

## Medical Coverage Policy | Islet Transplantation for Chronic Pancreatitis



**EFFECTIVE DATE:** 01|01|2026

**POLICY LAST REVIEWED:** 10|01|2025

### OVERVIEW

Performed in conjunction with pancreatectomy for chronic pancreatitis, autologous islet transplantation is proposed to reduce the likelihood of insulin-dependent diabetes. Allogeneic islet cell transplantation with donislecel-jujn is also being investigated as a treatment or cure for patients with type 1 diabetes.

### MEDICAL CRITERIA

Not applicable

### PRIOR AUTHORIZATION

Not applicable

### POLICY STATEMENT

#### Autologous Pancreas Islet Transplantation:

##### Medicare Advantage Plans and Commercial Products

Autologous pancreas islet transplantation is considered medically necessary as an adjunct to a total or near total pancreatectomy in individuals with chronic pancreatitis.

#### Allogeneic Islet Transplantation:

##### Medicare Advantage Plans

Allogeneic Pancreatic islet cell transplantation is covered for Medicare Advantage Plan individuals only as part of an approved clinical trial. Refer to Related Policies section.

**Note:** Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plan policies. Therefore, Medicare Advantage Plan policies may differ from Commercial Products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by the CMS.

##### Commercial Products

Allogeneic islet transplantation using an FDA-approved cellular therapy product (donislecel-jujn [ie, Lantidra]) is considered-medically necessary.

### COVERAGE

Benefits vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement, for applicable/transplant surgery/ benefits/coverage.

### BACKGROUND

Performed in conjunction with pancreatectomy, autologous islet transplantation is proposed to reduce the likelihood of insulin-dependent diabetes. Allogeneic islet cell transplantation is also being investigated as a treatment or cure for individuals with type 1 diabetes.

### Islet Transplantation

In autologous islet transplantation during the pancreatectomy procedure, islet cells are isolated from the resected pancreas using enzymes, and a suspension of the cells is injected into the portal vein of the patient's liver. Once implanted, the beta cells in these islets begin to make and release insulin.

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. Islet transplantation has generally been reserved for individuals 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. In 2000, a modified immunosuppression regimen increased the success of allogeneic islet transplantation. This regimen is known as the "Edmonton protocol."

The U.S. Food and Drug Administration (FDA) regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation Title 21, parts 1270 and 1271. Allogeneic islet cells are included in these regulations. Donislecel-jujn (Lantidra™), a first-in-class deceased donor-derived allogeneic pancreatic islet cellular therapy product, was approved by the FDA in June 2023 for the treatment of type 1 diabetes in adults who are unable to approach target hemoglobin A1c due to repeated episodes of severe hypoglycemia despite intensive diabetes management and education.

### Medicare Advantage Plans

Medicare covers pancreatic islet transplantation in individuals with type 1 diabetes participating in a clinical trial sponsored by the National Institutes of Health. Partial pancreatic tissue transplantation or islet transplantation performed outside a clinical trial are not covered.

### CODING

#### Medicare Advantage Plans and Commercial Products

The following CPT code(s) is covered:

**48160** Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells

The HCPCS code(s) listed below are allowed for Medicare Advantage Plans as part of a CMS approved clinical study. Claims for services rendered as part of a CMS approved clinical study must be billed with an appropriate modifier:

**Modifier Q0** – Investigational clinical service provided in a clinical research study that is in an approved research study (Medicare Advantage Plan claims filed without the Q0 modifier will deny as not covered)

**Modifier Q1** – Routine clinical service provided in a clinical research study that is in an approved clinical research study

**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

**Note:** If you are treating a Medicare Advantage Plan member as part of a CMS approved study, please follow the procedures for correct billing and coding of services found in the policy for Clinical Trials Medicare Advantage Plans.

The following code(s) are invalid for Medicare Advantage Plans and should be filed with the appropriate "G" code(s) above:

**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

**S2102** Islet cell tissue transplant from pancreas, allogeneic

### Commercial Products

The following CPT code(s) is covered

**48160** Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells

The following code(s) are covered:

**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

**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

**S2102** Islet cell tissue transplant from pancreas, allogeneic

### RELATED POLICIES

Clinical Trials Medicare Advantage Plans

Medicare Advantage Plans National and Local Coverage Determinations

### PUBLISHED

Provider Update, January/November 2025

Provider Update, February 2024

Provider Update, October 2022

Provider Update, April 2021

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