Pharmacy Drug Policy & Procedure

Policy Name:	Reblozyl (luspatercept)	Policy #:	2733P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Reblozyl.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Reblozyl under the specialty medical benefit when the following criteria has been met.

Criteria

1. Coverage Criteria for Anemia due to Beta-Thalassemia

1.1 Documented diagnosis of anemia due to beta thalassemia
1.2 Age 18 years or older
1.3 Prescribed by or in consultation with a hematologist (blood doctor)
1.4 Documentation that the patient has had at least 6 red blood cell units transfused within the past 24 weeks

2. Coverage Criteria for Anemia due to Myelodysplastic Syndrome

2.1 Documented diagnosis of anemia due to myelodysplastic syndrome with ring sideroblasts or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis
2.2 Documentation that the patient has had at least 2 red blood cell units transfused over the past 8 weeks
2.3 Age 18 years or older
2.4 Prescribed by or in consultation with a hematologist (blood doctor)
2.5 Documentation of very low to intermediate risk disease as defined by one of the following tools:
- Revised International Prognostic Scoring System (IPSS-R): Very low, low, intermediate (score of 0 to less than or equal to 4.5)
- International Prognostic Scoring System (IPSS): Low/Intermediate-1 (Score 0 to 1)
- WHO-Based Prognostic Scoring System (WPSS): Very low, low, intermediate (Score of 0 to 2)

2.6 Hemoglobin level less than (<) 10g/dL

3. Exclusion Criteria

3.1 Hemoglobin (sickle) S/beta thalassemia or alpha thalassemia (e.g. Hemoglobin H)
3.2 Use as a substitute for red blood cell transfusion in patients who require immediate correction of anemia

4. Approval Period

4.1 Initial Approval: 12 months
4.2 Reapproval: 12 months with documentation that the member's disease has stabilized and not progressed (member has experienced a clinically meaningful decrease in transfusion burden)

CPT Codes

HCPCS Codes

References

1. Reblozyl (luspatercept) [prescribing information]. Summit, NJ: Celgene Corporation; August 2023.
2. Cappellini MD, Viprakasit V, Taher AT, et al. A Phase 3 Trial of Luspatercept in Patients with Transfusion-

Dependent β-Thalassemia. N Engl J Med 2020; 382:1219.
3. Cappellini MD., Farmakis D., Porter J, et al. 2021 Thalassaemia International Federation Guidelines for the Management of Transfusion-dependent Thalassemia. Hemasphere. 2022 Jul 29;6(8):e732.
4. Fenaux P, Haase D, Santini V, et al; ESMO Guidelines Committee. Myelodysplastic syndromes: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2021 Feb;32(2):142-156.
5. Platzbecker U, Della Porta MG, Santini V, et al. Efficacy and safety of luspatercept versus epoetin alfa in erythropoiesis-stimulating agent-naive, transfusion-dependent, lower-risk myelodysplastic syndromes (COMMANDS): interim analysis of a phase 3, open-label, randomised controlled trial. Lancet. 2023 Jul 29;402(10399):373-385.

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