

Clinical Policy: Lantidra (donislecel): Allogeneic Pancreatic Islet Cellular Therapy

Reference Number: L.A.CP.MP.250

Date of Last Revision: 08/25

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

This policy describes the medical necessity criteria for Lantidra (donislecel), an allogeneic pancreatic islet cellular therapy, used for the treatment of type 1 diabetes in those who are unable to reach target hemoglobin A1c (HbA1c).¹

Policy/Criteria

- I. It is the policy of Louisiana Healthcare Connections that Lantidra (donislecel) is **medically necessary** when all of the following criteria are met:
 - A. Member/enrollee is ≥ 18 years of age;
 - B. Diagnosis of type 1 diabetes;
 - C. Member/enrollee is unable to approach target HbA1c due to current repeated episodes of severe hypoglycemia, despite intensive diabetes management and education;
 - D. Therapy will be used in conjunction with concomitant immunosuppression;
 - E. No more than three infusions will be given;
 - F. Member/enrollee does not have concomitant diseases or conditions, including pregnancy, that contraindicate the procedure for Lantidra infusion or immunosuppression.

Background

Type 1 diabetes is a chronic autoimmune disease, characterized by the destruction of pancreatic beta cells, causing insulin deficiency.^{2,3} Intensive diabetes management is the standard of care for type 1 diabetes, and includes coordinating frequent blood glucose monitoring and insulin replacement with meals and activity.³ Type 1 diabetes requires lifelong insulin treatment, but some people have difficulty managing hyperglycemia without causing hypoglycemia, especially in those who develop hypoglycemia unawareness.² Insulin dosing becomes challenging in these situations, but Lantidra is a possible treatment option.²

In June 2023, the U.S. Food and Drug Administration (FDA) approved Lantidra, an allogeneic pancreatic islet cellular therapy.² Lantidra is produced from deceased donor pancreatic islet cells that include beta cells, which have the ability to produce and secrete insulin.¹ Lantidra is infused in the hepatic portal vein so that the infused cells are able to produce enough insulin to regulate blood glucose levels, eliminating the need for additional insulin administration.² The product is intended to be used in adult patients with type 1 diabetes who cannot reach target HbA1c due to having recurrent severe hypoglycemic episodes, despite intensive diabetes management and education.^{1,2} Additionally, immunosuppressive medicine is required to be taken before receiving Lantidra and needs to be continued after the infusion to keep the transplanted islet cells viable.¹

Two non-randomized, single-arm studies evaluated the safety and effectiveness of Lantidra and included a total of 30 enrollees with type 1 diabetes and hypoglycemic unawareness who received a minimum of one infusion and a maximum of three infusions. The studies found that 21 participants did not require insulin administration for one year or longer, 11 participants did not require insulin administration for one to five years, and 10 participants did not require insulin administration for over five years. Additionally, five of the total participants continued to require insulin administration without any resulting days of insulin independence.²

Coding Implications

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HCPCS Codes	Description
J3590	Unclassified biologics

Reviews, Revisions, and Approvals	Review Date	Approval Date	Effective Date
Policy developed.	09/23	11/27/23	
Removed maximum age requirement from Criteria I.A.	3/24	5/22/24	
Annual review. References reviewed and updated. Reviewed by external specialist.	08/24	10/23/24	11/22/24
Annual review. References reviewed and updated.	08/25	10/20/25	11/20/25

References

1. Lantidra [package insert]. Chicago, IL: CellTrans Inc.; 2023.
2. U.S. Food and Drug Administration. FDA Approves First Cellular Therapy to Treat Patients with Type 1 Diabetes. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-cellular-therapy-treat-patients-type-1-diabetes>. Published June 28, 2023. Accessed June 23, 2025.
3. Weinstock RS. Management of blood glucose in adults with type 1 diabetes mellitus. UpToDate. www.uptodate.com. Published May 27, 2025. Accessed June 23, 2025.
4. Islet Transplantation in Type I Diabetic Patients Using the University of Illinois at Chicago (UIC) Protocol. National Institutes of Health. <https://clinicaltrials.gov/study/NCT03791567?intr=donislecel&rank=1>. Published March 16, 2022 (updated October 10, 2024). Accessed June 23, 2025.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program

CLINICAL POLICY

Lantidra (donislecel): Allogeneic Pancreatic Islet Cellular Therapy

approval status; evidence-based guidelines and positions of leading national health professions organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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