NC Division of Medical Assistance **Medicaid**
Outpatient Pharmacy **Effective Date:**
Prior Approval Criteria **Amended Date:**
Vowst

Therapeutic Class Code: D6P
Therapeutic Class Description: Fecal Microbiota Transplantation (FMT)

Medications
Vowst

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
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.

***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 for Coverage

- Beneficiary ≥ 18 years of age;

  AND
- Beneficiary has a confirmed diagnosis of recurrent *Clostridioides difficile* infection (CDI) with a total of ≥3 episodes of CDI within 12 months;

  AND
- Antibiotic treatment for recurrent CDI must be completed 2 to 4 days prior to initiation of Vowst therapy;

  AND
- Beneficiary will take 10 oz of magnesium citrate (or 250 mL polyethylene glycol electrolyte solution for patients with impaired kidney function) the evening prior to initiation of Vowst therapy;

  AND
- Beneficiary must not have absolute neutrophil count (ANC) < 500 cells/mm3, toxic megacolon, or small bowel ileus

Procedures:

Length of therapy may be approved for up to 30 days.

References

1. Vowst [package insert]. Cambridge, MA; Seres; April 2023.

Criteria Change Log

xx/xx/xxxx	Criteria effective date