

Corporate Medical Policy

Pancreas Transplant

File Name:	pancreas_transplant
Origination:	1/2000
Last CAP Review:	4/2008
Next CAP Review:	10/2011
Last Review:	11/2010

Description of Procedure or Service

This policy addresses three different transplantation services: 1) a simultaneous pancreas and kidney transplant; 2) a pancreas transplant some time following a kidney transplant; and 3) a pancreas transplant alone.

Transplantation of a normal pancreas is a treatment method for patients with diabetes mellitus. Pancreas transplantation can restore glucose control and is intended to prevent, halt, or reverse the secondary complications of type 1 diabetes mellitus. Achievement of insulin independence with resultant decreased morbidity and increased quality of life is the primary health outcome. 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 transplantation occurs in several different clinical situations such as:

- 1) a type 1 diabetic patient with renal failure who may receive a cadaveric simultaneous pancreas/kidney transplant (SPK);
- 2) a type 1 diabetic patient who may receive a cadaveric or living-related pancreas 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 pancreas transplant alone (PTA).

The experience with SPK transplant is more extensive than that of other transplant options.

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.

This policy does not address autologous islet cell transplantation. Refer to the policy: Islet Transplantation.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Pancreas Transplantation, (a pancreas alone, simultaneous with a kidney transplant, or following a kidney transplant) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

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Benefits Application

Please refer to Certificate language to determine if benefits are provided for pancreas transplant. There may be certificates which exclude benefits for pancreas transplant alone. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

See member's certificate for eligible coverage.

Coverage is not provided for organs sold rather than donated to a recipient.

Coverage is not provided for artificial organs or human organ transplant service for which the cost is covered or funded by governmental, foundation, or charitable grants.

When Pancreas Transplantation is covered

Listed below are the clinical indications for the three types of pancreas transplants:

- **Combined Pancreas-Kidney transplant** may be considered medically necessary in diabetic patients with uremia.
- **Pancreas transplant after a prior kidney transplant** may be considered **medically necessary** in patients with insulin dependent diabetes mellitus.
- **Pancreas transplant alone** may be considered **medically necessary** in patients with severely disabling and potentially life-threatening complications due to hypoglycemia (abnormally low level of glucose in the blood) unawareness and labile diabetes that persists in spite of optimal medical management.
- **Pancreas retransplant after a failed primary pancreas transplant** may be considered **medically necessary** for all three types of pancreas transplants (i.e., combined pancreas-kidney transplant, pancreas transplant after a prior kidney transplant, and pancreas transplant alone).

When Pancreas Transplantation is not covered

- 1) Pancreas transplants are not covered for indications other than those cited above.
- 2) Contraindications for the combined pancreas/kidney transplantation include the following:
 - poor physiologic age;
 - significant emotional problems that may impair the patient's ability to adhere to follow-up;
 - recent substance abuse;
 - current tobacco use (impairs wound and microvascular healing);
 - history of non-compliance with medical management;
 - lack of support to the extent that adequate follow-up and adherence to post operative treatment plan is impaired;
 - other major organ system disease or infection, including major vascular disease;
 - morbid obesity;
 - uncontrolled HIV positive patients.

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Policy Guidelines

It is recommended that all transplant requests be reviewed by the Plan Medical Director or his or her designee. Only those patients accepted for transplantation by an approved transplantation center and actively listed for transplant should be considered for precertification or prior approval. Guidelines should be followed for transplant network or consortiums, if applicable.

Guidelines should be followed for transplant networks, where applicable.

Candidates for **any type** of pancreas transplant should meet **ALL** of the following criteria:

- A.) Adequate cardiopulmonary status, and
- B.) Absence of active infection, and
- C.) Absence of uncontrolled HIV infection. HIV infection is considered controlled when the following criteria are met:
 - 1) the CD4 count >200 cells/mm³ for >6 months; and
 - 2) the HIV-1 RNA undetectable; and
 - 3) the patient is stable on anti-retroviral therapy >3 months; and
 - 4) the patient has no other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm; and
- D.) No history of malignancy within 5 years of transplantation, excluding nonmelanomatous skin cancers, and
- E.) Documentation of patient compliance with medical management.

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

- 1) documentation of severe hypoglycemia unawareness as evidence by chart notes or emergency room visits; OR
- 2) documentation of potentially life-threatening labile diabetes as evidenced by chart notes or hospitalization for diabetic ketoacidosis.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 48160, 48550, 48551, 48552, 48554, 48556, 50300, 50320, S2065, S2152

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual - 12/95

BCBSA Medical Policy Reference Manual - 4/1/98

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Medical Policy Advisory Group - 11/98

Medical Policy Advisory Group - 12/99

Specialty Matched Consultant Advisory Panel - 9/2000

Medical Policy Advisory Group - 10/2000

BCBSA Medical Policy Reference Manual, 2/15/2002; 7.03.02

Specialty Matched Consultant Advisory Panel - 6/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.02, 10/9/2003.

Specialty Matched Consultant Advisory Panel - 5/2004

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.02, 9/27/2005

Specialty Matched Consultant Advisory Panel - 4/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.02, 2/14/2008

Specialty Matched Consultant Advisory Panel - 4/2008

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.02, 4/24/09

Policy Implementation/Update Information

For Pancreas/Kidney transplant

11/90 Evaluated: Investigational when performed without a kidney transplant or after a kidney transplant. Simultaneous pancreas and kidney transplantation is considered eligible for coverage.

Local Review Dates:

1/93 Reviewed: PCP Physician Advisory Group

11/94 Reviewed: PCP Physician Advisory Group

11/95 Reviewed: PCP Physician Advisory Group

12/95 Evaluated: Confirmed policy

5/96 Evaluated: Confirmed policy

4/97 Added: Policy guidelines should be followed for transplant networks, where applicable. Also, coverage is not provided for artificial organs or human organ transplant services for which the cost is covered/funded by governmental, foundation, or charitable grants.

6/98 Reviewed: Comments regarding need to review member's individual certificate added.

9/99 Reformatted, Definition of Procedure or Service changed, Medical Term Definitions added, Combined Pancreas Transplant with Pancreas/Kidney Transplant.

For Pancreas transplant

5/85 Evaluated: Experimental/Investigative

8/88 Reviewed: Investigational

11/90 Evaluated: Investigational when performed without a kidney transplant or after a kidney transplant. Simultaneous pancreas and kidney transplantation is considered eligible for coverage.

Local Review Dates:

Pancreas Transplant

- 1/93 PCP Physician Advisory Group
- 11/94 PCP Physician Advisory Group
- 4/94 Evaluated: Confirmed policy; pancreas retransplantation considered investigational
- 11/95 PCP Physician Advisory Group
- 5/96 Evaluated: Confirmed policy. Pancreas transplantation remains investigational when performed alone
- 4/97 Reaffirmed
- 6/98 Reviewed: Adopted BCBS Association policy. Considered medically necessary for indications specified under Policy section. Pancreas retransplantation continues to be investigational. Refer to member's specific certificate language to see if pancreas transplant is a covered benefit. Certificate language will be updated on renewal.
- 9/99 Reformatted, Definition of Procedure or Service changed, Medical Term Definitions added, Combined Pancreas Transplant with Pancreas/Kidney Transplant.
- 12/99 Medical Policy Advisory Group
- 10/00 Specialty Matched Consultant Advisory Panel. Corrected description to correctly identify insulin as a hormone. No change in criteria. System coding changes. Medical Policy Advisory Group review. No change in criteria. Approve.
- 4/02 Revised policy statement under when it is covered to include, "pancreas retransplant after a failed primary pancreas transplant may be considered medically necessary" and under when it is not covered to include, "pancreas retransplant after 2 or more prior failed pancreas transplants is considered investigational". Format changes.
- 6/02 Specialty Matched Consultant Advisory Panel review. Revised policy statement under when it is not covered. Added indications for clarity. Added statement under when it is covered to state, please see below "When Pancreas Transplant is not covered" for clarity.
- 4/04 Benefits Application and Billing/Coding sections updated for consistency. Code S2152 added to Billing/Coding section.
- 6/04 HCPCS code S2065 added to Billing/Coding section.
- 6/10/04 Specialty Matched Consultant Advisory Panel review. No change to criteria. Removed CPT 50340, 50360, and 50365. References added. Notification given 6/10/2004. Effective 8/12/2004.
- 1/6/05 Codes 48551, 48552 added to Billing/Coding section of policy.
- 5/22/06 Specialty Matched Consultant Advisory Panel review 4/20/2006. Added information to "When Covered" section to indicate the following criteria; "Absence of uncontrolled HIV infection. HIV infection is considered controlled when the following criteria are met: the CD4 count >200 cells/ mm-3 for >6 months; and the HIV-1 RNA undetectable; and the patient is stable on anti-retroviral therapy >3 months; and the patient has no other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm." Also added the following statement; "Candidates for pancreas transplant alone should additionally meet one of the following severity of illness criteria: documentation of severe hypoglycemia unawareness as evidenced by chart notes or emergency room visits; OR documentation of potentially life-threatening labile diabetes as evidenced by chart notes or hospitalization for diabetic ketoacidosis. Clarified "uncontrolled HIV positive patients as a contraindication in the "When Not Covered" section. Moved information in "Policy Guidelines" related to additional criteria for candidates for pancreas transplant alone to "When Covered" section. References added.
- 6/16/08 Specialty Matched Consultant Advisory Panel review 4/30/08. "Description" section updated.

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Removed statement from the "When Not Covered" section that had indicated; "Pancreas retransplant after 2 or more prior failed pancreas transplants is considered investigational." References added. (btw)

6/22/10 Policy Number(s) removed (amw)

12/7/10 Description section revised. Information regarding eligible candidates for transplant moved from the When Covered section to the Policy Guidelines section. No change in policy statement. Medical Director review 11/12/10. (adn)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.