Medical Policy
Allogeneic Pancreas Transplant

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Policy Number: 328
BCBSA Reference Number: 7.03.02
NCD/LCD: National Coverage Determination (NCD) for Pancreas Transplants (260.3)

Related Policies
- Kidney Transplant, #196
- Islet Transplantation, #324

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

A combined pancreas-kidney transplant may be MEDICALLY NECESSARY in insulin dependent diabetic patients with uremia.

Pancreas transplant after a prior kidney transplant may be MEDICALLY NECESSARY in patients with insulin dependent diabetes.

Pancreas transplant alone may be MEDICALLY NECESSARY in patients with severely disabling and potentially life-threatening complications due to hypoglycemia unawareness and labile insulin-dependent diabetes that persists in spite of optimal medical management.

Pancreas retransplant after a failed primary pancreas transplant may be MEDICALLY NECESSARY in patients who meet criteria for pancreas transplantation.

In addition to the above information, we do not cover pancreas transplantation when any of the following conditions are present:
- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
Note: the assessment of risk of recurrence for a previously treated malignancy is made by the transplant team; providers must submit a statement with an explanation of why the patient with a recently treated malignancy is an appropriate candidate for a transplant.

- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage disease not attributed to kidney disease
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

Candidates for pancreas transplant alone should additionally meet 1 of the following severity of illness criteria:

- Documentation of severe hypoglycemia unawareness as evidenced by chart notes or emergency department visits; OR
- Documentation of potentially life-threatening labile diabetes, as evidenced by chart notes or hospitalization for diabetic ketoacidosis.

In addition, most pancreas transplant patients will have type 1 diabetes mellitus. Those transplant candidates with type 2 diabetes mellitus, in addition to being insulin-dependent, should also not be obese (body mass index [BMI] should be 32 or less).

Pancreas transplant is considered INVESTIGATIONAL in all other situations.

**Medicare HMO Blue℠ and Medicare PPO Blue℠ Members**

**Nationally Covered Indications**

Effective for services performed on or after July 1, 1999, whole organ pancreas transplantation is nationally covered by Medicare when performed simultaneous with or after a kidney transplant. If the pancreas transplant occurs after the kidney transplant, immunosuppressive therapy begins with the date of discharge from the inpatient stay for the pancreas transplant.

Effective for services performed on or after April 26, 2006, pancreas transplants alone (PA) are reasonable and necessary for Medicare beneficiaries in the following limited circumstances:

1. PA will be limited to those facilities that are Medicare-approved for kidney transplantation. (Approved centers can be found at [http://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations/index.html](http://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations/index.html))
2. Patients must have a diagnosis of type I diabetes:
   - Patient with diabetes must be beta cell autoantibody positive; or
   - Patient must demonstrate insulinopenia defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose ≤ 225 mg/dL;
3. Patients must have a history of medically-uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization. Aforementioned complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;
4. Patients must have been optimally and intensively managed by an endocrinologist for at least 12 months with the most medically-recognized advanced insulin formulations and delivery systems;
5. Patients must have the emotional and mental capacity to understand the significant risks associated with surgery and to effectively manage the lifelong need for immunosuppression; and
6. Patients must otherwise be a suitable candidate for transplantation.
Nationally Non-Covered Indications
Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial (see section 260.3.1 of the National Coverage Determinations Manual).

National Coverage Determination (NCD) for Pancreas Transplants (260.3)

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 indicated that this services is primarily performed in an inpatient setting.

| Outpatient | Commercial Managed Care (HMO and POS) | NA |
| Commercial PPO and Indemnity | NA |
| Medicare HMO BlueSM | NA |
| Medicare PPO BlueSM | NA |

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, and Indemnity:

CPT Codes
| CPT codes: | Code Description |
| 48554 | Transplantation of pancreatic allograft |

HCPCS Codes
| HCPCS codes: | Code Description |
| S2065 | Simultaneous pancreas kidney transplantation |

ICD-9 Procedure Codes
| ICD-9-CM procedure codes: | Code Description |
| 52.80 | Pancreatic transplant, not otherwise specified |
| 52.81 | Reimplantation of pancreatic tissue |
Heterotransplant of pancreas

ICD-10 Procedure Codes

<table>
<thead>
<tr>
<th>ICD-10-PCS procedure codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>0FYG0Z0</td>
<td>Transplantation of Pancreas, Allogeneic, Open Approach</td>
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<tr>
<td>0FSG0ZZ</td>
<td>Reposition Pancreas, Open Approach</td>
</tr>
<tr>
<td>0FSG4ZZ</td>
<td>Reposition Pancreas, Percutaneous Endoscopic Approach</td>
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**Description**

Achievement of insulin independence with resultant decreased morbidity and increased quality of life is the primary health outcome of pancreas transplantation. While pancreas transplantation is generally not considered a life-saving treatment, in a small subset of patients who experience life-threatening complications from diabetes, pancreas transplantation could be considered life-saving. Pancreas transplant alone (PTA) has also been investigated in patients following total pancreatectomy for chronic pancreatitis. In addition to the immune rejection issues common to all allograft transplants, autoimmune destruction of beta cells has been observed in the transplanted pancreas, presumably from the same mechanism responsible for type 1 diabetes.²

Pancreas transplantation occurs in several different scenarios such as: (1) a diabetic patient with renal failure who may receive a cadaveric simultaneous pancreas/kidney (SPK) transplant; (2) a diabetic patient who may receive a cadaveric or living-related pancreas transplant after a kidney transplantation (pancreas after kidney [PAK]); or (3) a nonuremic diabetic patient with specific severely disabling and potentially life-threatening diabetic problems who may receive a PTA. The total number of adult pancreas transplants (pancreas and pancreas/kidney) in the United States peaked at 1484 in 2004; the number has since declined.³ In 2013, 214 PTAs and 651 SPKs were performed in the United States.

According to International Registry data, the proportion of pancreas transplant recipients worldwide who have type 2 diabetes has increased over time, from 2% in 1995 to 7% in 2010.¹ In 2010, approximately 8% of SPK, 5% of PAK, and 1% of PTA were performed in patients with type 2 diabetes.

The approach to retransplantation varies according to the cause of failure. Surgical/technical complications such as venous thrombosis are the leading cause of pancreatic graft loss among diabetic patients. Graft loss from chronic rejection may result in sensitization, increasing both the difficulty of finding a cross-matched donor and the risk of rejection of a subsequent transplant. Each center has its own guidelines based on experience; some transplant centers may wait to allow reconstitution of the immune system before initiating retransplant with an augmented immunosuppression protocol.

**Summary**

Transplantation of a normal pancreas is a treatment method for patients with insulin-dependent diabetes mellitus. Pancreas transplantation can restore glucose control and is intended to prevent, halt, or reverse the secondary complications from diabetes mellitus.

The literature, consisting primarily of case series and registry data, demonstrate graft survival rates comparable with other solid organ transplants, as well as attendant risks associated with the immunosuppressive therapy necessary to prevent allograft rejection. No randomized controlled trials have compared any form of pancreas transplant with insulin therapy. Pancreas transplant may be considered medically necessary in patients who are undergoing, or have undergone, kidney transplantation for renal failure. It may also be considered medically necessary as a standalone treatment in patients with
hypoglycemia unawareness and labile diabetes, despite optimal medical therapy and in whom severe complications have developed.

**Policy History**

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<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>5/2015</td>
<td>Clarified coding language.</td>
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<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<tr>
<td>4/2008</td>
<td>BCBSA National medical policy review. No changes to policy statements.</td>
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**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**


4. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Pancreas Transplantation. TEC Assessments. 1998;Volume 13, Tab 7. PMID

5. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Pancreas Retransplantation. TEC Assessments. 2001;Volume 16, Tab 23. PMID


