



## Medical Policy

### Islet Transplantation

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#### Policy Number: 324

New Policy Number: 7.03.12

#### 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 **MEDICALLY NECESSARY** as an adjunct to a total or near total pancreatectomy in patients with chronic pancreatitis.

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

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

##### Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

###### Indications and Limitations of Coverage

###### Nationally Covered Indications

Medicare will pay for the routine costs, as well as transplantation and appropriate related items and services, for Medicare beneficiaries participating in a National Institutes of Health (NIH)-sponsored clinical trial(s). The term 'routine costs' means reasonable and necessary routine patient care costs, including immunosuppressive drugs and other follow-up care, as defined in section 310.1 of the NCD Manual.

Specifically, Medicare 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.

###### Nationally Noncovered Indications

Partial pancreatic tissue transplantation or islet cell transplantation performed outside the context of a clinical trial continues to be noncovered.

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

<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=286&ncdver=1&bc=AgAAgAAAAAA&>

**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.

	<b>Outpatient</b>
<b>Commercial Managed Care (HMO and POS)</b>	N/A
<b>Commercial PPO and Indemnity</b>	N/A
<b>Medicare HMO Blue<sup>SM</sup></b>	N/A
<b>Medicare PPO Blue<sup>SM</sup></b>	N/A

**CPT Codes / HCPCS Codes / ICD-9 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. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

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

**CPT Codes**

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

**HCPCS Codes**

<b>HCPCS codes:</b>	<b>Code Description</b>
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-9 Procedure Codes**

<b>ICD-9-CM procedure codes:</b>	<b>Code Description</b>
52.84	Autotransplantation of cells of Islets of Langerhans
52.85	Allotransplantation of cells of Islets of Langerhans

**ICD-10 Procedure Codes**

<b>ICD-10-PCS procedure codes:</b>	<b>Code Description</b>
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

Autologous islet transplantation, performed in conjunction with pancreatectomy, is proposed to reduce the likelihood of insulin-dependent diabetes. Moreover, allogeneic islet cell transplantation is being investigated as a treatment or cure for patients with type 1 diabetes.

## Background

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. In the case of allogeneic islet cell transplantation, cells are harvested from the 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. Allogeneic transplantation may be performed in the radiology department.

## Chronic pancreatitis

Primary risk factors for chronic pancreatitis include toxic-metabolic, idiopathic, genetic, autoimmune, recurrent and severe acute pancreatitis, or obstructive (the 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. Autologous islet transplantation has been investigated as a technique to prevent this serious morbidity.

## Type 1 diabetes

Allogeneic islet transplantation has been used for type 1 diabetes to restore normoglycemia and, ultimately, to reduce or eliminate the long-term complications of diabetes such as retinopathy, neuropathy, nephropathy, and cardiovascular disease. Islet transplantation potentially offers an alternative to whole-organ pancreas transplantation. 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.

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

## Summary

Autologous islet transplantation is proposed in conjunction with pancreatectomy for patients with chronic pancreatitis. Although the published experience with autologous islet cell transplantation is limited, the procedure appears to significantly decrease the incidence of diabetes after total or near total pancreatectomy in patients with chronic pancreatitis. In addition, this procedure is not associated with serious complications itself and is performed as an adjunct to the pancreatectomy procedure. Thus, this may be considered medically necessary.

The techniques for allogeneic islet cell transplants are evolving, and the impact on the net health outcome is still uncertain. Moreover, longer follow-up with larger numbers of patients is needed before conclusions can be drawn about the safety of allogeneic islet transplantation and its impact on diabetes mellitus and

associated complications. Thus, this technology is considered investigational for patients with diabetes type 1.

## Policy History

Date	Action
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](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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