VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

LANTIDRA® (Donislecel-~~jujn~~)

Effective Date:

Date Developed: 12/5/24 by Howard Taekman MD

Date Approved by P&T Committee: 2/18/25

LANTIDRA is a cellular therapy for treatment of adults with Type 1 diabetes who are unable to reach target HbA1c because of repeated episodes of severe hypoglycemia despite intensive diabetes management and education (otherwise known as brittle diabetes). Lantidra is an allogeneic pancreatic islet cellular therapy derived from single donor pancreas that regulates blood glucose levels through secretion of multiple hormones in response to blood glucose levels. These hormones include 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 alpha- and beta-cell secretions; pancreatic peptide inhibits pancreatic exocrine secretion; and ghrelin inhibits insulin secretion.

Authorization Criteria:
Diagnosis Patient must have the following:
Type 1 diabetes mellitus

AND ALL of the following:
1. HbA1c > 7.0%
2. Frequent severe hypoglycemic episodes
3. Patient has completed an intensive diabetes education program
4. Patient is on combination long-acting and short-acting insulin therapy
4. Used in combination with an immunosuppressant (e.g., basiliximab, sirolimus, tacrolimus, mycophenolate mofetil, etc.)

ADULTS – Intravenous (IV) through catheter of hepatic portal vein and to be infused through an infusion bag by gravity flow over approximately 30 minutes at rates ≤ 25 mL/kg/h.
Initial Infusion Minimum dose is 5,000 EIN/kg
A second dose may be administered if independence from exogenous insulin is not achieved within 1 year of initial infusion or within 1 year after losing independence from exogenous insulin after a previous infusion. A third infusion may be administered using the same dose and criteria as the second dose if needed; there are no data for administration of >3 infusions. Minimum effective dose for subsequent infusions is 4,500 EIN/kg.

Note: 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 x 106

EIN per bag) (https://www.fda.gov/media/169920/download).

CONTRAINDICATIONS:
LANTIDRA is contraindicated in patients for whom immunosuppression is contraindicated, pregnant women, pediatric patients.

REFERENCES

Lantidra [prescribing information]. Chicago, IL: CellTrans Inc.; (2023, June). https://www.fda.gov/media/169920/download

LANTIDRA. U.S. Food & Drug Administration (FDA), (2023, August 7). https://www.fda.gov/vaccines-blood-biologics/lantidra

UpToDate Donislecel

A. Attachments: None

B. History:

Policy created by Howard Taekman, MD; Robert Sterling MD
Date Approved by P&T Committee: 2/18/25
Date Reviewed/No Updates:

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes