MEDICAL MUTUAL®

Drug Policy

Policy:	Auvi-Q (epinephrine auto-injector)	Annual Review Date: 06/17/2021 Last Revised Date: 06/17/2021

OVERVIEW

Anaphylaxis is an acute, serious life-threatening generalized or systemic hypersensitivity reaction. It is typically (but not always) mediated by an immunologic mechanism that involves a sudden systemic release of mast cells and basophil mediators. Auvi-Q is an epinephrine auto-injector indicated for the emergency treatment of allergic reactions (Type 1) including anaphylaxis, idiopathic anaphylaxis, or exercise-induced anaphylaxis.

POLICY STATEMENT

This policy involves the use of Auvi-Q. Prior authorization is recommended for pharmacy benefit coverage of Auvi-Q. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Auvi-Q is recommended in those who meet the following criteria:

1. **Emergency Treatment of Allergic Reaction Anaphylaxis, Idiopathic Anaphylaxis, or Exercise-Induced Anaphylaxis**
   Criteria. *Patient must meet the following criteria*
   - **A.** The patient meets ALL of the following criteria [documentation required]:
     - **a.** The patient has tried and failed Mylan generic epinephrine auto-injector product; AND
     - **b.** The patient has tried and failed another generic epinephrine auto-injector product (such as Lineage Therapeutics generic product); AND
     - **c.** The patient has tried and failed a brand Epipen product (i.e. Epipen or Epipen Jr.); AND
     - **d.** The patient has tried and failed Symjepi; AND
     - **e.** The patient has tried and failed Adrenaclick; OR
   - **B.** The request is for the 0.1 mg strength and the patient weighs between 7.5 kg (16.5 lbs) and 15 kg (33 lbs) [documentation of weight in medical chart records required]

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Auvi-Q has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Lieberman P, Nicklas RA, Oppenheimer J, Kemp SF, Lang DM. The diagnosis and management of anaphylaxis practice parameter: 2010 update. *J Allergy Clin Immunol.* 2010;126:477-480.
2. Auvi-Q® auto-injector [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; September 2019
3. Dhami S, Panesar SS, Roberts G, et al on behalf of the EAACI Food Allergy and Anaphylaxis Guidelines Group. Management of anaphylaxis: a systematic review. *Allergy*. 2014;69:168-175.
4. Edwards ES, Gunn R, Simons ER, et al. Bioavailability of epinephrine from Auvi-Q compared with EpiPen. *Ann Allergy Asthma Immunol*. 2013;111(2):132-137.
5. Updated: Sanofi US issues voluntary nationwide recall of all Auvi-Q® due to potential inaccurate dosage delivery. U.S. Food and Drug Administration Web site: http://www.fda.gov/safety/recalls/ucm469980.htm. Created October 30, 2015. Accessed on November 18, 2015
6. Epinephrine. In: DRUGDEX (online database). Truven Health Analytics; Greenwood Village, CO. Last updated 12 May 2021. Accessed on 13 June 2021.