Medical Policy:
Lantidra (donislecel-jujn) allogeneic pancreatic islet cellular suspension

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.401	November 09, 2023	November 09, 2023

Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Lantidra is an allogeneic pancreatic islet cellular therapy indicated for the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. Use Lantidra in conjunction with concomitant immunosuppression.

Length of Authorization

12 months

Dosing Limits [Medical Benefit]

Maximum 3 doses per lifetime

- The recommended minimum dose is 5,000 EIN/kg for initial infusion and 4,500 EIN/kg for subsequent infusion in the same recipient. The maximum dose per infusion is dictated by the estimated tissue volume, which should not exceed 10 cc per infusion, and the total EIN present in the infusion bag (up to a maximum of 1 × 106 EIN per bag).
- A second infusion may be performed if the patient does not achieve independence from exogenous insulin within one year of infusion or within one year after losing independence from exogenous insulin

after a previous infusion. A third infusion may be performed using the same criteria as for the second infusion. There are no data regarding the effectiveness or safety for patients receiving more than three infusions.

Guideline

I. Initial

1. **Type 1 Diabetes- First Infusion**

A. Diagnosis of T1D, duration >5 years; **AND**
B. Patient must be 18 years or older **AND**
C. Patient is T- and B-cell crossmatch assay negative; **AND**
D. Patient has recurrent, acute, and severe metabolic and potentially life-threatening complications requiring medical attention, as documented by chart notes and frequent emergency room visits and/or hospitalizations: One or more over the previous 12 months. They may include:
   i. Hyperglycemia; **OR**
   ii. Hypoglycemia; **OR**
   iii. Hypoglycemia Unawareness (HU) associated with high risk of injury; **OR**
   iv. Ketoacidosis
E. Patient has consistent failure of exogenous insulin-based management, defined as inability to achieve sufficient glycemic control (HbA1c >8%) or recurrent HU, despite aggressive conventional therapy (usually including insulin pump),including **ALL** of the following:
   i. Adjusting frequencies and amounts of insulin injected; **AND**
   ii. Taking multiple blood glucose measurements on a daily basis; **AND**
   iii. Modifying diet and exercise; **AND**
   iv. Monitoring HbA1c levels

II. Renewal

1. **Type 1 Diabetes- Second Infusion**
   A. A second infusion may be performed if the patient does not achieve independence from exogenous insulin within one year of infusion or within one year after losing independence from exogenous insulin after a previous infusion.

2. **Type 1 Diabetes- Third Infusion**
   A. A third infusion may be performed if the patient does not achieve independence from exogenous insulin within one year of second infusion or within one year after losing independence from exogenous insulin after a previous infusion.

Exclusions/Limitations

1. Cardiac disease: myocardial infarction, heart failure, etc.
2. BMI >27 kg/m2
3. C-peptide response to glucagon stimulation, any C-peptide >0.3 ng/mL (undetectable or very low levels of C-peptide). C-peptide is a biomarker used to assess production of insulin by functional pancreatic beta cells.
4. Abnormal kidney or liver function or disease
5. Positive pregnancy test, intent for pregnancy, male's intent to procreate, unwilling to use effective contraception, breastfeeding
6. Insulin requirement >0.7 IU/kg/day, HbA1c >12%
7. Psychiatric disorder: schizophrenia, bipolar disorder, or major depression that is unstable on medication

Proprietary information of EmblemHealth/ConnectiCare, Inc. © 2022 EmblemHealth & Affiliates

Applicable Procedure Codes

Code	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Applicable NDCs

Code	Description
73539-0001-01	Lantidra- purified allogeneic islets of Langerhans suspended in buffered transplant medium
73539-0002-01	750 mL Rinse Bag containing 200 mL of supplied volume transplant media for use in rinsing the 1000 mL bag containing Lantidra and infusion line

ICD-10 Diagnoses

Code	Description
E10.65	Type 1 diabetes mellitus with hyperglycemia
E10.649	Type 1 diabetes mellitus with hyp0glycemia

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	11/09/2023	New Policy

References

1. Product Information: LANTIDRA allogeneic pancreatic islet cellular suspension, donislecel-jujn allogeneic pancreatic islet cellular suspension. CellTrans Inc (per FDA), Chicago, IL, 2023.

Proprietary information of EmblemHealth/ConnectiCare, Inc. © 2022 EmblemHealth & Affiliates