Lantidra (donislecel)

Humana
Medicaid Medical Coverage Policy

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Description

Diabetes mellitus (DM) is a complex endocrine disorder characterized by hyperglycemia (abnormally high levels of glucose). DM usually occurs when the body does not produce enough insulin or cannot respond to the insulin in the body. Insulin controls blood sugar levels in the body and insufficient glucose leads to diabetes symptoms such as excessive thirst, frequent urination and increased hunger.[5] Type 1 diabetes (T1D) or insulin-dependent diabetes is an autoimmune disease that affects around 8 million people in the world. These individuals are prone to immediate life-threatening complications, including hypoglycemia and diabetic ketoacidosis (DKA).[2]

Conventional therapy for T1D includes exogenous (outside the body) insulin administered through several subcutaneous injections per day, or via an insulin pump, as well as self-monitoring or continuous monitoring of blood glucose with automatic monitoring technologies. Some individuals with T1D have difficulty controlling their blood glucose levels and may have episodes of severe hypoglycemia without feeling or having an awareness of symptoms. These episodes can negatively impact quality of life, require hospitalization and lead to death.

Lantidra (donislecel) is an allogenic (deceased donor) pancreatic islet cellular therapy for the treatment of T1D. It is composed of single donor pancreatic islet cells and is believed to function through the secretion of insulin from the donor islet beta cells. It is indicated for adults with T1D who are unable to approach target glycated hemoglobin (average blood glucose levels) because of current repeated episodes of severe hypoglycemia (low blood sugar) despite intensive diabetes management and education.[5]

Lantidra (donislecel) cell therapy is given as a single infusion into the hepatic portal vein, which may be repeated***** if the initial dose is inadequate. *Repeat intraportal islet infusions are not recommended in an individual who has experienced prior portal vein thrombosis unless limited to second- or third-order portal vein branches.*[9]

Requests for Lantidra (donislecel) require review by a medical director.

Coverage Determination

Refer all requests or questions regarding Lantidra (donislecel) to the Corporate Transplant Department.

Phone	***Fax***	***Email***
1-866-421-5663	*502-508-9300*	*transplant@humana.com*

Humana members may be eligible under the Plan for **Lantidra (donislecel)** when the following criteria are met[9]:

- Absence of limitations; **AND**
- Individual has T1D and is unable to approach target hemoglobin A1c **due to one of the following** *despite intensive diabetes management and education*:
  - Current repeated episodes of severe hypoglycemia; **OR**
  - Hypoglycemic unawareness (individual is unable to prevent repeated severe hypoglycemic events without intervention of a third party); **AND**
- Individual is 18 through 65 years of age; **AND**
- Use Lantidra (donislecel) in conjunction with concomitant immunosuppression

Repeat infusions

*****Infusion *may be repeated* when the individual meets all initial approval criteria **AND** has not achieved independence from exogenous insulin within one year of infusion **OR** within one year after losing independence from exogenous insulin after a previous infusion. **Administration has not exceeded a maximum of 3 infusions (transplants)**.[9]

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **Lantidra (donislecel)** for any indications other than those listed above including, but may not be limited to[9]:

- Individual for whom immunosuppression is contraindicated; **OR**
- Individual has desire to become pregnant/reproduce **OR** unwilling to use effective contraception; **OR**
- Individual is pregnant or breastfeeding; **OR**
- Kidney/renal failure; **OR**
- Liver/hepatic disease (any condition that causes impaired function of the liver [eg, hepatitis B or C]); **OR**
- Portal vein thrombosis; **OR**
- Prior kidney/renal transplant

A review of the current medical literature shows that there is **no evidence** to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	**Description**	**Comments**
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells	
CPT® Category III Code(s)	**Description**	**Comments**
0584T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous	
0585T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic	
0586T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open	
HCPCS Code(s)	**Description**	**Comments**

C9399	Unclassified drugs or biologicals	
G0341	Percutaneous islet cell transplant, includes portal vein catheterization and infusion	
G0342	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion	
G0343	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion	
J3590	Unclassified biologics	
S2102	Islet cell tissue transplant from pancreas; allogeneic	**Not Covered**

References

1. Ajmal N, Bogart MC, Khan P, et al. Identifying promising immunomodulators for type 1 diabetes (T1D) and islet transplantation. *J Diabetes Res*. 2024;2024:5151171.

2. Alam S, Khan SJ, Lee CYF, et al. Type 1 diabetes mellitus management and islet cell therapy: a new chapter in patient care. *Cureus*. 2023;15(10):e46912.

3. American Diabetes Association. 6. Glycemic targets: *standards of medical care in diabetes-2021*. *Diabetes Care*. 2021;44(Suppl 1):S73-S84.

4. ClinicalKey. Drug Monograph. Donislecel. https://clinicalkey.com. Revised September 28, 2023.

5. Hayes, Inc. Evidence Analysis Research Brief. Donislecel-jujn (Lantidra; CellTrans Inc) for treatment of type 1 diabetes. https://evidence.hayesinc.com. Published October 5, 2023.

6. IBM Micromedex. Donislecel-jujn. https://micromedexsolutions.com. Updated February 28, 2024.

7. Parums DV. Editorial: first regulatory approval for allogeneic pancreatic islet beta cell infusion for adult patients with type 1 diabetes mellitus. *Med Sci Monit*. 2023;29:e941918

8. UpToDate, Inc. Pancreas and islet transplantation in diabetes mellitus. https://uptodate.com. Updated February 10, 2025.

9. US Food & Drug Administration (FDA). Full prescribing information: Lantidra (donislecel-jujn). https://fda.gov. Revised June 2023.

Appendix

Appendix A - Summary of glycemic goals for many nonpregnant adults with diabetes[3]

A1C	<7.0% (53 mmol/mol)

More or less stringent glycemic goals may be appropriate for individual patients. Goals should be individualized based on duration of diabetes, age/life expectancy, comorbid conditions, known cardiovascular disease or advanced microvascular complications,

hypoglycemia unawareness and individual patient considerations.

Change Summary

05/06/2025 New Policy.