Auvi-Q® (epinephrine auto-injector)

Policy # 00553
Original Effective Date: 04/19/2017
Current Effective Date: 01/08/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Auvi-Q®‡ (epinephrine auto-injector) to be **eligible for coverage**** when the patient selection criterion is met.

Patient Selection Criterion

Coverage eligibility for Auvi-Q (epinephrine auto-injector) will be considered when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of the GENERIC versions of the EpiPen®‡ (epinephrine auto-injector) products will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Auvi-Q (epinephrine auto-injector) when the patient selection criterion is not met to be **not medically necessary.****

Background/Overview

Auvi-Q, like other epinephrine products, is approved for the emergency treatment of allergic reactions. Auvi-Q has voice instructions as part of its administration apparatus. There are now various other epinephrine products on the market, including the generic equivalents of the EpiPen line of products. The previously mentioned products offer prices that are substantially more economical than Auvi-Q's price. There is no clinical advantage of using Auvi-Q over the generic equivalents of the EpiPen line of products.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Auvi-Q is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criterion presented in this policy takes into consideration clinical evidence or patient history that suggests the use of the GENERIC versions of the EpiPen (epinephrine auto-injector) line of products will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using Auvi-Q (epinephrine auto-injector) over the generic equivalents of the EpiPen (epinephrine auto-injector) line of products.

References

1. Auvi-Q [package insert]. Kaleo, Inc. Richmond, Virginia. Updated May 2016.

Policy History

Original Effective Date: 04/19/2017
Current Effective Date: 01/08/2024
04/06/2017 Medical Policy Committee review
04/19/2017 Medical Policy Implementation Committee approval. New policy.
04/06/2017 Medical Policy Committee review
04/19/2017 Medical Policy Implementation Committee approval. No change to coverage.

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04/05/2018	Medical Policy Committee review
04/18/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/04/2019	Medical Policy Committee review
04/24/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/03/2020	Medical Policy Committee review
12/09/2020	Medical Policy Implementation Committee approval. Updated the products to use prior to Auvi-Q to the generic equivalents of the EpiPen line of products, since those now have generic equivalents.
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2022	Medical Policy Committee review
12/14/2022	Medical Policy Implementation Committee approval. No change to coverage.
12/07/2023	Medical Policy Committee review
12/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 12/2024

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.