

**NC Division of Medical Assistance
Outpatient Pharmacy
Prior Approval Criteria
Oral Iron Chelators**

**Medicaid and Health Choice
Effective Date:
Amended Date:**

Therapeutic Class Code: C8A

Therapeutic Class Description: Metallic Poisons, Agents to Treat

Medication
Exjade
Ferriprox
Jadenu

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.

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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://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 Exjade:

- Diagnosis of chronic iron overload due to blood transfusions in beneficiaries two years of age and older; **AND**
 - Serum ferritin > 1,000 mcg/L (within 30 days of the request); **OR**
 - Liver iron concentration is > 3.2 Fe/g dw L (within 30 days of the request); **OR**
- Diagnosis of non-transfusion-dependent thalassemia (NTDT) in beneficiaries aged 10 and older; **AND**
 - Serum ferritin > 300 mcg/L (within 30 days of the request); **AND**
 - Liver iron concentration is ≥ 5 mg Fe/g dw L (within 30 days of the request) **AND**
- Will not be approved for beneficiaries with creatinine clearance less than 40 mL/min or for beneficiaries with platelet count less than $50 \times 10^9/L$. **AND**
- Approval duration shall be for 6 months

Criteria for Continuation of Coverage of Exjade:

- Diagnosis of chronic iron overload due to blood transfusions in beneficiaries two years of age and older; **AND**
 - Serum ferritin > 500 mcg/L within 30 days of the request; **AND**
 - Creatinine Clearance > 40 mL/min; **AND**
 - Platelet count > $50 \times 10^9/L$
- Diagnosis of non-transfusion-dependent thalassemia (NTDT) in beneficiaries aged 10 and older; **AND**
 - Serum ferritin > 300 mcg/L within 30 days of the request; **AND**
 - Liver iron concentration is ≥ 5 mg Fe/g dw L within 30 days of the request; **AND**
 - Creatinine Clearance > 40 mL/min; **AND**
 - Platelet count > $50 \times 10^9/L$

Criteria for Initial Coverage of Ferriprox:

- Diagnosis of transfusional iron overload due to thalassemia syndromes; **AND**
 - Beneficiary has tried and failed or has had an inadequate response to Exjade® defined by serum ferritin >2,500 mcg/L before treatment with Ferriprox; **OR**
 - Beneficiary has been intolerant to or experienced clinically significant adverse effects to Exjade® such as evidence of cardiac iron overload or iron-induced cardiac dysfunction
- Approval Duration: 6 months

Criteria for Continuation of Coverage of Ferriprox:

- Diagnosis of transfusional iron overload due to thalassemia syndromes; **AND**
 - Serum ferritin > 500 mcg/L (within 30 days of the request);

Criteria for Initial Coverage of Jadenu or Jadenu Sprinkles:

- Diagnosis of chronic iron overload due to blood transfusions in beneficiaries two years of age and older, **AND**
 - Serum ferritin > 1,000 mcg/L (within 30 days of the request); **OR**
 - Liver iron concentration > 3.2 mg Fe/g dw L (within 30 days of the request); **AND**
- Clinically valid reason as to why beneficiary cannot use Exjade®; **OR**
- Diagnosis of non-transfusion-dependent thalassemia (NTDT) in beneficiaries aged 10 and older, **AND**
 - Serum ferritin > 300 mcg/L (within 30 days of the request); **OR**
 - Liver iron concentration ≥ 5 mg Fe/g dw L (within 30 days of the request); **AND**
- Clinically valid reason as to why beneficiary cannot use Exjade®
- Will not be approved for beneficiaries with creatinine clearance < 40 mL/min or for beneficiaries with platelet count < $50 \times 10^9/L$.
- Approval duration: 6 months

Criteria for Continuation of Jadenu & Jadenu Sprinkles:

- Diagnosis of chronic iron overload due to blood transfusions in beneficiaries two years of age and older; **AND**
 - Serum ferritin > 500 mcg/L (within 30 days of the request); **AND**
 - Creatinine Clearance > 40 mL/min; **AND**
 - Platelet count > $50 \times 10^9/L$
- Diagnosis of non-transfusion-dependent thalassemia (NTDT) in beneficiaries aged 10 and older; **AND**
 - Serum ferritin > 300 mcg/L (within 30 days of the request); **AND**
 - Liver iron concentration is ≥ 5 mg Fe/g dw L (within 30 days of the request); **AND**
 - Creatinine Clearance > 40 mL/min; **AND**
 - Platelet count > $50 \times 10^9/L$

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References

1. Exjade [package insert]. East Hanover, NJ; Novartis; July 2019.
2. Ferriprox [package insert]. Weston, FL; ApoPharma; July 2019.
3. Jadenu [package insert]. East Hanover, NJ; Novartis; July 2019.
4. Pennell DJ, Udelson JE, Arai AE, et al. Cardiovascular function and treatment in β -thalassemia major. A consensus statement from the American Heart Association. *Circulation*.2013;128:281-308.

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Criteria Change Log

xx/xx/xxxx	Criteria effective date
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