Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 323.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Lantidra (donislecel-jujn)

I. Policy:
Lantidra (donislecel-jujn)

II. Purpose/Objective:
To provide a policy of coverage regarding Lantidra (donislecel-jujn)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Lantidra (donislecel-jujn) is an allogeneic pancreatic islet cellular therapy. 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. The primary mechanism of action of Lantidra is believed to be secretion of insulin by infused (transplanted) β- cells.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Lantidra (donislecel-jujn) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Lantidra is prescribed by or in consultation with an endocrinologist **AND**
- Medical record documentation of a diagnosis of Type I diabetes mellitus for at least 5 years **AND**
- Medical record documentation of failure to achieve target HbA1c with current treatment regimens **AND**
- Medical record documentation of intensive diabetes management and education, including all of the following:
    - Documentation of use of greater than or equal to three daily injections of prandial and/or basal insulin or continuous subcutaneous insulin through an insulin pump **AND**
    - Documentation of use of a continuous glucose monitor OR both of the following:
        - Documentation of reason why a continuous glucose monitor cannot be used **AND**
        - Documentation of daily monitoring of blood glucose levels

    AND
    - Documentation that member has received education on insulin administration and dosing and dietary management **AND**
- Medical record documentation of repeated severe uncontrolled hypoglycemia including BOTH of the following:
    - 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) as reported by the subject

  AND
- Medical record documentation that Lantidra will be used in conjunction with concomitant immunosuppression

AUTHORIZATION DURATION: Initial authorization will be for one (1) infusion of Lantidra. Reauthorization for Lantidra will be for one (1) additional infusion, up to three (3) infusions per lifetime, and will require all of the following:

- Medical record documentation that member has not achieved exogenous insulin independence within one year following the first or second Lantidra infusion (islet transplantation) OR within one year after losing independence from exogenous insulin after a previous infusion **AND**
- Medical record documentation that member has not exceeded the maximum of three (3) infusion per lifetime

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Lantidra [Prescribing Information]. Chicago, Illinois. CellTrans Inc. June 2023.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 7/16/24

Revised:

Reviewed:

MA UM Committee approval: 8/30/24