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Effective 1/24/2026

Area Medical Policy

Lines Of Business All Lines of Business

Pancreatic Islet Cell Transplantation

PURPOSE:

This policy addresses emerging technology surrounding pancreatic islet cell transplantation. Please refer to the policy *Transplant Services* for information regarding solid organ transplants. Providers are encouraged to check eligibility and benefits prior to submitting any request for pancreatic islet cell transplantation as some plans limit certain types of services.

DEFINITIONS:

Allogeneic: Taken from different individuals of the same species. Also called allogenic. For this policy, it will refer to human cadaver cells.

Allogeneic transplantation: Islet cell allotransplantation is the transplantation of islet cells from a genetically non-identical donor of the same species. This type of transplantation is also known as allogeneic pancreatic islet cellular therapy

Autologous: (of cells or tissues) obtained from the same individual**.**

Bioartificial device (BAP): A bioartificial device is meant for long-term use and incorporates living cells. It combines biological components (insulin-secreting cells, or islets) with a synthetic device, such as a membrane or capsule, to create a hybrid therapy. The goal is to implant this device into the patient's body for long-term blood glucose regulation.

Ex-situ machine pancreas: Ex-situ machine pancreas infusion is a short-term process for evaluating or treating a donor pancreas outside the body. It involves using a machine to perfuse a donor pancreas with a warm, oxygenated solution outside of the body before it is transplanted.

Islet cell auto-transplantation, or autologous islet cell transplantation: The infusion of a patient's own pancreatic islet cells into the portal vein of the liver.

Islet Cell: According to the NIH National Cancer Institute an islet cell is a “pancreatic cell that produces hormones (e.g., insulin and glucagon) that are secreted into the bloodstream. These hormones help control

the level of glucose (sugar) in the blood. Also called endocrine pancreas cell and islet of Langerhans cell."

COVERAGE POLICY:

Pancreatic Islet Cell Allogeneic Transplantation (Allogeneic Pancreatic Islet Cellular Therapy)

Pancreatic islet cell allogeneic transplantation (allogeneic pancreatic islet cellular therapy) is covered under the following circumstances;

- Member is 18 years of age or older; and
- Member has type 1 diabetes and is unable to approach target hemoglobin A1C (HbA1c) due to current repeated episodes of severe hypoglycemia despite intensive diabetes management and education; and
- Lantidra will be used in conjunction with concomitant immunosuppression therapy (e.g., mycophenolate mofetil, sirolimus, tacrolimus); and
- Member has not received a renal transplant; and
- Administration has not exceeded a maximum of 3 infusions (transplants).
- Lantidra infusion (transplant) may be repeated when member meets all initial approval criteria and has not achieved independence from exogenous insulin within one year of infusion or within one year after losing independence from exogenous insulin after a previous infusion. (Note: There is no data regarding the effectiveness or safety for more than 3 infusions).
- Pancreatic islet cell allogeneic transplantation is considered **investigational and not medically necessary** when the above criteria are not met and for all other indications.

Note: Per CMS, Lantidra is only utilized in the inpatient setting and therefore does not have an individual HCPCS code. If it is needed, it would be billed under J3590 (unclassified biologics) or C9399 (unclassified drugs or biologicals).

Autologous Pancreas Islet Transplantation

Autologous pancreas islet transplantation is covered in the following circumstances:

- Autologous pancreas islet transplantation may be considered medically necessary as an adjunct to a total or near total pancreatectomy in individuals with severe chronic pancreatitis and cannot be managed by other treatments.
- Autologous pancreatic islet cell transplantation is considered **investigational and not medically necessary** when the above criteria are not met and for all other indications.
- Note: Allogeneic islet cell transplant using an FDA approved cellular therapy product (donislecel-juin [i.e., Lantidra]) is considered investigational for the treatment of type 1 diabetes

EXCLUSIONS/NON-COVERED SERVICES:

- Bioartificial pancreas device (BAP).
- Ex-situ machine pancreas perfusion (in hypothermic or normothermic settings) for pancreas transplantation.
- Pancreatic islet xenotransplantation.
- Islet transplantation, all other situations other than what is listed as covered in the Coverage Policy

section such as but not limited to; increased longevity and/or if primary indication is for life-style issues, i.e., a desire to no longer take insulin.

CODING GUIDELINES:

0584T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; ***percutaneous***
0585T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; ***laparoscopic***
0586T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; ***open***
G0341	Percutaneous islet cell transplant, includes portal vein catheterization and infusion
G0342	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion
G0343	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion
S2102	Islet cell tissue transplant from pancreas; allogeneic
No Specific code	Donislecel-hyphenjujn (Lantidra; CellTrans Inc) If it is needed, it would be billed under J3590 (unclassified biologics) or C9399 (unclassified drugs or biologicals).

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RELATED POLICIES:

Transplant Services Policy # 17718688

POLICY HISTORY:

01/01/2026 New

POST PAYMENT AUDIT STATEMENT:

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by THP at any time pursuant to the terms of your provider agreement.

DISCLAIMER:

This policy is intended to serve as a guideline only and does not constitute medical advice, any guarantee of payment, plan pre-authorization, an explanation of benefits, or a contract. This policy is intended to address medical necessity guidelines that are suitable for most individuals. Each individual's unique clinical situation may warrant individual consideration based on medical records. Individual claims may be affected by other factors, including but not necessarily limited to state and federal laws and regulations, legislative mandates, provider contract terms, and THP's professional judgment. Reimbursement for any services shall be subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification, and utilization management guidelines. Unless otherwise noted within the policy, THP's policies apply to both participating and non-participating providers and facilities. THP reserves the right to review and revise these policies periodically as it deems necessary in its discretion, and it is subject to change or termination at any time by THP. THP has full and final discretionary authority for its interpretation and application. Accordingly, THP may use reasonable discretion in interpreting and applying this policy to health

care services provided in any particular case.

All Revision Dates

12/10/2025

Approval Signatures

Step Description	Approver	Date
EMT		12/10/2025
MDOC		12/10/2025
	I	12/9/2025
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