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
• Artificial Pancreas Device Systems, #720
• 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 BlueSM and Medicare PPO BlueSM Members**

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

[National Coverage Determination (NCD) for Pancreas Transplants (260.3)](https://www.hcfa.gov/CoveredServices/HCPCScontent.html)

**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).

**Prior Authorization Information**

**Inpatient**

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed inpatient.

**Outpatient**

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed outpatient.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Outpatient</th>
<th>This procedure is performed in the inpatient setting.</th>
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<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>Outpatient</td>
<td>This procedure is performed in the inpatient setting.</td>
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<tr>
<td>Medicare HMO BlueSM</td>
<td>Outpatient</td>
<td>This procedure is performed in the inpatient setting.</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>Outpatient</td>
<td>This procedure is performed in the inpatient setting.</td>
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**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 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**

<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-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>
</tr>
<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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</tbody>
</table>

**Description**

Pancreas transplantation occurs in several different scenarios such as (1) a diabetic patient with renal failure who may receive a simultaneous cadaveric pancreas plus kidney transplants; (2) a diabetic patient who may receive a cadaveric or living-related pancreas transplant after a kidney transplantation (pancreas after kidney); or (3) a nonuremic diabetic patient with specific severely disabling and potentially life-threatening diabetic problems who may receive a pancreas transplant alone. The total number of adult pancreas transplants (pancreas and pancreas plus kidney) in the U. S. peaked at 1484 in 2004 and has since steadily declined. In 2017, 213 received a pancreas transplant alone and 789 simultaneous pancreas plus kidneys were performed in the U. S.

According to the International Pancreas Transplant 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. In 2010, approximately 8% of simultaneous pancreas plus kidney transplants, 5% of pancreas transplant after kidney transplant, and 1% of a pancreas transplant alone were performed in patients with type 2 diabetes.

**Summary**

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

For individuals who have insulin-dependent diabetes who receive a pancreas transplant after a kidney transplant, the evidence includes case series and registry studies. The relevant outcomes are overall survival (OS), change in disease status, and treatment-related mortality and morbidity. Data from national and international registries have found relatively high patient survival rates with a pancreas transplant after a kidney transplant (eg, a 3-year survival rate of 93%). A 2012 analysis of data from a single-center found similar patient survival and death-censored pancreas graft survival rates with a pancreas transplant.
after a kidney transplant or a simultaneous pancreas and kidney (SPK) transplant. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have insulin-dependent diabetes with uremia who receive SPK transplants, the evidence includes registry studies. The relevant outcomes are OS, change in disease status, and treatment-related mortality and morbidity. Data from national and international registries have found relatively high patient survival rates after SPK transplant. A retrospective analysis found a higher survival rate in patients with type 1 diabetes who had an SPK transplant vs those on a waiting list. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have insulin-dependent diabetes and severe complications who receive pancreas transplant alone, the evidence includes registry studies. The relevant outcomes are OS, change in disease status, and treatment-related mortality and morbidity. Data from international and national registries have found that graft and patient survival rates after pancreas transplant alone have improved over time (e.g., 3-year survival of 95%). The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have had a prior pancreas transplant who still meet criteria for a pancreas transplant who receive pancreas retransplantation, the evidence includes case series and registry studies. The relevant outcomes are OS, change in disease status, and treatment-related mortality and morbidity. National data and specific transplant center data have generally found similar graft and patient survival rates after pancreas retransplantation compared with initial transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Policy History**

<table>
<thead>
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<th>Date</th>
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<tbody>
<tr>
<td>9/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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<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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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


