Clinical Policy: Pancreas Transplantation

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Revision Log
Coding Implications

Description

This policy describes the medical necessity requirements for pancreas transplantation procedures. These pancreas transplants are effective therapeutic options to arrest the progression of the complications of diabetes mellitus, and to improve the quality of life for diabetic patients, including: simultaneous pancreas kidney transplant (SPK), pancreas after kidney transplant (PAK), pancreas transplant alone (PTA), and islet cell transplant. The SPK procedure is most commonly performed transplant procedure, and has the highest post-operative graft survival rates.

Policy/Criteria

I. It is the policy of Pennsylvania Health and Wellness® (PHW), that a pancreas transplant is **medically necessary** when meeting the all of the following*:*

- **A.** Medical therapy for condition does not exist or has failed;
- **B.** Diagnosis of diabetes mellitus, as demonstrated by one of the following:
  1. Dependent on insulin and C-peptide value ≤ 2 ng/mL,
  2. Dependent on insulin and C-peptide value ≥ 2 ng/mL and BMI ≤ maximal allowable value;
- **C.** Does not have ANY of the following contraindications:
  1. Malignancy in the past two years, except for either of the following:
     a. Non-melanoma localized skin cancer that has been treated appropriately;
     b. Early prostate cancer with a low Gleason score;
  2. Malignancy metastasized to or extending beyond the margins of the kidney and/or pancreas;
  3. Untreatable significant dysfunction of another major organ system, unless combined organ transplantation can be performed;
  4. Acute medical instability, including, but not limited to, acute sepsis or myocardial infarction;
  5. Uncorrectable bleeding diathesis;
  6. Chronic infection with highly virulent and/or resistant microbes that are poorly controlled pre-transplant;
  7. Current non-adherence to medical therapy or a history of repeated or prolonged episodes of non-adherence to medical therapy that are perceived to increase the risk of non-adherence after transplantation;
  8. Psychiatric or psychological condition associated with the inability to cooperate or comply with medical therapy;
  9. Absence of an adequate or reliable social support system;
  10. Severely limited functional status with poor rehabilitation potential;
  11. Substance abuse or dependence (including tobacco and alcohol) without convincing evidence of risk reduction behaviors, such as meaningful and/or long-term participation in therapy for substance abuse and/or dependence. Serial blood and urine testing may be used to verify abstinence from substances that are of concern.

D. Request is for one of the following procedures and meets the corresponding criteria:
1. *PTA*, meets all:
   a. Recurrent, severe, and potentially life-threatening metabolic complications that require medical attention, as documented by chart notes, emergency room visits, or hospitalizations, including any of the following:
      i. Severe hypoglycemia unawareness;
      ii. Marked hyperglycemia;
      iii. Recurring severe ketoacidosis;
   b. Clinical and emotional problems with exogenous insulin therapy that are so severe as to be incapacitating or consistent failure of insulin based management to prevent acute complications.
2. *SPK*, meets all:
   a. End-stage renal disease (ESRD), as defined by both
      i. Presence of uremia;
      ii. Requires dialysis or is expected to require dialysis in the next 12 months;
   b. Glomerular filtrate rate (GFR) < 20mL/min *or* creatinine clearance (CrCl) < 20mL/min
3. *PAK transplant*, meets all:
   a. Underwent successful kidney transplant without significant chronic rejection of kidney transplant;
   b. Stable kidney transplant function, as defined by both:
      i. Stable creatinine clearance ≥ 30 mL/min,
      ii. Absence of significant proteinuria.

II. It is the policy of PHW that *autologous islet cell transplants* are considered **medically necessary** as an adjunct procedure to a total or near total pancreatectomy for severe, refractory pancreatitis.

III. It is the policy of PHW that *pancreas re-transplantation* is considered **medically necessary** after one failed primary pancreas transplant.

IV. It is the policy of PHW that pancreas transplant procedures are considered **experimental/investigational** for any of the following indications:
A. Re-transplantations after two or more failed primary pancreas transplantations;
B. Allogenic islet cell transplantation or xenotransplantation;
C. SPK transplantation for patients with amputation due to peripheral obstructive vascular disease;
D. For the treatment of all other conditions than those specified above.

Background
The American Diabetes Association defines diabetes mellitus as a group of metabolic diseases, which is characterized by hyperglycemia that results from defects in insulin secretion, insulin action, or both.[1] According to the Centers for Disease Control and Prevention (CDC)'s estimations in 2012, approximately 29.1 million people or 9.3% of the U.S. population have diabetes, with an approximate 8.1 million undiagnosed cases.[3] The chronic hyperglycemia existing in diabetic patients facilitates long term organ damage, especially to the eyes, kidneys, nerves, and blood vessels.[1]

The prevalent type 2 diabetes is caused by a resistance to insulin action and an inadequate compensatory insulin secretory response.[1] Type 1 diabetes is caused by immune mediated destruction of the insulin secreting pancreatic β cells.[2] Islet cell autoantibodies, insulin autoantibodies, autoantibodies to glutamic acid decarboxylase, zinc transporter 8 (ZnT8A), and autoantibodies to the tyrosine phosphatase IA-2 and IA-2β are serological markers of the pancreatic β cell destruction observed in type 1 diabetes.[1,2,4]

Due to the loss of glucose homeostasis in diabetes mellitus and the dependency of exogenous insulin for glycemic control, pancreatic transplantations presents options to restore glucose regulated endogenous insulin secretion, arrest the progression of the complications of diabetes, and to improve the quality of life for diabetic patients.[5] In fact, pancreas transplantation is the only proven method to restore normoglycemia in type 1 diabetic patients.

There are multiple iterations of pancreas transplantation procedures available to diabetic patients: simultaneous pancreas kidney transplant (SPK), pancreas after kidney transplant (PAK), and pancreas transplant alone (PTA), as well as islet cell transplantation. SPK, performed for patients with type 1 diabetes with end stage renal disease, is the most common pancreas transplant procedure.[6] A comprehensive analysis of the 35,000 pancreas transplantations reported to the International Pancreas Transplant Registry as of 2010, 75% of the procedures are SPK, 18% are PAK transplant, and 9% are PTA.[6]

Patient survival rates were reported at > 95% at 1 year and > 83% at 5 years.[6] The best graft survival rates were observed in SPK transplants at 86% for pancreas and 93% for kidney at one year; PAK procedures displayed graft function at 80%, while PTA had graft function at 78%.[6] Graft survival rate is defined as total freedom from insulin therapy, normal fasting blood glucose concentrations, and normal or only slightly elevated HbA1c values.[8] Patient survival rates were 95 to 98% at one year, 91 to 92 % at 3 years and 78 to 88% at 5 years post operatively.[5] In all three categories, cardio/cerebrovascular problems as well as infections were the leading cause of early and late death.[6]

Patients undergoing the pancreas transplantation, especially the SPK procedure, require extensive immunosuppression regiments; pancreas transplants recipients are believed to require higher levels of immunosuppression than other solid organ transplants, possibly related to the immunogenicity of the pancreas, and or the autoimmune status of the recipients.[7]

Pancreatic islet auto transplantation is performed following a pancreatectomy in patients with severe chronic pancreatitis. Islet β cells transferred into the liver through the portal vein of the recipient.[5] One of the primary symptoms and complications observed in patients with chronic pancreatitis is excessive pain. Therefore control of pain is a primary goal of pancreatectomy and pancreatic islet autotransplantation. Post-operative opiate usage has been reported as an outcome metric for pain relief, and reductions ranging from approximately 20-80% have been reported due to pancreatic islet autotransplantation.[8]

Coding Implications

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CPT®* Codes	Description
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas of pancreatic islet cells
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48551	Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery
48552	Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each
48554	Transplantation of pancreatic allograft
48556	Removal of transplanted pancreatic allograft
50300	Donor nephrectomy (including cold preservation) from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy

HCPCS Codes	Description
S2065	Simultaneous pancreas kidney transplantation

ICD-10 Diagnosis Codes that Support Coverage Criteria
+ Indicates a code requiring an additional character

ICD-10-CM Code	Description
E10.10-E10.9	Type 1 diabetes mellitus with kidney complications
K86.0	Alcohol-induced chronic pancreatitis
K86.1	Other chronic pancreatitis
K18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
Z94.0	Kidney transplant status

Reviews, Revisions, and Approvals	Date	Approval Date
Removed "islet cell transplantation" from III. References reviewed and updated. ICD-10 and HCPCS codes added.	06/18	
Added "early prostate cancer with low Gleason score," as an exception to malignancy contraindications, I.b. Removed "and/or islet cell" from IV.A. References reviewed and updated. Specialist reviewed.	03/19	

References

1. American Diabetes Association. "Diagnosis and classification of diabetes mellitus." *Diabetes Care* 37.Supplement 1 (2014): S81-S90.
2. Atkinson, Mark A., George S. Eisenbarth, and Aaron W. Michels. "Type 1 diabetes." *The Lancet* 383.9911 (2014): 69-82
3. Centers for Disease Control and Prevention. *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014*. Atlanta, GA: U.S. Department of Health and Human Services; 2014
4. Chiang, Jane L., et al. "Type 1 diabetes through the life span: A position statement of the American Diabetes Association." *Diabetes Care* 37.7 (2014): 2034-2054.
5. Robertson, RP. "Pancreas and islet transplantation in diabetes mellitus." In: UpToDate, Hirsch, IB. Ed. UpToDate, Waltham, MA. (Accessed on January 24, 2019).
6. Gruessner, Angelika C. "2011 update on pancreas transplantation: comprehensive trend analysis of 25,000 cases followed up over the course of twenty-four years at the International Pancreas Transplant Registry (IPTR)."*The review of diabetic studies: RDS* 8.1 (2011): 6.
7. Redfield, Robert R., Joseph R. Scalea, and Jon S. Odorico. "Simultaneous pancreas and kidney transplantation: current trends and future directions." *Current opinion in organ transplantation* 20.1 (2015): 94.
8. Robertson, R. Paul, et al. "Pancreas and islet transplantation for patients with diabetes." *Diabetes care* 23.1 (2000): 112-116.
9. Mittal, Shruti, Paul Johnson, and Peter Friend. "Pancreas transplantation: solid organ and islet." *Cold Spring Harbor perspectives in medicine* 4.4 (2014): a015610.

10. Kesseli, Samuel J., Kerrington A. Smith, and Timothy B. Gardner. "Total Pancreatectomy with Islet Autologous Transplantation: The Cure for Chronic Pancreatitis & quest." Clinical and translational gastroenterology 6.1 (2015): e73.
11. Klein CL, Alhamad T. Patient selection for and immunologic issues relating to kidney-pancreas transplantation in diabetes mellitus. In: UpToDate, Brennan DC, Nathan DM, (Eds). UpToDate, Waltham, MA. (Accessed on January 23, 2018)
12. Hayes Medical Technology Directory. Simultaneous Pancreas-Kidney (SPK) Transplantation in Diabetic Patients. March 27, 2013. Updated February 21,2017
13. Alhamad T, Stratta RJ. Pancreas-kidney transplantation in diabetes mellitus: Patient selection and pretransplant evaluation. In: UpToDate, Brennan DC, Nathan DM (Eds). UpToDate, Waltham, MA. Accessed Jan 27, 2019.