MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	ESA/Anemia of Chronic Disease	**P&T DATE:**	12/09/2025
CLASS:	Renal Disease/Genitourinary Disorders	**REVIEW HISTORY:** (MONTH/YEAR)	12/24, 01/24, 12/22,12/21, 2/21, 2/20, 2/19, 9/17, 12/16, 9/15, 9/11, 2/11
LOB:	MCL		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the Health Plan Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit https://medi-calrx.dhcs.ca.gov/home/ for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit.

All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.
Any biosimilars pending litigations or not officially available in the US Market for consumer use is not an available treatment option or covered on the medical benefit. Biosimilars that are FDA approved and available in the US Market for consumer use will follow the reference brand name criteria as available per our PH05 - Prior Authorizations processes. Certain biosimilars may be subject to alternative criteria based on the preferences of Health Plan.

This coverage policy is updated on an annual basis. For more recent or up-to-date criteria, reference the Medi-Cal Provider Manual and/or the Medicare National Coverage Determination/Local Coverage Determination (NCD/LCD) for specific criteria. If the Medi-Cal Provider Manual and/or the Medicare NCD/LCD do not have medical necessity criteria, please refer to the "Evaluation Criteria" section in this policy for specific criteria. It is also important to reference the Medicare Benefit Manuals - Chapter 15 and Chapter 16 - when determining benefit coverage and criteria for review of physician administered drugs on the Medicare benefit.

OVERVIEW

For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the Health Plan Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, Health Plan will make the determination based on Medical Necessity criteria as described in Health Plan Medical Review Guidelines (UM06).

Iron Supplements

Ferric carboxymaltose (Injectafer)

- ❒ **Coverage Criteria:** Reserved for patients with one or more of the following **AND has documented history of treatment failure or inability to tolerate Infed, Ferrlecit, Venofer or Feraheme**:

a) Absolute iron deficiency anemia with a ferritin <30µg/L or TSAT <20% with treatment failure or inability to tolerate oral iron.
b) Iron deficiency anemia associated with **inflammatory conditions (e.g. inflammatory bowel disease, heart failure)** with a ferritin <100 µg/L or TSAT <20%.
c) Chronic kidney disease with or without dialysis with ferritin < 500µg/L and TSAT <30% with treatment failure or inability to tolerate oral iron for non-dialysis patients.
d) Chemotherapy-induced anemia with ferritin 30-500µg/L **or** TSAT <50% in patients receiving ESAs. Ferritin must not exceed 800µg/L, and TSAT must not be ≥50%.

- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Updated ferritin and/or TSAT levels with documented history of treatment failure or inability to tolerate oral iron.

Ferric Derisomaltose (Monoferric)

- ❒ **Coverage Criteria:** Reserved for patients with one or more of the following **AND has documented history of treatment failure or inability to tolerate Infed, Ferrlecit, Venofer or Feraheme**:
  a) Absolute iron deficiency anemia with a ferritin <30µg/L or TSAT <20% with treatment failure or inability to tolerate oral iron.
  b) Iron deficiency anemia associated with **inflammatory conditions (e.g. inflammatory bowel disease, heart failure)** with a ferritin <100 µg/L or TSAT <20%.
  c) Chronic kidney disease with or without dialysis with ferritin < 500µg/L and TSAT <30% with treatment failure or inability to tolerate oral iron for non-dialysis patients.
  d) Chemotherapy-induced anemia with ferritin 30-500µg/L **or** TSAT <50% in patients receiving ESAs. Ferritin must not exceed 800µg/L, and TSAT must not be ≥50%.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Updated ferritin and/or TSAT levels with documented history of treatment failure or inability to tolerate oral iron.

Luspatercept (Reblozyl)

- ❒ **Coverage Criteria:** Reserved for adult patients over 18 years of age with one or more of the following:
  a) Anemia in Beta thalassemia who require regular red blood cell (RBC) transfusions
     a. with symptomatic anemia, as evidenced by pretreatment Hgb of Hgb <11 g/dL
     b. a clinically documented diagnosis of beta thalassemia (β-thalassemia) or Hemoglobin E/β-thalassemia.
        i. β-thalassemia with mutation and/or multiplication of alpha globin is allowed.
        ii. Patient does not have a diagnosis of Hemoglobin S/β-thalassemia or alpha (α)-thalassemia
     c. Requiring at least 6 red blood cell (RBC) units transfused in the previous 24 weeks and no transfusion-free period for equal to or greater than 35 days during that period.
  b) Anemia in Very low- to intermediate-risk myelodysplastic syndromes (MDS)
     a. who may require regular red blood cell (RBC) transfusions
     b. requiring 2 or more RBC units over 8 weeks
  c) Anemia in Very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
     a. inadequate response to or ineligible for erythropoiesis stimulating agent (ESA) therapy for 3 months
     b. requiring 2 or more RBC units over 8 weeks
- ❒ **Limits:** Initial approval limits for up to 6 months.
- ❒ **Required Information for Approval:** Updated Hgb with documented evidence of diagnosis (including transfusion history and genetic testing), history of treatment failure or inability to tolerate ESA such as serum EPO levels ≥ 500 mU/mL (where applicable).

Imetelstat (Rytelo)

- ❒ **Coverage Criteria:** Reserved for adult patients over 18 years of age with the following:
  d) Anemia in Very low- to intermediate-risk myelodysplastic syndromes (MDS) with
     a. inadequate response to or ineligible for erythropoiesis stimulating agent (ESA) therapy for 3 months
     b. requiring 4 or more RBC units over 8 weeks
- ❒ **Limits:** Initial approval limits for up to 6 months.
- ❒ **Required Information for Approval:** Updated Hgb with documented evidence of diagnosis (including transfusion history and genetic testing), history of treatment failure or inability to tolerate ESA such as serum EPO levels ≥ 500 mU/mL.
- ❒ **Other:** The manufacturer recommends discontinuing RYTELO if a patient does not experience a decrease in RBC transfusion burden after 24 weeks of treatment (administration of 6 doses) or if unacceptable toxicity occurs at any time.

Erythropoietin Stimulating Agents (ESA)

Epoetin Alfa (Retacrit, Epogen, Procrit)

- ❒ **Coverage Criteria:**
  - **Retacrit, Epogen, or Procrit** are reserved for patients who have Hemoglobin (Hgb) < 10 g/dl, with TSAT > 20% **or** serum ferritin > 100 ng/ml at initiation. Hgb should be checked monthly and is not to exceed 11 g/dl. Authorization is for **12** months at a time. For renewal, Hgb must be below 11 g/dL.
- ❒ **Limits:** When initiating therapy for anemia due to CKD, cumulative weekly dosing does not exceed the target range of 50 to 100 units/kg 3 times a week (300 units/kg weekly).
- ❒ **Required Information for Approval:** Submit chart notes including the patient's most recent iron studies and CBC.
- ❒ **Additional Notes:**
  - Epoetin is approved for **12** months at a time.
  - Submission of Hgb levels with the prior authorization renewal request is required and must not exceed 11g/dL.

Darbepoetin Alfa (Aranesp)

- ❒ **Coverage Criteria:**
  - Aranesp is reserved for patients who have
    - Hemoglobin (Hgb) < 10 g/dl, with TSAT > 20% **or** serum ferritin > 100 ng/ml at initiation
  - Hgb should be checked monthly and is not to exceed 11 g/dl.
  - Authorization is for **12** months at a time. For renewal, Hgb must be below 11 g/dL.
- ❒ **Limits:** When initiating therapy for anemia due to CKD, cumulative weekly dosing does not exceed the target range of 0.45 mcg/kg once weekly or 0.75 mcg/kg once every 2 weeks.
- ❒ **Required Information for Approval:** Submit chart notes including the patient's most recent iron studies and CBC.
- ❒ **Additional Notes:**
  - is approved for **12** months at a time.
  - Submission of Hgb levels with the prior authorization renewal request is required and must not exceed 11g/dL.

Epoetin Beta (Mircera)

- ❒ **Coverage Criteria:**
  - Mircera is reserved for patients who have
    - Hemoglobin (Hgb) < 10 g/dl, with TSAT > 20% **or** serum ferritin > 100 ng/ml at initiation
  - Hgb should be checked monthly and is not to exceed 11 g/dl.
  - Authorization is for **12** months at a time. For renewal, Hgb must be below 11 g/dL.

- ❒ **Limits:** When initiating therapy for anemia due to CKD, cumulative weekly dosing does not exceed the target range 0.6 mcg/kg once every 2 weeks.
- ❒ **Required Information for Approval:** Submit chart notes including the patient's most recent iron studies and CBC.
- ❒ **Additional Notes:**
    - is approved for **12** months at a time.
    - Submission of Hgb levels with the prior authorization renewal request is required and must not exceed 11g/dL.

REFERENCES

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⌗ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Parenteral Iron Therapeutic Class Review 2-15-11.docx	2/2011	Allen Shek, PharmD BCPS
Update to Policy	ESA Criteria Review 9-20-11.docx	9/2011	Allen Shek, PharmD BCPS
Update to Policy	HPSJ Coverage Policy - Renal - Anemia 2015-09.docx	9/2015	Jonathan Szkotak, PharmD, BCPCS
Update to Policy	HPSJ Coverage Policy - Renal - Anemia 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Renal - Anemia 2017-09.docx	9/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Renal - Anemia 2019-02.docx	2/2019	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy - Renal - Anemia.docx	2/2020	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy - Renal - Anemia 2021-02.docx	2/2021	Matthew Garrett, PharmD
Update to Policy	Anemia	12/2021	Matthew Garrett, PharmD
Update to Policy	Anemia	12/2022	Matthew Garrett, PharmD
Review of Policy	Anemia	1/2024	Matthew Garrett, PharmD
Update to Policy	Anemia	12/2024	Matthew Garrett, PharmD
Review of Policy	Anemia	12/2025	Matthew Garrett, PharmD

Note: All changes are approved by the Health Plan P&T Committee before incorporation into the utilization policy