

DRAFT Medical Coverage Policy | Islet Transplantation for Chronic Pancreatitis and Donislecel-jujn for Type 1 Diabetes



EFFECTIVE DATE: 04|01|2024

POLICY LAST REVIEWED: 12|06|2023

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.

Islet transplantation is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products in all other situations as the evidence is insufficient to determine the effects of the technology on health outcomes.

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 not medically necessary for the treatment of type 1 diabetes as the evidence is insufficient to determine the effects of the technology on health outcomes.

Islet transplantation with donislecel-jujn in all other situations is not medically necessary for Commercial Products for the treatment of type 1 diabetes as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement, for applicable not medically necessary/not covered/transplant surgery/experimental/investigational 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.

For individuals with chronic pancreatitis undergoing total or near-total pancreatectomy who receive autologous pancreas islet transplantation, the evidence includes nonrandomized studies and systematic reviews. Relevant outcomes are overall survival (OS) change in disease status, medication use, resource utilization, and treatment-related morbidity. Autologous islet transplants are performed in the context of total or near-total pancreatectomies to treat intractable pain from chronic pancreatitis. The procedure appears to decrease significantly the incidence of diabetes after total or near-total pancreatectomy in patients with chronic pancreatitis. Also, this islet procedure is not associated with serious complications and is performed in patients who are already undergoing a pancreatectomy procedure. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with type 1 diabetes who receive allogeneic pancreas islet transplantation with donislecel-jujn, the evidence includes single-arm prospective trials conducted at a single study site without strict protocols demonstrating insulin independence for over 1 year in a majority of participants, with mean insulin independence of approximately 5 years, resulting in Food and Drug Administration approval of donislecel for adults who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education and for use in conjunction with concomitant immunosuppression. Additional well-designed studies are required to determine the effects of allogeneic islet transplantation in patients with type 1 diabetes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

The following CPT code(s) is covered with a diagnosis of Chronic Pancreatitis:

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

ICD-10 Diagnosis Code: **K86.1** Other Chronic Pancreatitis

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 with a diagnosis of chronic pancreatitis:

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

ICD-10 Diagnosis Code: **K86.1** Other Chronic Pancreatitis

The following code(s) are considered not medically necessary:

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
New Technology and Miscellaneous Services
NonReimbursable Health Service Codes

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Provider Update, February 2024
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