

**NC Division of Health Benefits
Outpatient Pharmacy
Prior Approval Criteria
Treatment for Movement Disorders**

Medicaid and Health Choice
Effective Date: February 8, 2018
Amended Date: April 13, 2021

Therapeutic Class Code: H6L

Therapeutic Class Description: Drugs to Treat Movement Disorders

Medication
Ingrezza
Austedo
Austedo XR
Xenazine
tetrabenazine

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];

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

1. Ingrezza

a. Tardive Dyskinesia

Criteria for Initial Coverage:

- ✓ Beneficiary has a diagnosis of moderate to severe Tardive Dyskinesia.
- ✓ Beneficiary is age 18 or older.
- ✓ Provider has completed baseline evaluation of the condition using either: Abnormal Involuntary Movement Scale (AIMS) or Extrapyrimal Symptom Rating Scale (ESRI) and has submitted score
- ✓ Beneficiary has had a previous trial of an alternative method to manage the condition.
- ✓ Beneficiary is not receiving dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors.
- ✓ Beneficiary is not concurrently using a MAOI (monoamine oxidase inhibitor) or reserpine.
- ✓ Initial approval shall be for up to 6 months.

Criteria for Continuation of Coverage:

- ✓ All of the above criteria are met.

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- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
- Reauthorization shall be for up to 12 months.

b. Huntington's Disease

Criteria for Initial Coverage:

- Beneficiary has a diagnosis of Huntington's Disease and is experiencing signs and symptoms of chorea
- Beneficiary is age 18 or older.
- Beneficiary is not receiving dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors.
- Beneficiary is not concurrently using a MAOI (monoamine oxidase inhibitor) or reserpine.
- Initial approval shall be for up to 6 months.
- Beneficiaries with a history of depression or suicidal ideation are being treated and/or are stable

Criteria for Continuation of Coverage:

- All of the above criteria 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.

2. Austedo and Austedo XR

a. Tardive Dyskinesia

Criteria for Initial Coverage:

- Beneficiary has a diagnosis of moderate to severe Tardive Dyskinesia.
- Beneficiary is age 18 or older.
- Provider has completed baseline evaluation of the condition using either: Abnormal Involuntary Movement Scale (AIMS) or Extrapyrimalidal Symptom Rating Scale (ESRI) and has submitted score
- Beneficiary has had a previous trial of an alternative method to manage the condition.
- Beneficiary is not receiving dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors.
- Beneficiary is not concurrently using a MAOI (monoamine oxidase inhibitor) or reserpine.
- Initial approval shall be for up to 6 months.

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- Beneficiary is not concurrently using a MAOI (monoamine oxidase inhibitor) or reserpine.
- Beneficiaries with a history of depression or suicidal ideation are being treated and/or are stable.
- Initial approval shall be for up to 6 months.

Criteria for Continuation of Coverage:

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

3. Xenazine and tetrabenazine

a. Huntington's Disease

Criteria for Initial Coverage:

- Beneficiary has a diagnosis of Huntington's Disease and is experiencing signs and symptoms of chorea
- Beneficiary is age 18 or older.
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- Beneficiary is not receiving dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors.
- Beneficiary is not concurrently using a MAOI (monoamine oxidase inhibitor) or reserpine.
- Initial approval shall be for up to 6 months.
- Beneficiaries with a history of depression or suicidal ideation are being treated and/or are stable.

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- ✓ Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
- ✓ Reauthorization shall be for up to 12 months.

References

1. Prescriber Information—Ingrezza®. Neurocrine Biosciences, Inc., San Diego, CA. April 2017. Updated August 2023
2. Prescriber Information—Xenazine®. Lundbeck, Deerfield, IL. revised September 2017.
3. Prescriber Information—Austedo®. Austedo XR®. Teva Pharmaceuticals, USA, Inc., North Wales, PA. revised August 2017. Revised July 2019. Updated February 2023.

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Criteria Change Log	
02/08/2018	Criteria effective date
11/21/2018	Added criteria for Austedo, Xenazine, and tetrabenazine
04/13/2021	Removed requirement for documentation of baseline assessment to be submitted for tardive dyskinesia indication. Replaced with submission of score.
04/13/2021	Remove Step through Austedo added for Ingrezza and Remove Step through tetrabenazine added for diagnosis of HD for Austedo
xx/xx/xxxx	Added Austedo XR. Added Ingrezza criteria for chorea associated with Huntington's Disease Remove NC Health Choice