Lantidra™ (donislecel-jujn)
(Intravenous)

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I. Length of Authorization

Coverage will be provided for 1 dose (infusions) and may be renewed annually for up to 3 doses total.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Lantidra up to a maximum of 1 x 10^6 EIN per bag: 1 infusion bag yearly x 3 doses only

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1 infusion up to a maximum of 1 x 10^6 EIN per bag per year x 3 doses total

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**

Universal Criteria [1]

- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will not receive live vaccines during treatment with immunosuppression; **AND**
- Patient will be clinically monitored for malignancy, including skin cancer, during treatment; **AND**
- Patient does not have a history of a prior portal vein thrombosis *(Note: Excludes thrombosis limited to second- or third-order portal vein branches)*; **AND**
- Patient does not have a history of liver disease or renal failure and has not been the recipient of a renal transplant; **AND**
- Patient does not have a concomitant disease or condition *(including pregnancy)* that contraindicates the procedure for infusion or immunosuppression*****; **AND**

Diabetes Mellitus (Type 1) † [1-3]

- Patient is unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education *(Note: There is no evidence to show a benefit of administration of LANTIDRA in patients whose diabetes is well-controlled with insulin therapy or patients with hypoglycemic unawareness who are able to prevent current repeated severe hypoglycemic events using intensive diabetes management)*; **AND**
- Patient will receive concomitant immunosuppression***** *(i.e., non-depleting monoclonal anti-interleukin-2 receptor antibody [or T-cell-depleting antibody if not a candidate], calcineurin inhibitor, mTOR inhibitor, TNF-blocker)*; **AND**
- Patient is T- and B-cell crossmatch assay negative; **AND**
- Patient has a confirmed diagnosis of Type 1 diabetes mellitus for more than 5 years which is complicated by BOTH of the following situations that persist despite intensive insulin management efforts:
    - At least one episode of severe hypoglycemia in the past 3 years defined as an event with symptoms compatible with hypoglycemia in which the subject required the assistance of another person, and which was associated with either a blood glucose level < 50 mg/dL (2.8 mmol/L) or prompt recovery after oral carbohydrate, intravenous glucose, or glucagon administration; **AND**
    - Reduced awareness of hypoglycemia, as defined by the absence of adequate autonomic symptoms at capillary glucose levels of < 54 mg/dL (3 mmol/L)

*** Considerations for discontinuation of immunosuppression therapy include the following: [1]**
– If a patient develops a life-threatening infection or cancer and treatment requires discontinuation of immunosuppression.
– If a patient has been dependent on exogenous insulin for two years after their last infusion, then immunosuppression should be discontinued. However, the treatment team may consider continuation of immunosuppression if they determine that the patient has achieved target HbA1c without recurrent severe hypoglycemia in the presence of clinically relevant C-peptide, that provides a potential ongoing benefit that outweighs the risks of severe and potentially life-threatening effects of immunosuppression.
– If a patient becomes pregnant.

† FDA Approved Indication(s); **‡** Compendium Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infections, portal vein thrombosis, portal hypertension, islet graft rejection, etc.; **AND**

- A second infusion may be performed due to failure to achieve independence from exogenous insulin within one year of infusion (or within one year after losing independence from exogenous insulin after a previous infusion); **OR**
- A third infusion may be performed using the same criteria as stated above for a second infusion *(Note: there is no data regarding the effectiveness or safety for patients receiving more than three infusions)*

V. Dosage/Administration [1]

Indication	Dose
T1DM	The recommended minimum dose is 5,000 equivalent islet number (EIN) per kg patient body weight for initial infusion (transplant) and 4,500 EIN/kg for subsequent infusions (same recipient): • Administer cells through the hepatic portal vein. • The maximum dose per infusion should not exceed 10 cc per transplant infusion or 1 x 10^6 EIN per bag. • Pre-procedural immunosuppression must be provided. • Periprocedural antibiotic prophylaxis is recommended. • Monitoring during infusion must include portal pressure, blood glucose, and portal vein thrombosis. • Hospitalization is required for a minimum of 24 hours post-infusion.
– Do not irradiate. – Do not use leukodepleting filters. – Do not use if product time exceeds 6-hours post product release or if temperature is not maintained between 15 and 25º C. – Interventional radiologists and surgeons with expertise in islet cell infusion may administer treatment in an interventional radiology suite or operating suite under controlled aseptic conditions.	

VI. Billing Code/Availability Information

HCPCS code(s):

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals

NDC:

- Lantidra is contained in one 1000 mL infusion bag filled with a supplied volume of 400 mL, containing not more than 10 cc of estimated packed islet tissue and not more than 1 x 10^6 EIN: 73539-0001-xx

VII. References

1. Lantidra [package insert]. Chicago, IL; CellTrans, Inc.; June 2023. Accessed December 2023.
2. Luu QF, Villareal CJ, Fritschi C, et al. Concerns and hopes of patients with type 1 diabetes prior to islet cell transplantation: A content analysis. J Diabetes Complications. 2018 Jul;32(7):677-681. doi: 10.1016/j.jdiacomp.2018.04.002. Epub 2018 Apr 17. PMID: 29779835; PMCID: PMC6015784.

3. Qi M, Kinzer K, Danielson KK, et al. Five-year follow-up of patients with type 1 diabetes transplanted with allogeneic islets: the UIC experience. Acta Diabetol. 2014 Oct;51(5):833-43. doi: 10.1007/s00592-014-0627-6. Epub 2014 Jul 18. PMID: 25034311; PMCID: PMC4801517.
4. Williams J, Jacus N, Kavalackal K, et al. Over ten-year insulin independence following single allogeneic islet transplant without T-cell depleting antibody induction. Islets. 2018;10(4):168-174. doi: 10.1080/19382014.2018.1451281. Epub 2018 Jul 19. PMID: 30024826; PMCID: PMC6281363.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC