

**NC Medicaid  
Outpatient Pharmacy  
Prior Approval Criteria  
Entresto (sacubitril/valsartan)**

**Medicaid and Health Choice  
Effective Date: November 1, 2016  
Amended Date: July 15, 2019**

**Therapeutic Class Code: A4L**

**Therapeutic Class Description:** Angiotensin II Receptor Blocker-Nepriylsin Inhibitor Comb. (ARNi)

<b>Medication</b>	<b>Generic Code Number(s)</b>	<b>NDC Number(s)</b>
Entresto	39046, 39047, 39048	

**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 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 recipient'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 recipient'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://medicaid.ncdhhs.gov/>

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

**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 DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

**Criteria:**

- Beneficiary has a diagnosis of chronic heart failure (NYHA class II-IV) with a left ventricular ejection fraction (EF) less than or equal to 40%. **AND**
- Beneficiary does not have a history of angioedema related to therapy with an ACE inhibitor or ARB. **AND**
- If the beneficiary is currently taking an ACE inhibitor or ARB, Entresto will replace that current therapy. **AND**
- If the beneficiary has diabetes, he or she is not taking a medication containing aliskiren (e.g. Tekturna or Tekturna HCT). **AND**
- Reauthorization requests must include documentation that the beneficiary is receiving clinical benefit from the medication such as stabilization of symptoms, improvement or stability of EF, or a reduction in hospitalizations.

**Procedures:**

- Approval up to 1 year.

**References:**

Prescriber Information-Entresto ® Novartis Pharmaceuticals East Hanover, NJ 07936, August 2015.

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**Criteria Change Log**

11/01/2016	Criteria effective date
02/26/2019	Add continuation criteria
07/15/2019	Remove beta blocker requirement