Clinical Policy: Lantidra (donislecel): Allogeneic pancreatic islet cellular therapy

Reference Number: MC.CP.MP.250
Date of Last Revision: 02/24

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]

The criteria below are taken from the Lantidra package insert, which includes safety data derived from two non-randomized studies that evaluated the safety and effectiveness of Lantidra in participants with type 1 diabetes and hypoglycemic unawareness.[1] The approval of Lantidra from the United States Food and Drug Administration (FDA) is based off examination of the risks and benefits of Lantidra, as evidenced by the results of these studies.[2] Current evidence, based on these two studies, indicates that Lantidra is an effective islet cellular therapy that can improve glycemic control, thus eliminating the need for insulin therapy and improving quality of life and can replace the need for whole pancreas transplantation.[1,2] The results of these studies demonstrate that the benefits of receiving Lantidra, when meeting the criteria below, outweigh the potential risk of adverse outcomes.

Note: *For criteria applicable to non-Medicare plans, please see CP.MP.250 Lantidra (donislecel): Allogeneic pancreatic islet cellular therapy.*

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that Lantidra (donislecel) is **medically necessary** when all of the following criteria are met[1,2,3]:
- 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
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics

Reviews, Revisions, and Approvals	Review Date	Approval Date
Policy developed.	02/24	02/24

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 January 31, 2024.
3. 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. Accessed February 01, 2024.
4. Weinstock RS. Management of blood glucose in adults with type 1 diabetes mellitus. UpToDate. www.uptodate.com. Published January 02, 2024. Accessed February 01, 2024.

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 approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.