BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.30.089

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Endocrine and Metabolic Agents	**Original Policy Date:**	October 13, 2023
Subject:	Lantidra	**Page:**	1 of 4

Last Review Date: March 8, 2024

Lantidra

Description

Lantidra (donislecel-jujn)

Background
Pancreatic islets regulate blood glucose levels through secretion of multiple hormones in response to increases and decreases in blood glucose. Endocrine cells within pancreatic islets release insulin, glucagon, somatostatin, pancreatic peptide, and ghrelin. Insulin stimulates glucose uptake by peripheral tissues; glucagon mobilizes glucose from the liver into circulation; somatostatin inhibits both α- and β-cell secretions; pancreatic peptide inhibits pancreatic exocrine secretion; and ghrelin inhibits insulin secretion. The primary mechanism of action of Lantidra is believed to be secretion of insulin by infused (transplanted) β-cells (1).

Regulatory Status
FDA-approved indication: 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 in conjunction with concomitant immunosuppression (1).

Limitations of Use:
There is no evidence to show a benefit of administration of Lantidra in patients whose diabetes is well-controlled with insulin therapy or in patients who are able to prevent current repeated severe hypoglycemic events using intensive diabetes management. Repeated intraportal islet infusions are not recommended in patients who have experienced prior portal thrombosis unless the thrombosis was limited to second- or third-order portal vein branches. There is no evidence

to support the safe and effective use of Lantidra in patients with liver disease, renal failure, or who have received a renal transplant (1).

Lantidra is contraindicated in patients for whom immunosuppression is contraindicated (1).

Due to immunosuppression, there is an increased risk of severe infection including opportunistic infections, malignancy, and severe anemia. In order to mitigate the risks of infection, the patient should receive recommended immunizations prior to treatment. PCP and CMV prophylaxis should be administered following administration of Lantidra (1).

Liver laceration, hemorrhage and intra-abdominal bleeding have occurred with portal administration of Lantidra. Monitor for bleeding, portal hypertension, and portal vein thrombosis during and immediately following infusion (1).

Patients with a positive T- and B-cell crossmatch between recipient serum and donor lymphocytes may be at increased risk for graft rejection. Both T- and B-cell crossmatch need to be negative prior to Lantidra administration (1).

Donor-derived infections can also be a cause of concern. Monitor for signs of infection following infusion and treat accordingly if infection is suspected (1).

Administration of Lantidra may elevate panel reactive antibodies and negatively impact candidacy for renal transplant. Consider benefit-risk of administering Lantidra to a patient who may require a renal transplant in the future (1).

The safety and effectiveness of Lantidra have not been established in pediatric patients (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lantidra may be considered **medically necessary** if the conditions indicated below are met.

Lantidra may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Type 1 diabetes mellitus

AND ALL of the following:

1. HbA1c > 7.0%
2. Frequent severe hypoglycemic episodes despite following an intensive insulin therapy regimen
3. Patient has completed a comprehensive diabetes education program
4. Used in combination with an immunosuppressant (e.g., basiliximab, sirolimus, tacrolimus, mycophenolate mofetil, etc.)

Prior – Approval *Renewal* Requirements

Age **1**8 years of age or older

Diagnosis

Patient must have the following:

Type 1 diabetes mellitus

AND ALL of the following:

1. Patient has not achieved independence from exogenous insulin
2. Used in combination with an immunosuppressant (e.g., basiliximab, sirolimus, tacrolimus, mycophenolate mofetil, etc.)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Duration 6 months (**TWO** renewals **only**)

Rationale

Summary
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. Lantidra must be used in combination with an immunosuppressant. Complications include increased risk of severe infection, including donor-derived infections, procedural complications, increased risk of graft rejection, and elevated panel reactive antibodies which can negatively impact candidacy for a renal transplant (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Lantidra while maintaining optimal therapeutic outcomes.

References

1. Lantidra [prescribing information]. Chicago, IL: CellTrans Inc.; June 2023.

Policy History

Date	Action
October 2023	Addition to PA
December 2023	Annual review
March 2024	Annual review. Per SME, clarified initiation requirement that patient must have frequent severe hypoglycemic episodes “despite following an intensive insulin therapy regimen”

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.