

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

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

**DRAFT**

**Therapeutic Class Code:** A5C

**Therapeutic Class Description:** Cardiac Myosin Inhibitor

Medication
Camzyos

**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.

**EPSDT and Prior Approval Requirements**

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.

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**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>***

**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 approval**

- Beneficiary is 18 years of age or older;  
AND
- Beneficiary has a diagnosis of obstructive hypertrophic cardiomyopathy (oHCM) consistent with current guidelines (e.g., American College of Cardiology Foundation/American Heart Association, European Society of Cardiology guidelines);  
AND
- Beneficiary has New York Heart Association (NYHA) Class 2 or Class 3  
AND
- Beneficiary has documented left ventricular ejection fraction (LVEF)  $\geq 55\%$  (for initiation of treatment only);  
AND
- Beneficiary will be monitored for LVEF, Valsalva left ventricular outflow tract (LVOT) gradient assessment, and heart failure symptoms (e.g., shortness of breath, chest pain, arrhythmia, heart palpitations, fatigue, swelling in the legs);  
AND
- Beneficiary has adequate echocardiogram or cardiovascular magnetic resonance imaging (CMR);  
AND
- Beneficiary will avoid concomitant use with moderate to strong CYP2C19 inhibitors, strong CYP3A4 inhibitors, and moderate to strong CYP2C19 and CYP3A4 inducers (e.g., carbamazepine, cimetidine, esomeprazole, omeprazole, phenobarbital, phenytoin, rifampin, St. John's wort);  
AND
- For females of childbearing potential, a pregnancy test is performed ensuring beneficiary is not pregnant;  
AND
- Mavacamten is prescribed by or in consultation with a cardiologist;  
AND
- Beneficiary must have an adequate trial and failure of  $\geq 1$  beta-blocker.

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**Procedures**

- Approve for up to 12 months.

**Criteria for continuation:**

- Beneficiary must continue to meet the above criteria (not including prerequisite therapy);  
AND
- Beneficiary must have disease improvement and/or stabilization of disease from baseline (e.g., NYHA class improvement [class 3 to class 2],  $\geq 1.5$  mL/kg/min in pVO<sub>2</sub> increase or  $\geq 3$  mL/kg/min in pVO<sub>2</sub> without NYHA class worsening)  
AND
- Beneficiary has documented left ventricular ejection fraction (LVEF)  $\geq 50\%$ ;  
AND
- Beneficiary has NOT have experienced any treatment-restricting adverse effects (e.g., heart failure)

**Procedures**

- Approve for up to 12 months.

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Systemic Immunomodulators**

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**References**

1. Camzyos [package insert]. Brisbane, CA; MyoKardia; April 2022.

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