

# Medical Policy



## Pancreatic Islet Cell Transplantation, Autologous, Allogeneic

Policy Number: PG0415  
Last Review: 12/01/2024

HMO AND PPO  
ELITE (MEDICARE ADVANTAGE)  
MARKETPLACE

### GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

### SCOPE:

☒ Professional  
☐ Facility

### DESCRIPTION:

Chronic pancreatitis (CP) is a progressive disease of the pancreas characterized by inflammation and fibrosis of the pancreatic parenchyma, the functional tissue of the gland. This leads to loss of exocrine (e.g., digestive enzymes) and endocrine (e.g., insulin and glucagon) functions, resulting in severe abdominal pain, maldigestion, and diabetes mellitus that can negatively impact quality of life (QOL).

Standard treatments for CP are not curative but rather aimed at relieving symptoms of pain, maldigestion, and exocrine/endocrine insufficiency. Analgesics are given for pain relief, with narcotics reserved for severe pain. For patients who do not respond to medical therapy, endoscopic therapy (e.g., pancreatic and biliary sphincterotomy [enlargement of the duct opening], stricture dilation and stenting, stone extraction, and lithotripsy) may be attempted. Surgery is an option for patients who continue to have debilitating symptoms despite optimal medical and endoscopic therapies. Common surgical indications include bile duct obstruction, gastric outlet obstruction, and pseudocyst formation. Procedures include lateral pancreaticojejunostomy, duodenum-preserving pancreatic head resection or pancreaticoduodenectomy (Whipple procedure), simple gastroenterostomy, and distal pancreatectomy.

Total pancreatectomy (TP) is the complete surgical removal of the pancreas, most often performed by open laparotomy, or occasionally by robotically assisted techniques. While TP relieves pain and other symptoms due to CP, complete pancreatic removal leads to a complete insulin and glucagon deficiency (type 3 diabetes) since the gland's islet cells play a role in regulating blood glucose levels and insulin release.

Autologous pancreatic islet cell transplantation involves a total or near-total pancreatectomy, separation of islet cells from pancreatic tissue, followed by islet cell reinfusion. This has been reported to decrease the incidence of diabetes mellitus following a total or near-total pancreatectomy.

Allogeneic pancreatic islet cell transplantation (allotransplantation) involves procurement of cadaver donor pancreatic islet cells, followed by infusion or implantation of the donor cells into the recipient (pancreatic islet cell allograft transplantation). This procedure is usually performed using percutaneous and laparoscopic techniques.

In islet cell autotransplantation (IAT), endocrine function and insulin secretion can be preserved by harvesting and transplanting islet cells from the patient's own resected pancreas. The islet cells are infused into the patient's portal vein during the open procedure or postoperatively by a percutaneous approach.

The rationale for TP/IAT is to relieve severe and intractable pain in patients with an impaired QOL due to CP or recurrent acute pancreatitis (RAP) who have not responded adequately to standard therapies (medical, endoscopic, or surgical) while preserving endocrine function. After TP, glycemic control is difficult to achieve with standard pharmacologic insulin therapy due to the loss of glucagon-dependent counter regulation. The harvesting and reinfusion of a sufficient mass of islet cells from the patient's resected pancreas through IAT is aimed at preserving endogenous insulin secretion.

Allogeneic islet transplantation potentially offers an alternative to whole-organ pancreas transplantation. In the case of allogeneic islet cell transplantation, cells are harvested from a deceased donor's pancreas, processed, and injected into the recipient's portal vein. Up to three donor pancreas transplants may be required to achieve insulin independence. However, a limitation of islet transplantation is that two or more donor organs are usually required for successful transplantation, although experimentation with single-donor transplantation is occurring. A pancreas that is rejected for whole-organ transplant is typically used for islet transplantation. Therefore, islet transplantation has generally been reserved for patients with frequent and severe metabolic complications who have consistently failed to achieve control with insulin-based management. Allogeneic transplantation may be performed in the radiology department.

#### **POLICY:**

##### **Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans**

Autologous pancreatic islet cell transplantation as an adjunct to a total or near total pancreatectomy or partial pancreatectomy requires prior authorization (48160)

Allogeneic is covered when in a clinical investigation trial. Allogeneic pancreatic islet cell transplantation, using FDA-approved donislecel (Lantidra), (G0341, G0342, G0343, 48999\*) is covered with a prior authorization when coverage criteria are met. Coverage will include the costs of acquisition and delivery of the pancreatic islet cells, as well as clinically necessary inpatient and outpatient medical care and immunosuppressants

Codes 0584T, 0585T, and 0586T are non-covered

#### **COVERAGE CRITERIA:**

##### **Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans**

Autologous pancreatic islet cell transplantation (48160) is considered medically necessary and eligible for reimbursement providing that all of the following criteria are met:

- Severe, chronic pancreatitis refractory to conventional medical therapy; and
- Performed as an adjunct to total or near-total pancreatectomy.

Islet transplantation is considered not medically necessary in all other situations, as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure is effective.

Allogeneic pancreatic islet cell transplantation, using FDA-approved donislecel (Lantidra) for hepatic portal vein infusion, (HCPCS Codes G0341, G0342, G0343, 48999\*) is considered medically necessary providing that ALL of the following are met:

For initial approval:

1. Age 18 years or older; and
2. Type 1 diabetes; and
3. Unable to approach target hemoglobin A1C due to current, repeated episodes of severe hypoglycemia,
4. particularly hypoglycemic unawareness, despite intensive diabetes management and education; and
5. Lantidra will be used in conjunction with immunosuppression therapy; and
6. No contraindications to the use of Lantidra (please see below for contraindications and important notes); and

7. Up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating Lantidra therapy; and
8. No active infections; and
9. Patient will not receive live vaccines during Lantidra therapy; and
10. Patient will be monitored for malignancy during Lantidra therapy; and
11. No history of portal vein thrombosis (excluding thrombosis limited to second- or third-order portal vein branches); and
12. No history of liver disease, renal failure, or renal transplant; and
13. Patient is T- and B-cell crossmatch assay negative.
14. Patient participating in a National Institutes of Health (NIH)-sponsored clinical trial(s). Partial pancreatic tissue
15. Transplantation or islet cell transplantation performed outside the context of a clinical trial is non-covered.

For continuation of therapy (not to exceed 3 infusions in total):

1. All initial approval criteria are met; and
2. Absence of unacceptable toxicity from drug; and
3. Patient 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.

Allogeneic pancreatic islet cell transplantation other than FDA approved donislecel (Lantidra) has not demonstrated equivalence or superiority to currently accepted standard means of treatment. Paramount considers allogeneic pancreatic islet cell transplantation **other than donislecel (Lantidra)** (CPT Code 48999\*, HCPCS Codes G0341, G0342, G0343) experimental/investigational and not eligible for reimbursement.

**CONTRAINDICATIONS:** Lantidra should not be administered to patients who have concomitant diseases or conditions, including pregnancy, that contraindicate the procedure for Lantidra infusion or immunosuppression.

#### IMPORTANT NOTES:

- Portal vein branch thrombosis may occur following infusion of Lantidra. Repeated intraportal islet infusions are not recommended in patients who have experienced prior portal thrombosis unless the thrombosis was limited to second- or third-order portal vein branches.
- For patients who may require a renal transplant in the future: Administration of Lantidra may elevate panel reactive antibodies and negatively impact candidacy for renal transplant.
- If a patient has been dependent on exogenous insulin for two years after their last infusion, then immunosuppression should be discontinued. However, the treatment team may consider continuation of immunosuppression if they determine that the patient has achieved target HbA1c without recurrent severe hypoglycemia in the presence of clinically relevant C-peptide, that provides a potential ongoing benefit that outweighs the risks of severe and potentially life-threatening effects of immunosuppression.

One or more pancreata are obtained from donor(s). The islets must be removed within hours after the recovery of the donor pancreas to ensure viability. The islet cells are transplanted by injection into the portal vein of the recipient either using direct visualization, guided ultrasound or percutaneously. The islet cell transplant may be performed alone, in combination with a kidney transplant, or after a kidney transplant. Islet recipients require immunosuppressant therapy to prevent rejection of the transplanted islet cells. Routine follow-up care is necessary for each trial participant.

Specifically, Paramount will cover transplantation of pancreatic islet cells, the insulin producing cells of the pancreas. Coverage will include the costs of acquisition and delivery of the pancreatic islet cells, as well as clinically necessary inpatient and outpatient medical care and immunosuppressants.

#### CODING/BILLING INFORMATION:

**The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other**

services rendered.

#### CPT CODES

<b>48160</b>	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells
<b>48999</b>	Unlisted procedure, pancreas * When unlisted procedure, pancreas (48999) is determined to be allogeneic pancreatic islet cell transplantation for donislecel (Lantidra).
<b>0584T</b>	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous
<b>0585T</b>	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic
<b>0586T</b>	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open

#### HCPCS CODES

<b>G0341</b>	Percutaneous islet cell transplant, includes portal vein catheterization and infusion
<b>G0342</b>	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion
<b>G0343</b>	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion

#### REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 10/27/2017

Date	Explanation & Changes
<b>10/27/2017</b>	<ul style="list-style-type: none"> <li>Autologous pancreatic islet cell transplantation (48160) for an individual undergoing total or near total pancreatectomy is covered with prior authorization for all product lines</li> <li>Allogeneic pancreatic islet cell transplantation (S2102) is non-covered for HMO, PPO, Individual Marketplace, &amp; Advantage</li> <li>Allogeneic pancreatic islet cell transplantation (S2102) is covered with prior authorization for Elite</li> <li>Codes G0341, G0342, &amp; G0343 are non-covered for all product lines</li> <li>Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)</li> </ul>
<b>10/25/2018</b>	Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
<b>12/28/2020</b>	Medical policy placed on the new Paramount Medical policy format
<b>01/01/2023</b>	<ul style="list-style-type: none"> <li>Policy reviewed and updated to reflect most current clinical evidence</li> <li>Paramount added procedure codes 0584T, 0585T, 0586T, 48999</li> <li>Paramount clarified Medicare Advantage Plans noncoverage for CPT code 48160</li> </ul>
<b>02/01/2023</b>	<ul style="list-style-type: none"> <li>Placed medical policy in the new format</li> </ul>
<b>12/01/2024</b>	<ul style="list-style-type: none"> <li>Medical Policy reviewed and updated to reflect the most current clinical evidence</li> <li>Added coverage, with prior authorization when criteria met, for Autologous pancreatic islet cell transplantation, for Medicare product lines</li> <li>Added coverage, with prior authorization when criteria met, for Allogeneic pancreatic islet transplantation, for Commercial product lines</li> <li>Removed S-code S2102, Paramount does not recognize/reimburse for S-codes</li> </ul>

**Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to**

<https://www.paramounthealthcare.com/providers/medical-policies/policy-library>

#### REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs>

National Physician Fee Schedule Relative Value File Calendar Year XXXX, Centers for Medicare & Medicaid Services (CMS) <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files>

NCCI Policy Manual for Medicare Services, current version, Chapter 1, General Correct Coding Policies <https://www.cms.gov/files/document/medicare-ncci-policy-manual-2023-chapter-1.pdf>

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

Centers for Medicare & Medicaid Services (CMS), ICD-10-CM Official Guidelines for Coding and Reporting <https://www.cms.gov/medicare/coding/icd10>

Centers of Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Chapter 23-Fee Schedule administration and coding Requirements <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf>

Centers for Medicare & Medicaid Services (CMS), National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services <https://www.cms.gov/medicare-medicare-coordination/national-correct-coding-initiative-ncci/ncci-medicare>

Center for Medicare and Medicaid Services, Medicare NCCI Medically Unlikely Edits (MUEs) <https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medically-unlikely-edits>  
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Industry Standard Review

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