STEP THERAPY POLICY

POLICY: Epinephrine Auto-Injectors Step Therapy Policy
- EpiPen® (epinephrine injection, USP auto-injector – Mylan Specialty, generic)
- EpiPen Jr® (epinephrine injection, USP auto-injector – Mylan Specialty, generic)

REVIEW DATE: 02/05/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

EpiPen and EpiPen Jr. (generics) are indicated for the emergency treatment of **severe allergic reactions** (Type I) including anaphylaxis to stinging and biting insects, allergen immunotherapy, foods, drugs, diagnostic testing substances, and other allergens, as well as anaphylaxis to unknown substances and exercise-induced anaphylaxis.[1] Auvi-Q® (epinephrine injection, USP auto-injector), an authorized generic to Adrenaclick® (epinephrine injection, USP auto-injector) and Symjepi™ (epinephrine injection, USP prefilled syringe), a self-administered epinephrine prefilled syringe, are also available and have the same indication as the EpiPen/EpiPen auto-injectors.[2-5] However, these agents are not targeted in this policy.

All of the epinephrine auto-injectors are administered and dosed similarly.[1] Patients who weigh ≥ 30 kg should be administered a dose of 0.3 mg (given via EpiPen [generic]), while patients weighing 15 kg to 30 kg should be administered 0.15 mg (EpiPen Jr. [generic]).

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.
Note: Auvi-Q, Symjepi, Adrenaclick (no longer available) and the authorized generic to Adrenaclick are not targeted in this policy.

Step 1: epinephrine auto-injector 0.15 mg and 0.3 mg (generic to EpiPen/EpiPen Jr.)

Step 2: EpiPen 0.15 mg, EpiPen Jr. 0.3 mg

Epinephrine Auto-Injectors Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

REFERENCES

1. EpiPen® and EpiPen Jr® injection [prescribing information]. Morgantown, WV: Mylan Specialty; February 2023.
2. Auvi-Q® auto-injector [prescribing information]. Richmond, VA: Kaleo; February 2024.
3. Epinephrine auto-injector [prescribing information]. Bridgewater, NJ: Amneal; February 2021.
4. FDA listing of authorized generics. U.S. Food and Drug Administration Web site. Available at: https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm126391.htm. Updated January 13, 2025. Accessed on January 30, 2025.
5. Symjepi® injection [prescribing information]. San Diego, CA: Adamis; June 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/01/2023
Early Annual Revision	**Auvi-Q:** Auvi-Q 0.1 mg, 0.15 mg, and 0.3 mg auto-injectors were removed from Step 2 (will no longer be targeted in the policy). Exceptions for Auvi-Q were removed.	01/24/2024
Annual Revision	No criteria change.	02/05/2025