Corporate Medical Policy

Pancreas Transplant

File Name:	pancreas_transplant
Origination:	1/2000
Last CAP Review:	5/2020
Next CAP Review:	5/2021
Last Review:	5/2020

Description of Procedure or Service

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

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.

Pancreas transplantation occurs in several different scenarios such as: 1) a diabetic patient with renal failure who may receive a cadaveric simultaneous pancreas/kidney transplant (SPK); 2) a 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 diabetic patient with specific severely disabling and potentially life-threatening diabetic problems who may receive a PTA.

Most patients undergoing PTA are those with either hypoglycemic unawareness or labile diabetes. However, other exceptional circumstances may exist where nonuremic type 1 diabetes patients have significant morbidity risks due to secondary complications of diabetes (eg, peripheral neuropathy) that exceed those of the transplant surgery and subsequent chronic immunosuppression. Because virtually no published evidence addressing outcomes of medical management in this very small group of exceptional diabetic patients, it is not possible to generalize about which circumstances represent appropriate indications for pancreas transplantation alone. Case-by-case consideration of each patient's clinical situation may be the best option for determining the balance of risks and benefits.

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 guidelines based on experience; some transplant centers may wait to allow reconstitution of the immune system before initiating retransplant with an augmented immunosuppression protocol.

The total number of adult pancreas transplants pancreas and pancreas plus kidney in the U.S. peaked at 1,484 in 2004; the number has since declined. In 2017, 213 PTAs and 789 simultaneous pancreas/kidney transplants were performed in the U.S.

Pancreas Transplant

According to 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 SPK, 5% of PAK, and 1% of PTA were performed in patients with type 2 diabetes.

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

Related Policies
Renal (Kidney) Transplantation
Islet Cell 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.

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 insulin dependent diabetic patients with uremia.
- **Pancreas transplant after a prior kidney transplant** may be considered medically necessary in patients with insulin dependent diabetes.
- **Pancreas transplant alone** may be considered 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 considered medically necessary in patients who meet criteria for pancreas transplantation**.**

When Pancreas Transplantation is not covered

Pancreas transplants are considered not medically necessary for indications other than those cited above.

Policy Guidelines

Potential contraindications to pancreas transplant include:

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

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

- documentation of severe hypoglycemia unawareness as evidence 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.

The majority of pancreas transplant patients will have type 1 diabetes. Those transplant candidates with type 2 diabetes, in addition to being insulin-dependent, should have a body mass index (BMI) of 32 kg/m^2 or less. According to International Pancreas Transplant Registry data, in 2010, 7% of pancreas transplant recipients had type 2 diabetes.

Multiple Transplants
Although there are no standard guidelines regarding multiple pancreas transplants, the following information may aid in case review:

- If there is early graft loss resulting from technical factors (e.g., venous thrombosis), a retransplant may generally be performed without substantial additional risk.

- Long-term graft losses may result from chronic rejection, which is associated with increased risk of infection following long-term immunosuppression, and sensitization, which increases the difficulty of finding a negative cross-match. Some transplant centers may wait to allow reconstitution of the immune system before initiating retransplant with an augmented immunosuppression protocol.

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, S2065*

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

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.02, 2/10/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.02, 2/9/2012

Specialty Matched Consultant Advisory Panel – 4/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.02, 2/14/13

Specialty Matched Consultant Advisory Panel – 4/2013

Organ Procurement and Transplantation Network (OPTN). Available online at: http://optn.transplant.hrsa.gov/latestData/viewDataReports.asp. Last accessed January, 2014.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.02, 2/13/14

Specialty Matched Consultant Advisory Panel – 4/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.02, 2/12/15

Specialty Matched Consultant Advisory Panel – 5/2015

Medical Director review – 5/2015

Specialty Matched Consultant Advisory Panel – 5/2016

Medical Director review – 5/2016

Specialty Matched Consultant Advisory Panel 5/2017

Medical Director review 5/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.02, 8/2017

Medical Director review 8/2017

Specialty Matched Consultant Advisory Panel 5/2018

Medical Director review 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.02 8/2018

Specialty Matched Consultant Advisory Panel 5/2019

Medical Director review 5/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.02 9/2019

Specialty Matched Consultant Advisory Panel 5/2020

Medical Director review 5/2020

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:

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, coccidioses 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. 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)
5/10/11	Description section updated. No change in policy statement or coverage criteria. Information that was previously in Item 2 of the Not Covered section (list of contraindications) was moved to the Policy Guidelines section. Specialty Matched Consultant Advisory Panel review 4/27/11. (adn)
5/1/12	No change in policy statement or coverage criteria. Information that was previously in the Not Covered section (list of contraindications) was moved to the Policy Guidelines section. Specialty Matched Consultant Advisory Panel review 4/18/12. (sk)
4/30/13	Reference added. Specialty Matched Consultant Advisory Panel review 4/17/13. No change to policy statement. (sk)
4/15/14	References added. Statement on retransplantation modified to state that it applies to patients who meet criteria for pancreas transplant. Senior Medical Director review. (sk)
9/30/14	Specialty Matched Consultant Advisory Panel review 4/29/14. No change to policy statement. (sk)
3/31/15	References updated. Policy Statement remains unchanged. (td)
7/1/15	References updated. Specialty Matched Consultant Advisory Panel review 5/27/2015. Medical Director review 5/2015. Policy Statements unchanged. (td)
7/1/16	Specialty Matched Consultant Advisory Panel review 5/25/2016. Medical Director review 5/2016. No Changes to policy. (jd)
6/30/17	Specialty Matched Consultant Advisory Panel – 5/2017. Medical Director review – 5/2017. (jd)
9/15/17	Minor revision to Description section; the term “mellitus” was removed throughout the policy. No change to policy intent. Medical Director review. (jd)
6/8/18	Specialty Matched Consultant Advisory Panel 5/2018. Medical Director review 5/2018. (jd)
5/28/19	Refences updated.Specialty Matched Consultant Advisory Panel 5/2019. Medical Director review 5/2019. (jd)
6/9/20	Refences updated. Specialty Matched Consultant Advisory Panel 5/2020. Medical Director review 5/2020. (jd)