

SmartPA Criteria Proposal

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| Drug/Drug Class: | Epinephrine Agents, Self-Injectable PDL Edit |
| First Implementation Date: | April 14, 2010 |
| Revised Date: | July 7, 2022 |
| 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.

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| Program-Specific Information: | Preferred Agents | Non-Preferred Agents |
| | <ul style="list-style-type: none"> • Epinephrine Inj (gen EpiPen[®], Mylan Specialty) • Epinephrine Jr. Inj (gen EpiPen Jr.[®], Mylan Specialty) • EpiPen[®] • EpiPen Jr.[®] | <ul style="list-style-type: none"> • Epinephrine Inj (gen Adrenaclick[®]) • Epinephrine Inj (gen EpiPen[®], Teva) • Epinephrine Jr. Inj (gen Adrenaclick[®] Jr.) • Epinephrine Jr. Inj (gen EpiPen Jr.[®], Teva) • Symjepi[®] |

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 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:

Progress Notes:

MedWatch Form:

Other:

Disposition of Edit

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

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: "Self-Injectable Epinephrine Auto-Injectors", UMKC-DIC; February 2022.
- Evidence-Based Medicine and Fiscal Analysis: "Self-Injectable Epinephrine Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; February 2022.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.