OncoHealth

Erythropoietin Stimulating Agents:

Aranesp (Darbepoetin alfa), Procrit (Epoetin alfa), Epogen (Epoetin alfa), Retacrit (epoetin alfa-epbx)

Effective Date: 8/16/2024
Revision Date(s): 05/02/2022, 3/18/2023, 2/19/2024, 7/17/2024
Review Date: 7/17/2024
Policy type: Medical Necessity
Line of Business: Commercial

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Universal Criteria:

- Hemoglobin values are obtained within 28 days of the date of administration; **AND**
- Iron stores must be adequate with a transferrin saturation (TSAT) ≥ 20% AND a ferritin ≥ 100 ng/mL within the last 120 days; **AND**
- Other causes of anemia (such as to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, bone marrow fibrosis etc.) must be ruled out; **AND**
- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature; **AND**
- If a request is made in which NCCN Guidelines or NCCN Compendia make a statement that a specified use of a medication is not recommended that guidance is used to determine medical necessity. The absence of a supportive statement in the FDA indication does not imply universal support.

Indication Specific Criteria:

Chemotherapy Induced Anemia

- Patient has a diagnosis of non-myeloid, non-erythroid malignancy; **AND**
- Patient must be receiving concurrent myelosuppressive antineoplastic therapy; **AND**
- Patient's chemotherapy is administered without curative intent; **AND**
- Patient has a minimum of 60 days of planned chemotherapy; **AND**
- Hemoglobin level is ≤ 10g/dL OR Hematocrit is <30%

Anemia secondary to Myelodysplastic Syndrome

- The patient has a serum erythropoietin level ≤ 500 mUnits/mL; **AND**
- Hemoglobin level is ≤ 11g/dL or hematocrit is ≤ 33%

Anemia secondary to Myeloproliferative Neoplasms (MPN) – Myelofibrosis

- The patient has a serum erythropoietin level ≤ 500 mUnits/mL; **AND**
- Hemoglobin level is ≤ 11g/dL or hematocrit is ≤ 33%

Approval Criteria:

Unless otherwise noted in a specific medical necessity policy the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include the following:

- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA)
- Drugs and biologics may be considered medically accepted or necessary if supported by any of the following 5 compendia below:
    - NCCN Drugs & Biologics Compendium® (Category 1 and 2a)
    - Clinical Pharmacology (Strong For)
    - American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
    - Thompson Micromedex DrugDex® (Class I and IIa)
    - Wolters Kluwer Lexi-Drugs® (Level A)
- Other uses of drugs and biologics may be considered medically accepted if supported as safe and effective according to peer-reviewed articles from one of the following journals:
    - American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; JAMA Oncology, The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; New England Journal of Medicine: Evidence, Radiation Oncology
    - **Meeting abstracts and case reports are excluded from consideration**
- Other resources may be considered on a case-by-case basis per clinical judgement of the OH clinician
- Non-standard protocols may be approved based on unique clinical circumstances

Billing

Drug Name	HCPCS Code	Description
Aranesp	J0881 (non-ESRD)	Injection, darbepoetin alfa, 1 microgram
Epogen/Procrit	J0885 (non-ESRD)	Injection, epoetin alfa, 1000 units
Retacrit	Q5106 (non-ESRD)	Injection, epoetin alfa-epbx, 1000 units

OncoHealth

References

1. Aranesp [package insert]. Amgen Inc., Thousand Oaks, CA. Available at: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/aranesp/ckd/aranesp_pi_hcp_english.pdf
2. Aranesp. NCCN. Cancer Guidelines and Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/.
3. Epogen [package insert]. Amgen Inc., Thousand Oaks, CA. Available at: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/epogen/epogen_pi_hcp_english.pdf
4. Epogen. NCCN. Cancer Guidelines and Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/.
5. Procrit [package insert]. Janssen Products, LP, Horsham, PA. Available at: http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/PROCRIT-pi.pdf
6. Procrit. NCCN. Cancer Guidelines and Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/.
7. Retacrit [package insert]. Pfizer Inc., New York, NY. Available at: http://labeling.pfizer.com/ShowLabeling.aspx?id=10738
8. Retacrit. NCCN. Cancer Guidelines and Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/.
9. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed Jan 24th 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.

For Internal Use ONLY

Date	Updates
5/2/22	Policy creation

3/18/23	Updated Indication Specific Criteria; Updated references
2/19/24	Annual Review; Addition of Step Therapy Table; Updated Universal Criteria; Updated auth length to 6 months; Updated references
7/17/2024	Removed Step Therapy starting 8/16/2024