MVP Health Care Medical Policy

Medicare Part B: Donislecel

Type of Policy: **Drug Therapy**
Prior Approval Date: **N/A**
Approval Date: **02/01/2024**
Effective Date: **02/01/2024**
Related Policies: **Teplizumab**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Drugs Requiring Prior Authorization under the medical benefit

J3590 donislecel-JUJN, IV suspension

Overview/Summary of Evidence

Donislecel is the first allogeneic (donor) pancreatic islet cellular therapy made from deceased donor pancreatic cells. It is indicated for the treatment of adults with type 1 diabetes mellitus (T1DM) who are unable to approach target hemoglobin A1C because of current repeated episodes of severe hypoglycemia despite intensive T1DM management and education.

The primary mechanism of action of donislecel is believed to be secretion of insulin by infused (transplanted) pancreatic beta cells. 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 alpha and beta cell secretions; pancreatic peptide inhibits pancreatic exocrine secretion; and ghrelin inhibits insulin secretion.

Indications/Criteria

Type 1 Diabetes

Lantidra (donislecel) may be considered for coverage when:

- Prescribed by or in consultation with an endocrinologist
- Member is between18 years and <65 years of age
    - Safety and effectiveness has not been established in patients greater than 65 years of age
- Member has a confirmed diagnosis of Type 1 diabetes for more than 5 years AND one of the following complications:
    - Documentation of at least one episode of severe hypoglycemia in the past 3 years. Defined as:
        - Member required assistance from another person **AND**
        - Member had a blood glucose level <50mg/dL **OR**
        - Member recovered after oral carbohydrate, intravenous glucose or glucagon administration.
    - Reduced awareness of hypoglycemia
        - Defined as the absence of autonomic symptoms at capillary glucose levels of <54mg/dL.
- Documentation that member is unable to approach target HbA1c due to current repeated episodes of severe hypoglycemia.
- Documentation of intensive diabetes management and education.
- Documentation of PCP and CMV prophylaxis or Provider attestation that they will be provided.
- Documentation that member is up to date with all vaccinations prior to initiating therapy.
- Provider attestation that immunosuppression will continue permanently to prevent islet graft rejection.
- Documentation of negative T-cell and B-cell crossmatch assay.
    - Members with a positive T-cell and B-cell crossmatch between recipient serum and donor lymphocytes may reject the islet cells.
- If applicable, documentation of previous donislecel infusion including the date of infusion(s).

Initial approval for the first infusion will be for one infusion within 12 months.

Donislecel is eligible for 3 infusions total. **Extension requests** for a second or third infusion may be considered medically necessary when the following criteria are met in addition to updated clinical chart notes addressing all criteria above:

- A second infusion may be administered if the member 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. Approval will be for one infusion within 12 months.
    - Claims history is subject to review.
    - Not covered for members who experienced prior portal thrombosis, unless the thrombosis was limited to second- or third-order portal vein branches

- A third infusion may be administered using the same criteria as the second infusion. Approval will be for one infusion within 12 months.
    - Claims history is subject to review.
    - Not covered for members who experienced prior portal thrombosis, unless the thrombosis was limited to second- or third-order portal vein branches

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Exclusions

The use of donislecel will not be covered for the following situations:

- Members whom immunosuppression is contraindicated.
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- More than 3 infusions per lifetime.
- Member is pregnant
- Renal failure
- Hepatic disease
    - Liver Function Tests (LFTs) outside normal range
- Not covered for members who experienced prior portal thrombosis, unless the thrombosis was limited to second- or third-order portal vein branches

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References

1. Clinical Pharmacology. Donislecel. Revision date July 21, 2023. Accessed December 5, 2023.

2. Lantidra. Package Insert. Cell Trans. Chicago IL. June 2023. Package Insert - LANTIDRA (fda.gov)

3. Results Posted | Islet Transplantation in Type 1 Diabetic Patients Using the Edmonton Protocol of Steroid Free Immunosuppression | ClinicalTrials.gov

4. Islet Transplantation for Brittle Type 1 Diabetes: The UIC Protocol - American Journal of Transplantation (amjtransplant.org)

5. Study Details | Islet Transplantation in Type 1 Diabetic Patients Using the University of Illinois at Chicago (UIC) Protocol | ClinicalTrials.gov