Hematological: Anemia (Non-ESA)

Reblozyl (luspatercept-aamt) J0896, Enjaymo (sutimlimab-jome) J1302, Vafseo (vadadustat) J0901

Prior Authorization Request **Medicare Part B Form**

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ **Reblozyl**

☐ Patient has diagnosis of β-thalassemia and ALL of the following:

- ☐ Individual is 18 years of age or older; AND
- ☐ Individual has a diagnosis of beta thalassemia or hemoglobin E beta (E/β)-thalassemia; AND
- ☐ Documentation is provided that individual required regular red blood cell transfusions at initiation, defined as both of the following (NCT02604433):
  - ☐ Individual received six to twenty (6-20) RBC units in the last 24 weeks; AND
  - ☐ Individual had no transfusion-free period greater than 35 days in the last 24 weeks; AND
- ☐ Individual has a baseline hemoglobin (Hgb) level 11 g/dL or less.

☐ Patient has diagnosis of MDS-RS or MDS/MPN-RS-T or ESA-naïve MDS and ALL of the following:

- ☐ Individual is 18 years of age or older; AND
- ☐ Individual has one of the following (A, B, or C):

☐ A. Documentation is provided that individual has a diagnosis very low to intermediate risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) greater than or equal to 15% (or ring sideroblasts 5% to 14% with an SF3B1 mutation) (Label, NCCN 2A); AND

☐ Individual meets ONE of the following criteria:

☐ Serum erythropoietin (EPO) level of greater than 500 mU/mL; OR

☐ Serum EPO level of less than or equal to 500 mU/mL following no response to combination treatment with erythropoiesis-stimulating agent (ESA) and granulocyte-colony stimulating factor (G-CSF); OR

☐ B. Individual has a diagnosis of myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with all of the following:

☐ Ring sideroblasts greater than or equal to 15% (WHO 2017), and documentation is provided;

☐ Thrombocytosis (defined as platelets greater than or equal to 450 x109/L) (WHO 2017); OR

☐ C. Individual has a diagnosis of MDS; AND

☐ Documentation is provided that individual has serum EPO level less than 500 U/L;

☐ Documentation is provided that individual has required regular red blood cell transfusions of two (2) or more RBC units over eight (8) weeks in the last 16 weeks; AND

☐ Individual has a baseline hemoglobin (Hgb) level 11 g/dL or less.

☐ Enjaymo

☐ Patient has a diagnosis of cold agglutinin disease (CAD) defined as ALL of the following:

☐ The presence of chronic hemolysis;

☐ A positive polyspecific direct antiglobulin test result;

☐ A monospecific direct antiglobulin test result strongly positive for C3d;

☐ A cold agglutinin titer of 1:64 or higher measured at 4oC;

☐ A direct antiglobulin test result for IgG of 1+ or less;

☐ Presence of one or more symptoms associated with CAD (i.e. symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, disabling circulatory symptoms, or a major adverse vascular event); AND

☐ Patient is using Enjaymo to decrease the need for red blood cell transfusions due to hemolysis with cold agglutin disease (CAD)

☐ Vafseo

☐ Diagnosis of anemia due to chronic kidney disease (CKD) -AND

☐ Patient has been receiving dialysis for at least three months -AND

☐ Both of the following:

☐ Ferritin greater than 100 mcg/L

☐ Transferrin saturation (TSAT) greater than 20% -AND

☐ Hemoglobin level less than 11 g/dL

☐ Trial and failure, contraindication or intolerance to an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)]

☐ Prescribed by, or in consultation with a Hematologist or Nephrologist

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Hematological: Anemia (Non-ESA) PA

Drug Name(s):

REBLOZYL	**LUSPATERCEPT-AAMT**
ENJAYMO	**SUTIMLIMAB-JOME**
VAFSEO	**VADADUSTAT**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approvals will be for 6 months

FDA Indications:

Reblozyl

- Anemia, After erythropoiesis stimulating agent failure, requiring 2 or more RBC units over 8 weeks - Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis
- Anemia, After erythropoiesis stimulating agent failure, requiring 2 or more RBC units over 8 weeks - Myelodysplastic syndrome, Very low- to intermediate-risk disease with ring sideroblasts (MDS-RS)
- Anemia - Beta thalassemia

Enjaymo

- Cold autoimmune hemolytic anemia - Hemolysis

Vafseo

- Anemia in chronic kidney disease, In patients receiving dialysis for at least 3 months

Off-Label Uses:

N/A

Age Restrictions:

Reblozyl, Enjaymo, Vafseo:

Safety and effectiveness of luspatercept-aamt have not been established in pediatric patients

Other Clinical Considerations:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/2A458B/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/1D1D55/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActio

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