Medical Policy
Allogeneic Pancreas Transplant

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Policy Number: 328
BCBSA Reference Number: 7.03.02

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).

**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)

http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=107&ncdver=3&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCD&PolicyType=Final&s=24&Cntctr=205*1%7c208*1&KeyWord=pancreas+transplantation&KeyWordLookUp=Doc&KeyWordSearchType=Or&ICD=52.80&kq=true&bc=IAAAABAAAAA&

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.

<table>
<thead>
<tr>
<th>Provider Type</th>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>NA</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>NA</td>
</tr>
<tr>
<td>Medicare HMO Blue℠</td>
<td>NA</td>
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<tr>
<td>Medicare PPO Blue℠</td>
<td>NA</td>
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</tbody>
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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

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>48554</td>
<td>Transplantation of pancreatic allograft</td>
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HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>S2065</td>
<td>Simultaneous pancreas kidney transplantation</td>
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ICD-9 Procedure Codes

<table>
<thead>
<tr>
<th>ICD-9-CM procedure codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>52.80</td>
<td>Pancreatic transplant, not otherwise specified</td>
</tr>
<tr>
<td>52.81</td>
<td>Reimplantation of pancreatic tissue</td>
</tr>
<tr>
<td>52.83</td>
<td>Heterotransplant of pancreas</td>
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</table>

ICD-10 Procedure Codes

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<tr>
<th>ICD-10-PCS procedure</th>
<th>Code Description</th>
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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. Pancreas transplantation can restore glucose control and is intended to prevent, halt, or reverse the secondary complications of type 1 diabetes mellitus. While pancreas transplantation is generally not considered a life-saving treatment, in a small subset of patients who experience life-threatening complications from type 1 diabetes, pancreas transplantation could be considered life-saving. Pancreas transplant alone has also been investigated in patients following total pancreatectomy for chronic pancreatitis.

Simultaneous pancreas/kidney transplants are done most often because of the immunosuppression required post transplant and the side effects incurred upon each individual organ if already in a compromised state. Many physicians are reluctant to transplant a pancreas alone for diabetes without renal failure feeling that the side effects of the immunosuppressant drugs are more detrimental than the complications of diabetes. Pancreas transplantation occurs in several different scenarios such as: 1) a type 1 diabetic patient with renal failure who may receive a cadaveric simultaneous pancreas/kidney transplant (SPK); or 2) a type 1 diabetic patient who may receive a cadaveric or living-related pancreas transplant after a kidney transplantation (pancreas after kidney, i.e., PAK); or 3) a non-uremic type 1 diabetic patient with specific severely disabling and potentially life-threatening diabetic problems who may receive a PTA. The experience with SPK transplants is more extensive than that of other transplant options. After the double transplant is performed, there is an 80 percent to 85 percent chance that the patient will require no insulin and no dialysis for one year. In addition, there is a 70 percent chance that this success will continue over the next five years. The results from a pancreas transplant alone are very similar.

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.

Summary
The literature, primarily consisting of case series and registry data, demonstrate graft survival rates comparable to other solid organ transplants, as well as attendant risks associated with the immunosuppressive therapy necessary to prevent allograft rejection. Recent papers highlight research in the areas of surgical technique, immunosuppressive regimens, and cellular-based alternative therapies. No randomized controlled trials compare any form of pancreas transplant to insulin therapy; the PANCREAS trial (NCT01067950) is currently recruiting patients to compare isolated pancreas transplant to intensive insulin therapy in nonuremic diabetic patients with poorly controlled diabetes. 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 stand-alone treatment in patients with hypoglycemia unawareness and labile diabetes despite optimal medical therapy and in whom severe complications have developed. Pancreas transplantation is not medically necessary in patients in whom the procedure is expected to be futile due to comorbid disease or in whom post-transplantation care is expected to significantly worsen comorbid conditions.
Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<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