Medical Policy
Islet Transplantation

Table of Contents
- Policy: Commercial
- Policy: Medicare
- Authorization Information
- Coding Information
- Description
- Policy History
- Information Pertaining to All Policies
- References

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 **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℠ and Medicare PPO Blue℠ 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)

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.

<table>
<thead>
<tr>
<th>Outpatient</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>N/A</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>N/A</td>
</tr>
<tr>
<td>Medicare HMO Blue&lt;sup&gt;SM&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>Medicare PPO Blue&lt;sup&gt;SM&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>48160</td>
<td>Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells</td>
</tr>
</tbody>
</table>

HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0341</td>
<td>Percutaneous islet cell transplant, includes portal vein catheterization and infusion</td>
</tr>
<tr>
<td>G0342</td>
<td>Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion</td>
</tr>
<tr>
<td>G0343</td>
<td>Laparotomy for islet cell transplant, includes portal vein catheterization and infusion</td>
</tr>
</tbody>
</table>

ICD-10 Procedure Codes

<table>
<thead>
<tr>
<th>ICD-10-PCS procedure codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3E030U0</td>
<td>Introduction of Autologous Pancreatic Islet Cells into Peripheral Vein, Open Approach</td>
</tr>
<tr>
<td>3E030U1</td>
<td>Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Open Approach</td>
</tr>
<tr>
<td>3E033U0</td>
<td>Introduction of Autologous Pancreatic Islet Cells into Peripheral Vein, Percutaneous Approach</td>
</tr>
<tr>
<td>3E033U1</td>
<td>Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Percutaneous Approach</td>
</tr>
</tbody>
</table>

Description
CHRONIC PANCREATITIS
Primary risk factors for chronic pancreatitis include 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.

**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 autologous 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**
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 an RCT, 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**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/2017</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>7/2015</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>4/2014</td>
<td>Coding information clarified.</td>
</tr>
<tr>
<td>8/2013</td>
<td>New references from BCBSA National medical policy.</td>
</tr>
</tbody>
</table>
No changes to policy statement.

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

References