



Medical Policy

Islet Transplantation for Chronic Pancreatitis and Donislecel-jujn for Type 1 Diabetes

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Policy Number: 324

BCBSA Reference Number: 7.03.12 (For Plan internal use only)

Related Policies

- Insulin Delivery Devices, [#332](#)
- Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid, [#107](#)
- Allogeneic Pancreas Transplant, [#328](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Autologous pancreas islet transplantation may be considered **MEDICALLY NECESSARY** as an adjunct to a total or near total pancreatectomy in individuals with chronic pancreatitis.

Allogeneic islet transplantation transplantation using an FDA-approved cellular therapy product (donislecel-jujn [ie, Lantidra]) is considered **INVESTIGATIONAL** for the treatment of type 1 diabetes.

Islet transplantation with donislecel-jujn is considered **INVESTIGATIONAL** in all other situations.

Policy Guidelines

Only adult subjects were enrolled in donislecel-jujn (Lantidra) clinical studies, although clinical studies did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger patients. Risks of donislecel-jujn infusion in pregnancy has not been assessed.

There are risks associated with the infusion procedure and long-term immunosuppression. There is no evidence of donislecel-jujn benefit for individuals whose diabetes is well-controlled with insulin therapy or for those with hypoglycemic unawareness who are able to prevent current repeated severe hypoglycemic events (neuroglycopenia requiring active intervention from a third party) using intensive diabetes management (including insulin, devices, and education).

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. There is no evidence to support donislecel-jujn for individuals with liver disease, renal failure, or who have received a renal transplant.

Islet transplantation does not supplant future whole pancreatic transplantation (see policy [328 Allogeneic Pancreas Transplant prn.pdf](#)).

A specific target of HbA1c cannot be provided for all patients, as the target can be different based on age, duration of diabetes, and diabetic complications.

"Current repeated episodes" indicates risk within 1 year of the intended transplantation and is not related to events more than 1 year prior to the intended transplantation.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This procedure is performed in the inpatient setting.
Commercial PPO and Indemnity	This procedure is performed in the inpatient setting.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
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
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells

HCPCS Codes

HCPCS codes:	Code Description
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

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
3E030U0	Introduction of Autologous Pancreatic Islet Cells into Peripheral Vein, Open Approach
3E030U1	Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Open Approach
3E033U0	Introduction of Autologous Pancreatic Islet Cells into Peripheral Vein, Percutaneous Approach
3E033U1	Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Percutaneous Approach

Description

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.¹ 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 patients with type 1 diabetes.² 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 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.

In 2000, a modified immunosuppression regimen increased the success of allogeneic islet transplantation. This regimen is known as the "Edmonton protocol."

Summary

Description

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.

Summary of Evidence

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.

Policy History

Date	Action
11/2024	Annual policy review. References updated. Policy statements unchanged.

2/2024	Annual policy review. References added. Policy title updated and investigational statement added for use of donislecel-jujn in type 1 diabetes. Effective 2/1/2024.
10/2022	Annual policy review. References added. Minor editorial refinements to policy statement; intent unchanged.
9/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
10/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2020	Clarified coding information.
10/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
11/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2017	Annual policy review. New references added.
7/2015	Annual policy review. New references added.
10/2014	Annual policy review. New investigational indications described. Effective 10/1/2014.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
4/2014	Coding information clarified.
8/2013	Annual policy review. New references added.
11/2011 -4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group - Gastroenterology, Nutrition, and Organ Transplantation. No changes to policy statement.
5/2011	New policy effective 5/2011 describing ongoing non-coverage.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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