromedex; 2020.
5. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.

SmartPA PDL Proposal Form

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