



MASSACHUSETTS

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Medical Policy Islet Transplantation

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Policy Number: 324

BCBSA Reference Number: 7.03.12

NCD/LCD: National Coverage Determination (NCD) for Islet Cell Transplantation in the Context of a Clinical Trial (260.3.1)

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 patients with chronic pancreatitis.

Allogeneic islet transplantation is considered **INVESTIGATIONAL** for the treatment of type 1 diabetes.

Islet transplantation is considered **INVESTIGATIONAL** in all other situations.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance can be found through the link below.

[National Coverage Determination \(NCD\) for Islet Cell Transplantation in the Context of a Clinical Trial \(260.3.1\)](#)

Prior Authorization Information

Pre-service approval is required for all inpatient services for all products.

See below for situations where prior authorization may be required or may not be required for outpatient services.

Yes indicates that prior authorization is required.

No indicates that prior authorization is not required.

N/A indicates that this service is primarily performed in an inpatient setting.

Outpatient

Commercial Managed Care (HMO and POS)	N/A
Commercial PPO and Indemnity	N/A

Medicare HMO Blue SM	N/A
Medicare PPO Blue SM	N/A

CPT Codes / HCPCS Codes / ICD Codes

The following codes are included below for informational purposes. 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.

CPT Codes

CPT codes:	Code Description
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

CHRONIC PANCREATITIS

Primary risk factors for chronic pancreatitis may be categorized as the following: toxic-metabolic, idiopathic, genetic, autoimmune, recurrent and severe acute, or obstructive (TIGAR-O classification system). Patients with chronic pancreatitis may experience intractable pain that can only be relieved with a total or near total pancreatectomy. However, the pain relief must be balanced against the certainty that the patient will be rendered an insulin-dependent diabetic.

TYPE 1 DIABETES

Glucose control is a challenge for individuals with type 1 diabetes. Failure to prevent disease progression can lead to long-term complications such as retinopathy, neuropathy, nephropathy, and cardiovascular disease.¹

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. Up to 3 donor pancreas transplants may be required

to achieve insulin independence. However, a limitation of islet transplantation is that 2 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. In 2000, a modified immunosuppression regimen increased the success of allogeneic islet transplantation. This regimen is known as the “Edmonton protocol.”

Summary

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 patients with type 1 diabetes.

For individuals with chronic pancreatitis undergoing total or near total pancreatectomy who receive autologous pancreas islet transplantation, the evidence includes case series and systematic reviews. Relevant outcomes are overall survival, 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 a meaningful improvement in the net health outcome.

For individuals with type 1 diabetes who receive allogeneic pancreas islet transplantation, the evidence includes a randomized controlled trial, case series, and systematic reviews. Relevant outcomes are overall survival, change in disease status, medication use, resource utilization, and treatment-related morbidity. Results of a 2018 randomized trial have suggested some reduction in the number of severe hypoglycemic incidence annually, but limited follow-up and other trial limitations reduce the certainty in conclusions drawn. A wide range of insulin independence has been reported in case series. There is conflicting evidence whether allogeneic islet transplantation reduces long-term diabetic complications. Long-term comparative studies are required to determine the effects of allogeneic islet transplantation in type 1 diabetics. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
11/2018	BCBSA National medical policy review. Description, summary and references updated. Policy statement unchanged.
10/2018	BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified.
9/2017	New references added from BCBSA National medical policy.
7/2015	New references added from BCBSA National medical policy.
10/2014	BCBSA National medical 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	New references from BCBSA National medical policy.
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](#)

References

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