

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

**Effective Date: 11/14/2012**

**Amended Date: September 23, 2019**

**DRAFT**

**Therapeutic Class Code:** A7G

**Therapeutic Class Description:** C-GMP Type 5 Inhibitor

<b>Medication</b>	<b>Generic Code Number(s)</b>
Cialis 2.5mg tablet and generic tadalafil 2.5mg tablet	99409
Cialis 5mg tablet and generic tadalafil 5mg tablet	20736

**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.

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**

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

**Effective Date: 11/14/2012**

**Amended Date: September 23, 2019**

- 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 Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

**EPSDT provider page:** <https://medicaid.ncdhhs.gov/epsdt>

**Criteria:**

- Beneficiary is 18 or older  
**AND**
- Beneficiary is a male  
**AND**
- Beneficiary has confirmed diagnosis of Benign Prostatic Hyperplasia  
**AND**
- Beneficiary has no concurrent therapy with an alpha blocker or nitrates  
**AND**
- Beneficiary has tried and failed ~~all preferred medications~~ on at least two preferred medications (at least one alpha blocker and at least one hormone blocker) or has a clinical reason or other contraindication as to why two preferred medications (at least one alpha blocker and at least one hormone blocker) cannot be tried  
**AND**
- ~~May not be prescribed~~ **Is not covered** for Erectile Dysfunction (ED)

**Procedures:**

1. Approve for 1 year
2. Changes in strength do not require a new prior approval.

**References**

1. Prescriber Information - Cialis ® (tadalafil) Eli Lilly and Company, Indianapolis, Indiana 46285. October 2011.

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

**Effective Date: 11/14/2012**

**Amended Date: ~~September 23, 2019~~**

**Criteria Change Log**

11/14/2012	Criteria effective date
09/23/2019	Added generic tadalafil
xx/xx/xxxx	Changed from try and fail all preferreds to try and fail 2 preferreds