

**NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Arikayce**

**Medicaid and Health Choice
Effective Date:
Amended Date:**

Therapeutic Class Code: W1F

Therapeutic Class Description: Aminoglycoside Antibiotics

Medication

Arikayce

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.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries.**

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.

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.

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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 *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid and NC Health Choice Billing 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>

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within the **Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for Initial Coverage of Arikayce:

- Beneficiary is \geq 18 years of age;
- Beneficiary has a diagnosis of Mycobacterium Avium Complex (MAC) lung disease as determined by the following:
 - Chest radiography or high-resolution computed tomography (HRCT) scan;
 - At least 2 positive sputum cultures;
 - Other conditions such as tuberculosis and lung malignancy have been ruled out;
- Beneficiary has failed a multi-drug regimen with a macrolide (clarithromycin or azithromycin), rifampin, and ethambutol. (Failure is defined as continual positive sputum cultures for MAC while adhering to a multi-drug treatment regimen for a minimum duration of 6 months);
- Beneficiary has documented failure or intolerance to aerosolized administration of amikacin solution for injection, including pretreatment with a bronchodilator;
- Arikayce will be prescribed in conjunction with a multi-drug antimycobacterial regimen
- Initial approval shall be for up to 9 months.

Criteria for Continuation of Coverage of Arikayce:

- Beneficiary has demonstrated response to therapy with the addition of Arikayce, as defined as 3 consecutive monthly negative sputum cultures starting by month 6 of treatment with Arikayce;

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- Beneficiary has not experienced toxicity to amikacin treatment (e.g., ototoxicity, renal toxicity, neuromuscular blockade).
- Renewal approval shall be for up to 9 months

References

1. Arikayce [package insert]. Bridgewater, NJ; Inmed; September 2018.

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Criteria Change Log

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Criteria effective date