

**NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Epinephrine Auto-Injections**

**Effective Date: 12/05/2018
Amended Date: January 1, 2024**

DRAFT

Therapeutic Class Code: J5F

Therapeutic Class Description: Epinephrine injection

Medication
Auvi-Q
Epinephrine Pen (generic)
EpiPen 2-Pak
EpiPen Jr 2-Pak
Neffy Nasal Spray
Symjepi injection

Eligible Beneficiaries

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

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Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

- a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page: <https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents>

Criteria:

Exceeding Quantity Limit of 6 Pens or 6 spray containers per 180 days:

Prescriber must submit reason of medical necessity stating reasons the quantity limit needs to be exceeded.

Procedures:

Prior authorization request forms will be accepted when submitted by mail, facsimile telecommunication or web portal.

References:

1. Dey Pharma L.P. EpiPen package insert. Maryland: August 2012.
2. Sanofi-aventis LLC. Auvi-Q package insert. New Jersey: September 2012.
3. Amedra Pharmaceuticals LLC, Horsham, PA, Adrenaclick. 2013
4. Adamis Pharmaceutical Corporation. Symjepi prescribing information. San Diego, CA: Revised June 2017.
5. Kaleo, Inc., Auvi-Q package insert. Richmond Virginia: rev. November 2017.
6. **ARS Pharmaceutical Operations, Inc., Neffy package insert. San Diego, CA. Revised October 2025.**

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Criteria Change Log

01/01/2015	Criteria effective date
12/05/2018	Removed Auvi-Q due to non-rebate status
10/02/2019	Removed Adrenaclick- no longer manufactured. Add Symjepi.
01/01/2024	Add Auvi-Q and Remove Health Choice
<u>xx/xx/xxxx</u>	<u>Add Neffy and remove Symjepi injection</u>