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## **Injections: Drugs J-L Policy**

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This section outlines policy related to billing for injection services, listed in alphabetical order by generic drug name or drug type. For general billing policy information regarding injections services, refer to the *Injections: An Overview* section in this manual. Additional policy information for injection services can be found in the following sections of this manual:

- *Immunizations*
- *Injections: Drugs A Policy*
- *Injections: Drugs B Policy*
- *Injections: Drugs C Policy*
- *Injections: Drugs D Policy*
- *Injections: Drugs E Policy*
- *Injections: Drugs F Policy*
- *Injections: Drugs G Policy*
- *Injections: Drugs H Policy*
- *Injections: Drugs I Policy*
- *Injections: Drugs M Policy*
- *Injections: Drugs N-O Policy*
- *Injections: Drugs P-Q Policy*
- *Injections: Drugs R Policy*
- *Injections: Drugs S Policy*
- *Injections: Drugs T Policy*
- *Injections: Drugs U-Z Policy*
- *Injections: Hydration*

## **Labetalol (Trandate)**

Labetalol hydrochloride is an adrenergic receptor blocking agent that has both selective alpha<sub>1</sub>- and nonselective beta-adrenergic receptor blocking actions.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

No *Treatment Authorization Request* (TAR) is required for reimbursement.

### **Billing**

HCPCS codes:

- J1920 (Injection, labetalol hydrochloride, 5 mg)
- J1921 (Injection, labetalol hydrochloride (Hikma) not therapeutically equivalent to J1920, 5 mg)

### **Prescribing Restriction**

Maximum billing unit(s) equals 300 mg/60 units.

## **Lacosamide**

Lacosamide injection is indicated for intravenous use as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older when oral administration is temporarily not feasible. The precise mechanism by which lacosamide exerts its antiepileptic effects in humans remains to be fully elucidated.

### **Dosage**

The initial dose should be 100 mg intravenously in two divided doses and can be increased at weekly intervals by 100 mg per day in two divided doses up to the recommended maintenance dose of 200 to 400 mg per day.

The maximum daily dose is 400 mg.

### **Billing**

HCPCS code C9254 (injection, lacosamide, 1 mg).

## **Lanadelumab-flyo (Takhzyro)**

Lanadelumab-flyo is a human monoclonal antibody that inhibits the proteolytic activity of kallikrein to reduce the generation of bradykinin in patients with hereditary angioedema (HAE).

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates all of the following:

- FDA-approved indications and dosages.
- Patient must be 12 years of age or older.

- Diagnosis of HAE confirmed by one of the following two options:
  - Low C4 level and low C1-INH antigenic or functional level
  - Normal C4 level and normal C1-INH level, and both of the following:
    - ❖ History of recurrent angioedema
    - ❖ Family history of angioedema
- Patient is using medication for prophylaxis against acute attacks of hereditary angioedema for one of the following two options:
  - Short-term prophylaxis prior to surgery, dental procedures or intubation
  - Long-term prophylaxis and the individual has failed, or is intolerant to, or has a contraindication (such as pregnant or breastfeeding individuals) to 17 alpha-alkylated androgens (for example, danazol) or antifibrinolytic agents (for example, aminocaproic acid)
- Patient must not use Takhzyro with other FDA-approved products for long-term prophylaxis of HAE attaches such as Cinryze or Haegarda.
- Dose must not exceed 300 mg every two weeks.

**Age Limit**

Must be 12 years of age or older.

**Billing**

HCPCS code J0593 (injection, lanadelumab-flyo, 1 mg).

**Prescribing Restrictions**

Frequency of billing equal to every two weeks

Maximum billing units equal to 300 mg which equals 300 units.

## **Lanreotide (Somatuline® Depot)**

Lanreotide is a synthetic octapeptide analogue of natural somatostatin, which is a peptide inhibitor of multiple endocrine, neuroendocrine and exocrine mechanisms. Lanreotide displays a greater affinity for somatostatin type 2 (SSTR2) and type 5 (SSTR5) receptors found in pituitary gland, pancreas and growth hormone (GH) secreting neoplasms of pituitary gland and a lesser affinity for somatostatin receptors 1, 3 and 4. Lanreotide reduces GH secretion and also reduces the levels of insulin-like growth factor 1.

### **Indications**

All FDA-approved indications.

### **Dosage**

All FDA-approved dosages.

### **Authorization**

No *Treatment Authorization Request* (TAR) is required for reimbursement.

### **Age Limit**

Must be 18 years of age or older.

### **Billing**

HPCS code J1930 (injection, lanreotide, 1 mg).

### **Prescribing Restrictions**

Frequency of billing equals 120 mg/120 units every four weeks.

Maximum billing unit(s) equals 120 mg/120 units.

## **Laronidase**

For detailed billing policy information about laronidase, refer to the “Enzyme Replacement Drugs” topic in the *Injections: Drugs E Policy* section of the manual.

## **Lecanemab-irmb (LEQEMBI®)**

Lecanemab-irmb is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. LEQEMBI reduces amyloid beta plaques.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

### **TAR Criteria**

The TAR must include clinical documentation that demonstrates all of the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be 50 to 90 years old.
- Must be prescribed by or in consultation with a neurologist, geriatrician or psychiatrist.
- Patient must have a diagnosis of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild AD dementia and must have all of the following:
  - A global Clinical Dementia Rating (CDR) score of 0.5 or 1.0
  - Memory Box score of 0.5 or greater
  - Positive amyloid pathology by either visual read of PET or CSF assessment
  - Mini-Mental State Examination (MMSE) score of 22 or more
  - Objective evidence of cognitive impairment at screening

- Patient does not have any of the following:
  - Any neurological condition (other than Alzheimer’s disease) which may be contributing to cognitive impairment
  - History of transient ischemic attacks, stroke, or seizures within the prior 12 months
  - Evidence of clinically significant lesions that could indicate a dementia diagnosis other than Alzheimer’s disease on brain MRI
  - Bleeding disorder that is not under control
- Patient does not have baseline Brain MRI (within the past year) that shows evidence of any of the following: more than 4 microhemorrhages (defined as 10 millimeter [mm] or less at the greatest diameter), a single macrohemorrhage greater than 10 mm at greatest diameter, an area of superficial siderosis, vasogenic edema, cerebral contusion, encephalomalacia, aneurysms, vascular malformations, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease or space occupying lesions or brain tumors.
- Patient is not using anticoagulants or antiplatelets (except for aspirin at a prophylaxis dose or less).
- Patients receiving cholinesterase inhibitors or memantine or both must be on stable dose for at least 12 weeks.
- Leqembi will not be used in combination with any other amyloid beta-directed antibodies (for example, aducanumab [Aduhelm]).
- Patient must have an MRI at baseline and at 5<sup>th</sup>, 7<sup>th</sup> and 14<sup>th</sup> infusions to monitor for amyloid- related imaging abnormalities (ARIA).
  - Patients should be evaluated for brain hemorrhage, bleeding disorders, or cerebral abnormalities to assess potential risk for ARIA.

Initial approval is for 12 months.

**Continued therapy:**

- Patient has shown clinical benefit as evidenced by at least one of the following or shown by other standard assessment scales:
  - A reduction in amyloid beta plaque from baseline in PET imaging of brain
  - An improvement from baseline in Clinical Dementia Rating Scale-Sum of Boxes (CDR-SB) score.
  - An improvement from baseline in MMSE score
  - Change from baseline in Alzheimer Disease Assessment Scale - Cognitive Subscale 14 (ADAS-cog14)
- Patient does not have unacceptable toxicity such as severe infusion-related reactions, amyloid related imaging abnormalities-edema (ARIA-E), amyloid related imaging abnormality hemorrhage (ARIA-H), angioedema (swelling) and anaphylaxis (allergic reaction) etc.

Reauthorization is for 12 months.

**Age Limit**

Must be 50 to 90 years of age.

**Billing**

HCPCS code: J0174, (injection, lecanemab-irmb, 1 mg).

**Required ICD-10-CM Diagnosis Codes**

Primary diagnosis: G30.0, G30.1, G30.8, G30.9, G31.84

Secondary diagnosis: F03.90, F03.91.

## Guidance for Dually Eligible/Medi-Medi Enrollees

### CMS's 2023 Coverage Criteria:

Leqembi is covered under Medicare Part B. Medi-Cal is obligated to pay the Coinsurance and/or Deductibles. On April 7, 2022, CMS issued a National Coverage Determination (NCD) that covers monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease approved by the Food and Drug Administration (FDA). As of July 6, 2023, Medicare more broadly covers Leqembi (lecanemab-irmb) under this NCD.

The FDA gave traditional approval for Leqembi for treatment in July 2023. Medicare covers the drugs with traditional FDA approval in this class when a prescribing clinician or their staff decides the Medicare coverage criteria is met and also submits information to help answer treatment questions in a qualifying study. Providers can participate in the CMS National Patient Registry (or another CMS-approved study) to get Medicare payment for treating their patients with Leqembi. Additional information can be found in the [Provider Fact Sheet for Registry](#) through the [Alzheimer's CED Registry Resources](#).

To receive Medicare coverage, individuals will need to:

1. Be enrolled in Medicare
2. Be diagnosed with mild cognitive impairment or mild Alzheimer's disease dementia, with documented evidence of beta-amyloid plaque on the brain, and
3. Have a physician who participates in a qualifying registry with an appropriate clinical team and follow-up care.

Clinicians participating in the registry will only need to complete a short, easy-to-use data submission. Individuals with Medicare should speak to their physician about whether this drug is right for them. See [Registry Resources](#) for additional information.

## **Lefamulin Injection (Xenleta)**

Lefamulin is a semi-synthetic antibacterial agent. Lefamulin is a pleuromutilin that inhibits bacterial protein synthesis through interactions (hydrogen bond, hydrophobic interactions, and Van der Waals forces) with the A- and P- sites of the peptidyl transferase center in the domain V of the 23s ribosomal RNA of the 50S subunit. The binding pocket of the bacterial ribosome closes around the mutilin core for an induced fit that prevents correct positioning of transfer RNA.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

### **TAR Criteria**

TAR approval requires clinical documentation to show the following:

- For FDA-approved indications and treatment regimens and
- Must be 18 years of age or older and
- Must verify negative pregnancy status in females of child-bearing age and
- Must establish diagnosis; microbiologic Gram stain and culture of sputum for Community-acquired Pneumonia (CAP) and
- Must show justification for failure to use formulary alternatives such as macrolides, fluoroquinolones, or beta-lactam antibiotics, such as allergy or intolerance.

Documentation of recent hospitalization and parenteral antibiotics and/or locally validated risk factors for MRSA may also satisfy TAR requirements.

**Age Limit**

Must be 18 years of age or older.

**Billing**

HCPCS code J0691 (injection, lefamulin, 1 mg).

**Prescribing Restrictions**

Frequency of billing equal to 150 mg/150 units every 12 hours for five to seven days.

Maximum billing units equal to 150 mg/150 units

**Lenacapavir (Sunlenca®)**

Sunlenca is an HIV-1 antiretroviral agent. It is a multistage, selective inhibitor of HIV-1 capsid function that directly binds to the interface between capsid protein (p24) subunits in hexamers. Surface plasmon resonance sensorgrams showed dose-dependent and saturable binding of lenacapavir to cross-linked wild-type capsid hexamer with an equilibrium binding constant (KD) of 1.4 nM. Lenacapavir inhibits HIV-1 replication by interfering with multiple essential steps of the viral lifecycle, including capsid-mediated nuclear uptake of HIV-1 proviral DNA (by blocking nuclear import proteins binding to capsid), virus assembly and release (by interfering with Gag/Gag-Pol functioning, reducing production of capsid protein subunits), and capsid core formation (by disrupting the rate of capsid subunit association, leading to malformed capsids).

**Indications**

All FDA-approved indications.

**Dosage**

FDA-approved dosages.

**TAR Requirement**

No *Treatment Authorization Request* (TAR) is required for reimbursement.

## **Age Limit**

Must be 18 years of age or older.

## **Billing**

HCPCS code: J1961 (injection, lenacapavir, 1 mg).

## **Required ICD-10-CM Diagnosis Code**

B20

## **Prescribing Restriction(s)**

Frequency of billing equals 927 mg/927 units every 24 weeks from the date of previous injection.

Maximum billing unit(s) equals 927 mg/927 units.

## **«Lenacapavir Injection**

## **Clinical Use Parameters**

Use in accordance with FDA-approved labeling, including indication, dosage, frequency, age and any prescribing limitation.

## **TAR Requirement**

No *Treatment Authorization Request* (TAR) is required for reimbursement.

## **Billing**

HCPCS code J0738 (injection, lenacapavir, 1 mg, FDA approved prescription, only for use as HIV pre-exposure prophylaxis (not for use as treatment for HIV)).»

## **Leuprolide (Lupron Depot/Lupron Depot-Ped/Lupron Depot-3 month)**

Leuprolide acetate, a gonadotropin releasing hormone (GnRH) agonist, acts as a potent inhibitor of gonadotropin secretion when given continuously in therapeutic doses. Animal and human studies indicate that after an initial stimulation, chronic administration of leuprolide acetate results in suppression of testicular and ovarian steroidogenesis.

Refer to “Leuprolide Acetate Depot Suspension” in the *Chemotherapy: Drugs I-L Policy* section of the appropriate Part 2 manual for information on the use of leuprolide in malignant disease.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

No *Treatment Authorization Request* (TAR) is required for reimbursement.

### **Billing**

HCPCS Code: J1950 (injection, leuprolide acetate [for depot suspension], per 3.75 mg).

### **Required ICD-10-CM Diagnosis Codes**

- D25.0 thru D25.9
- E22.8
- F64.0 thru F64.9
- N80.0 thru N80.9
- Z87.890

### **Prescribing Restrictions**

Frequency of billing is once every 30 days.

## **Leuprolide Acetate (Fensolvi®)**

Leuprolide acetate, a gonadotropin releasing hormone (GnRH) agonist, acts as a potent inhibitor of gonadotropin secretion (LH and follicle stimulating hormone [FSH]) when given continuously in therapeutic doses. Following an initial stimulation of GnRH receptors, chronic administration of leuprolide acetate results in downregulation of GnRH receptors, reduction in release of Luteinizing Hormone (LH), FSH and consequent suppression of ovarian and testicular production of estradiol and testosterone respectively. This inhibitory effect is reversible upon discontinuation of drug therapy.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

No *Treatment Authorization Request* (TAR) is required for reimbursement.

### **Age Limit**

Must be two to 12 years of age.

### **Billing**

HCPCS code J1951 (injection, leuprolide acetate for depot suspension [Fensolvi], 0.25 mg.).

### **Suggested ICD-10 Diagnosis Codes**

E22.8

### **Prescribing Restriction (s)**

Frequency of billing is 45 mg/180 units every six months.

Maximum billing unit(s) is 45 mg/180 units.

## **Levetiracetam**

Levetiracetam, 10 mg (HCPCS code J1953) has a maximum daily dose of 3,000 mg. Claims billed for quantities exceeding the daily limitation require appropriate documentation for payment.

## **Levoleucovorin (Khapzory)**

Levoleucovorin counteracts the toxic (and therapeutic) effects of folic acid antagonists (for example, methotrexate) which act by inhibiting dihydrofolate reductase. Levoleucovorin is the levo isomeric and pharmacologic active form of leucovorin (levoleucovorin does not require reduction by dihydrofolate reductase). A reduced derivative of folic acid, leucovorin supplies the necessary cofactor blocked by methotrexate. Leucovorin enhances the activity (and toxicity) of fluorouracil by stabilizing the bindings of 5-fluoro-2'-deoxyuridine-5'-monophosphate (FdUMP; a fluorouracil metabolite) to thymidylate synthetase resulting in inhibition of this enzyme.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

No *Treatment Authorization Request* (TAR) is required for reimbursement.

### **Age Limit**

Must be six years of age or older.

### **Billing**

HCPCS code J0642 (injection, levoleucovorin [Khapzory], 0.5 mg).

## **«Levothyroxine sodium**

Levothyroxine sodium is a synthetic L-thyroxine (T4) hormone that exerts the same physiologic effect as endogenous T4. Thyroid hormones exert their physiologic actions through control of DNA transcription and protein synthesis. Triiodothyronine (T3) and T4 diffuse into the cell nucleus and bind to thyroid receptor proteins attached to DNA. This hormone nuclear receptor complex activates gene transcription and synthesis of messenger RNA and cytoplasmic proteins. The physiological actions of thyroid hormones are produced predominantly by T3, the majority of which (approximately 80 percent) is derived from T4 by deiodination in peripheral tissues.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

No *Treatment Authorization Request* (TAR) is required for reimbursement.

### **Age Limits**

Must be 18 years of age or older.

### **Billing**

HCPCS codes:

J0650 (injection, levothyroxine sodium, not otherwise specified, 10 mcg).

J0651 (injection, levothyroxine sodium [fresenius kabi] not therapeutically equivalent to J0650, 10 mcg).

J0652 (injection, levothyroxine sodium [hikma] not therapeutically equivalent to J0650, 10 mcg).»

**Prescribing Restriction(s)**

Frequency of billing equals 500 mcg / 50 units daily.

Maximum billing unit(s) equals 500 mcg / 50 units.

**«Lidocaine Hydrochloride and 5 Percent Dextrose Injection**

Lidocaine hydrochloride exerts an antiarrhythmic effect by increasing the electrical stimulation threshold of the ventricle during diastole.

**Indications**

All FDA-approved indications.

**Dosage**

FDA-approved dosages.

**TAR Requirement**

No *Treatment Authorization Request* (TAR) is required for reimbursement.

**Billing**

HCPCS code J2002 (injection, lidocaine hcl in 5 percent dextrose, 1 mg).»

## **«Lidocaine HCl Injection and Lidocaine HCl and Epinephrine Injection**

Lidocaine HCl stabilizes the neuronal membrane by inhibiting the ionic fluxes required for the initiation and conduction of impulses thereby effecting local anesthetic action.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

No *Treatment Authorization Request* (TAR) is required for reimbursement.

### **Billing**

HCPCS code J2003 (injection, lidocaine hydrochloride, 1 mg).

HCPCS code J2004 (injection, lidocaine hcl with epinephrine, 1 mg).

### **Prescribing Restriction(s)**

Maximum billing unit(s) for J2003 is equal to 300mg/300 units.

Maximum billing unit(s) for J2004 is equal to 500mg/500 units.>>

## **Linezolid (Hospira)**

Linezolid is a synthetic antibacterial agent of the oxazolidinone class, which has clinical utility in the treatment of infections caused by aerobic Gram-positive bacteria. The in vitro spectrum of activity of linezolid also includes certain Gram-negative bacteria and anaerobic bacteria. Linezolid binds to a site on the bacterial 23S ribosomal RNA of the 50S subunit and prevents the formation of a functional 70S initiation complex, which is essential for bacterial reproduction. The results of time-kill studies have shown linezolid to be bacteriostatic against enterococci and staphylococci. For streptococci, linezolid was found to be bactericidal for the majority of isolates.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

No *Treatment Authorization Request* (TAR) is required for reimbursement.

### **Billing**

HCPCS code J2021 (injection, linezolid [hospira] not therapeutically equivalent to J2020, 200 mg).

### **Prescribing Restriction(s)**

Frequency of billing equals 1200 mg/ six units per 24 hours.

Maximum billing unit(s) equals 1200 mg/ six units.

## **Linezolid (Zyvox®)**

Refer to the *Non-Injectable Drugs* section in this manual for more information.

## **Lumasiran (Oxlumo)**

Lumasiran reduces levels of glycolate oxidase (GO) enzyme by targeting the hydroxyacid oxidase 1 (HAO1) messenger ribonucleic acid (mRNA) in hepatocytes through RNA interference. Decreased GO enzyme levels reduce the amount of available glyoxylate, a substrate for oxalate production. As the GO enzyme is upstream of the deficient alanine: glyoxylate aminotransferase (AGT) enzyme that causes PH1, the mechanism of action of lumasiran is independent of the underlying AGXT gene mutation.

OXLUMO is not expected to be effective in primary hyperoxaluria type 2 (PH2) or type 3 (PH3) because its mechanism of action does not affect the metabolic pathways causing hyperoxaluria in PH2 and PH3.

### **Indications**

All FDA-approved indications.

### **Dosage**

FDA-approved dosages.

### **TAR Requirement**

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

### **TAR Criteria**

The TAR must include clinical documentation that demonstrates all of the following:

- Must be for FDA-approved indications and dosages.
- Must be prescribed by, or in consultation with, a nephrologist, endocrinologist, or other healthcare provider who is specialized in treating primary hyperoxaluria type 1 (PH1).
- Patient has a diagnosis of PH1 confirmed with one of the following:
  - Genetic testing confirmation of mutation of Alanine glyoxylate aminotransferase (AGXT)
  - Liver biopsy demonstrating decreased or absent activity of AGT for type 1 disease;  
and

- Patient has at least one of the following:
  - Elevated urinary oxalate excretion persistently greater than 0.7 mmol/1.73 m<sup>2</sup>/day or above the upper limit of normal (ULN) for age
  - Urinary oxalate-to-creatinine ratio greater than ULN for age in two of three single-void collections
  - Elevated urinary glycolic acid (glycolate) concentration
- Patient has tried and failed at least three months of pyridoxine (vitamin B6) at up to the maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced.
- Patient has not had a kidney or liver transplant.
- Patient does not have a history of extrarenal systemic oxalosis.

Initial approval is for six months.

#### Reauthorization

- Patient continues to meet the initial approval criteria.
- Patient has experienced clinical benefit as evidenced by reduction in signs and symptoms of PH1 with lumasiran treatment.
- Patient has shown improvement or normalization of laboratory values such as urinary oxalate excretion from baseline, or the percent change in spot urinary oxalate-to-creatinine ratio from baseline.

Reauthorization is for 12 months.

#### **Billing**

HCPCS code J0224 (injection, lumasiran, 0.5 mg).

## Required ICD-10 Diagnosis Codes

E72.53

## Prescribing Restriction(s)

Frequency of billing equals every 28 days.

The recommended dose is based on body weight.

**Recommended Dose Based on Body Weight Table**

<b>Body Weight</b>	<b>Loading Dose</b>	<b>Maintenance Dose (begin one month after the last loading dose)</b>
Less than 10 kg	6 mg/kg once monthly for 3 doses	3 mg/kg once monthly
10 kg to less than 20 kg	6 mg/kg once monthly for 3 doses	6 mg/kg once every 3 months (quarterly)
20 kg and above	3 mg/kg once monthly for 3 doses	3 mg/kg once every 3 months (quarterly)

## **Luspatercept-aamt (Reblozyl®)**

Luspatercept-aamt is an erythroid maturation agent. It is a recombinant fusion protein that binds several endogenous TGF- $\beta$  superfamily ligands, thereby diminishing Smad2/3 signaling. Luspatercept-aamt promoted erythroid maturation through differentiation of late-stage erythroid precursors (normoblasts) in mice. In a model of  $\beta$ -thalassemia, luspatercept-aamt decreased abnormally elevated Smad2/3 signaling and improved hematology parameters associated with ineffective erythropoiesis in mice.

## Indications

All FDA-approved indications.

## Dosage

FDA-approved dosages.

## TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

## TAR Criteria

Reblozyl will be considered medically necessary when all of the following criteria are met:

- Must be prescribed for FDA-approved indications and dosing regimens.
- Patient must be 18 years of age or older.
- Reblozyl must be prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and treatment of  $\beta$ -thalassemia.
- Patient has a clinically documented diagnosis of  $\beta$ -thalassemia or Hemoglobin E/ $\beta$ -thalassemia. ( $\beta$ -thalassemia with mutation and/or multiplication of alpha globin is allowed).
- Patient is regularly transfused, defined as: 6-20 Red Blood Cell (RBC) units in the 24 weeks prior and no transfusion-free period for equal to or greater than 35 days during that period.
- Patient does not have a diagnosis of Hemoglobin S/ $\beta$ -thalassemia or alpha ( $\alpha$ )-thalassemia (for example, Hemoglobin H).
- Patient is not pregnant or breastfeeding.

- Patient must not have any of the following conditions:
  - Active hepatitis C (HCV) infection
  - Active infectious hepatitis B (HBV) as demonstrated by a positive HCV-RNA test of sufficient sensitivity
  - Known human immunodeficiency virus (HIV) that is not controlled by antiretroviral (ART) therapy
  - Recent deep vein thrombosis or stroke requiring medical intervention less than or equal to 24 weeks prior
  - Major organ damage as evidenced by any of the following:
    - ❖ Liver disease with an ALT greater than 3x the ULN or history of evidence of cirrhosis
    - ❖ Heart disease, heart failure NYHA classification three or higher, or significant arrhythmia requiring treatment, or recent myocardial infarction within six months of treatment
    - ❖ Lung disease, including pulmonary fibrosis or pulmonary hypertension which are clinically significant, that is, equal to or greater than Grade 3
    - ❖ Renal insufficiency such as creatinine clearance less than 60 mL/min

Initial authorization will be for six months.

Continuation of Therapy:

- Patient continues to meet the initial coverage criteria.
- Patient has experienced a clinically significant reduction in transfusion burden from baseline.
- Patient has an absence of unacceptable toxicity from the drug such as severe thromboembolic events or hypertension.

Reauthorization will be for 12 months.

**Age Limit**

Must be 18 years of age or older.

**Billing**

HCPCS code J0896 (injection, luspatercept-aamt, 0.25 mg).

**Suggested ICD-10 Diagnosis Codes**

D46.1, D46.4, D46.9, D46.A, D46.B, D46.Z, D56.1, D56.5

**Prescribing Restriction(s)**

Frequency of billing equal to 1.25 mg/kg every three weeks.

## **Legend**

Symbols used in the document above are explained in the following table.

<b>Symbol</b>	<b>Description</b>
«	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
»	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.