NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Antiparkinson's Agents

Medicaid and Health Choice
Effective Date: February 26, 2019
Amended Date: October 1, 2021

Therapeutic Class Code: H6A
Therapeutic Class Description: Drugs to Treat Movement Disorders

Medication
Gocovri
Osmolex ER
Inbrija
Ongentys

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

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.

***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 Coverage of Gocovri:

- Beneficiary is age 18 or older; **AND**
- Beneficiary has no contraindications including ESRD (creatinine clearance <15 ml/min/1.73m^2); AND
- Beneficiary has failure, contraindication, or intolerance to immediate-release amantadine (capsule, tablet, or oral solution); AND
- Beneficiary has a diagnosis of dyskinesia due to Parkinson's disease and is receiving levodopa-based therapy, with or without dopaminergic medications; **OR**
- Beneficiary has a diagnosis of Parkinson's disease; **AND**
    - Beneficiary is experiencing "off" episodes; **AND**
    - Beneficiary will be concurrently receiving optimized carbidopa/levodopa therapy; AND
- Initial approval shall be for up to 6 months.

Criteria for Continuation of Coverage of Gocovri:

- All of the above criteria for initial coverage of Gocovri are met.
- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
- Reauthorization shall be for up to 12 months.

Criteria for Initial Coverage of Osmolex ER:

- Beneficiary has a diagnosis of Parkinson's disease or Drug-induced extrapyramidal reactions; **AND**
- Beneficiary is age 18 or older; **AND**
- Beneficiary has no contraindications including ESRD (creatinine clearance <15 ml/min/1.73m^2); **AND**
- Beneficiary has failure, contraindication, or intolerance to immediate-release amantadine (capsule, tablet, or oral solution)
- Initial approval shall be for up to 6 months.

Criteria for Continuation of Coverage of Osmolex ER:

- All of the above criteria for initial coverage of Osmolex ER are met.
- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
- Reauthorization shall be for up to 12 months.

Criteria for Initial Coverage of Inbrija:

- Beneficiary has a diagnosis of Parkinson's disease; **AND**
- Beneficiary is experiencing "off" episodes; **AND**
- Beneficiary will be concurrently receiving optimized carbidopa/levodopa therapy; **AND**
- Beneficiary is not currently taking a nonselective monoamine oxidase (MAO) inhibitor or has not recently (within two weeks) taken a nonselective MAO inhibitor; **AND**
- Beneficiary does not have asthma, COPD or other chronic lung disease. **AND**
- Initial approval shall be for up to 6 months

Criteria for Continuation of Coverage of Inbrija:

- All of the above criteria for initial coverage of Inbrija are met. **AND**
- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline. **AND**

- Reauthorization shall be for up to 12 months.

Criteria for Initial Coverage of Ongentys:

- Beneficiary is ≥ 18 years of age; **AND**
- Beneficiary has a diagnosis of Parkinson's disease (PD); **AND**
- Beneficiary is experiencing "off" episodes of PD at least 1.5 hours/day on average; **AND**
- Beneficiary does NOT have severe hepatic impairment (Child-Pugh C); **AND**
- Beneficiary does NOT have end stage renal disease (estimated creatinine clearance < 15 mL/min); **AND**
- Beneficiary will avoid concomitant use with non-selective monoamine oxidase-B (MAO-B) inhibitors; **AND**
- Beneficiary must be on a concomitant stable levodopa-based therapy regimen; **AND**
- Beneficiary has had an adequate trial and subsequent failure of at least 2 preferred adjunctive therapies (e.g., dopamine agonists, MAO-B inhibitors, catechol-O-methyltransferase [COMT] inhibitors) to control "off" symptoms.
- Initial approval shall be for up to 6 months.

Criteria for Continuation of Coverage of Ongentys:

- Beneficiary continues to meet the above initial criteria; **AND**
- Absence of unacceptable toxicity or treatment related adverse event from the drug (e.g., dyskinesias, hallucinations/psychotic behavior, impulse control/compulsive behaviors); **AND**
- Beneficiary has clinically meaningful response to treatment (e.g., patient shows a reduction in time of "off" episodes).
- Reauthorization shall be for up to 12 months.

References

1. Prescriber Information – Gocovri. Adamas Pharmaceuticals, Inc. Emeryville, CA. Revised 08/2017.
2. Prescriber Information- Osmolex ER. Vertical Pharmaceuticals, LLC. Bridgewater, NJ. Revised 07/2018.
3. Prescriber Information-Inbrija. Acorda Therapeutics, Inc. Ardsley, NY. 12/2018.
4. Ongentys [package insert]. San Diego, CA; Neurocrine Biosciences; April 2020

Criteria Change Log	
02/26/2018	Criteria effective date
10/14/2019	Added criteria for Osmolex ER. Added for age 18 and over to Gocovri. Clarified on continuation on Gocovri that you must have met the initial criteria for Gocovri in order to have approval for continuation of coverage. Added Osmolex to title
10/01/2021	Add criteria for new drug Inbrija
10/01/2021	Add criteria for Ongentys
10/01/2021	Add criteria for Gocovri for adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing off episodes