NC Medicaid
Outpatient Pharmacy **Effective Date: March 4, 2002**
Prior Approval Criteria
Hematinics **Revised Date: November 5, 2026**

Therapeutic Class Code: N1B, N1J
Therapeutic Class Description: Hematinics, Other, Blood Cell Stimulators

Medication
Procrit, Epogen (Erythropoietin)
Aranesp (Darbepoetin Alfa)
Mircera
Retacrit
Vafseo (vadadustat)

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

For Procrit, Epogen, Aranesp, Micera, and Retacrit

Approval will be considered in the following circumstances:

1. Anemia associated with renal failure **OR**
2. Anemia associated with HIV Infection **OR**
3. Anemia associated with chemotherapy **OR**
4. Anemia associated with myelodysplastic syndromes **OR**
5. Drug induced anemia such as with ribavirin or zidovudine **OR**
6. Sickle Cell Disease

Initial Therapy - Beneficiary shall meet all requirements:

1. Hemoglobin less than or equal to 11 for initial therapy (for anemia associated with renal failure, HIV, chemotherapy, myelodysplastic syndromes, and drug induced anemia) **OR** Hemoglobin less than or equal to 10 (for Sickle Cell) **AND**
2. Lab data within 3 months of PA

Continuation of Therapy - Beneficiary must meet all requirements:

1. Hemoglobin less than or equal to 12 (for anemia associated with renal failure, HIV, chemotherapy, myelodysplastic syndromes, and drug induced anemia) **OR** Hemoglobin less than or equal to 11(for Sickle Cell) **AND**
2. Lab data within 3 months of PA

For Vafseo

Approval will be considered in the following circumstances:

1. Beneficiary is age 18 or older **AND**
2. Beneficiary has diagnosis of anemia due to chronic kidney disease **AND**
3. Beneficiary has been receiving dialysis for at least 3 months **AND**
4. Beneficiary is receiving the lowest dose sufficient to reduce the need for red blood cell transfusions **AND**
5. Vafseo is not being used as a substitute for transfusion in beneficiaries requiring immediate

correction **AND**

6. Beneficiary does not have uncontrolled hypertension **AND**
7. Other causes of anemia have been excluded and corrected (ex. vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding) before beginning treatment with Vafseo **AND**
8. Beneficiary does not have a history of myocardial infarction, cerebrovascular event, or acute coronary syndrome within the 3 months prior to starting Vafseo **AND**
9. A risk/benefit evaluation has been performed for beneficiaries at increased risk for gastrointestinal erosions

Initial Therapy - Beneficiary shall meet all requirements:

1. Hemoglobin less than or equal to 11 for initial therapy (labs must be submitted with initial request)
2. Liver function tests (ALT, AST, alkaline phosphatase, and total bilirubin must be submitted with initial request
3. Lab data within 2 months of request

Continuation of Therapy - Beneficiary must meet all requirements:

1. Hemoglobin less than or equal to 12 (labs must be submitted with initial request
2. Lab data within 2 months of request
3. Treatment Vafseo is not being continued beyond 24 weeks of therapy if a clinically meaningful increase in hemoglobin level is not being achieved

Procedures

- May be approved for up to six months.
- Preferred Drug List (PDL) criteria also apply if requested medication is on the PDL. (ex. try and fail preferred(s)first or a clinical reason the preferred(s) cannot be tried or other criteria as noted on the PDL).

References

1. Epoetin alfa. Drug facts and comparisons. St. Louis (MO): Facts and Comparisons, Inc; Clinisphere 2.0 Tutorial; 2001.
2. Ortho-Biotech, Inc. Procrit package insert. Thousand Oaks (CA): 1999 Oct.
3. Turner R et al. Epoetin alfa in cancer patients; evidence-based guidelines. J Pain Symptom Manage 2001 Nov;22 (5):954-65.
4. Littlewood TJ. The impact of hemoglobin levels on treatment outcomes in patients with cancer. Semin Oncol 2001 Apr;28(2 Suppl 8):49-53.
5. Abrams DI, Steinhart C and Frascino R. Epoetin alfa therapy for anaemia in HIV-infected patients: impact on quality of life. Int J STD AIDS 2000 Oct; 11(10):659-65.
6. Soignet S. Management of cancer-related anemia: epoetin alfa and quality of life. Semin Hematol 2000 Oct;37(4 Suppl 6):9-13.
7. Gabrilove J. Overview: erythropoiesis, anemia and the impact of erythropoetin. Semin Hematol 2000 Oct;37(4 Suppl 6):1-3.
8. FDA Public Health Advisory on Epoetin alfa and Darbepoetin following publication of NEJM articles on Nov 16, 2006.
9. Meta-analysis is by Bohlius J Natl Cancer Inst 2006 98: 708-714.
10. NEJM editorial Remuzzi G, Ingelfinger JR. Correction of anemia – payoff and problems. NEJM. 2006. 355(20): 2144-2146.
11. Systematic review of the literature. Ross SD, Allen E, Henry DH, Seaman C, Sercus B, Goodnough LT. Clinical benefits and risks associated with epoeitin and darbepoetin in patients with chemotherapy induced anemia: a systematic review of the literature. Clinical Therapeutics. 2006. 28(6): 801-831.
12. Retacrit Prescribing information. Pfizer Labs. New York, NY 10017. January 2019.
13. Mircera Prescribing Information. Vifor Pharma. Switzerland. June 2018.
14. Vafseo Prescribing information. Akebia Therapeutics, Inc. Cambridge, MA. March 2024.

Criteria Change Log

04/04/2002	Criteria effective date (Procrit and Epogen)
07/01/2003	Added criteria for Aranesp
11/01/2014	Added new codes for Aranesp
02/25/2019	Removed discontinued GCN 97072
11/07/2019	Added Mircera and Retacrit
03/01/2024	Add diagnosis of Sickle Cell Disease with Hemoglobin less than or equal to 10 (for Sickle Cell) for initial and Hemoglobin less than or equal to 11 (for Sickle Cell) continuation. Remove NC Health Choice
11/05/2026	Added Vafseo and PDL language