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Therapeutic Class Code: N1B

Therapeutic Class Description: Hematinics, Other

Medication	Generic Code Number(s)	NDC Number(s)
Procrit, Epogen (Erythropoietin)	24059 , 25110, 25111, 25112, 25113, 25114,25115	
Aranesp (Darbepoetin Alfa)	14049, 14053,14054, 14055,14056, 14891, 14893, 14894, 15202, 27164, 97063, 97064, 97065, 97066, 97072	
<u>Mircera</u> (epoetin beta and methoxy polyethylene glycol)	<u>98874, 98890, 98891, 98893</u>	

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.

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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

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at <http://www.ncdhhs.gov/dma/epsdt/>.

Criteria for Procrit (erythropoietin), Epogen (erythropoietin), and Aranesp (darbepoetin alfa):

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 ribavarin or zidovudine

Initial Therapy - Beneficiary shall meet all requirements:

1. Hemoglobin less than or equal to 11 for initial therapy **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 **AND**
2. Lab data within 3 months of PA

Criteria for Mircera (epoetin beta and methoxy polyethylene glycol):

Approval will be considered in the following circumstances:

1. Anemia associated with renal failure

Initial Therapy - Beneficiary shall meet all requirements:

1. Hemoglobin less than or equal to 11 for initial therapy **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 **AND**

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2. Lab data within 3 months of PA

Procedures

May be approved for up to six months.

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. Mircera Package Insert: Hoffman La Roche c/o Genotech USA. South San Francisco, CA 94084, October 2014.
11. NEJM editorial Remuzzi G, Ingelfinger JR. Correction of anemia – payoff and problems. NEJM. 2006. 355(20): 2144-2146.
12. Systematic review of the literature. Ross SD, Allen E, Henry DH, Seaman C, Sercus B, Goodnough LT. Clinical benefits and risks associated with epoetin and darbepoetin in patients with chemotherapy induced anemia: a systematic review of the literature. Clinical Therapeutics. 2006. 28(6): 801-831.