Clinical Policy: Pancreas Transplantation

Reference Number: CP.MP.102 Revision Log
Last Review Date: 05/20 Coding Implications

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

This policy describes the medical necessity requirements for pancreas transplantation procedures. Multiple types of pancreas transplants are effective therapeutic options for arresting the progression of the complications of diabetes mellitus, and improving 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 health plans affiliated with Centene Corporation® that a *pancreas transplant* is **medically necessary** when meeting 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 (i.e., ≤30 to 35 kg/m2, depending on transplant center);

C. Does not have ANY of the following contraindications:

1. Malignancy, except for non-melanoma localized skin cancer that has been treated appropriately, early prostate cancer, cancer that has been completely resected, or that has been treated and poses acceptable future risk;
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 filtration rate (GFR) $\leq$ 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 $\geq$ 30 mL/min,
      ii. Absence of significant proteinuria.

II. It is the policy of health plans affiliated with Centene Corporation 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 health plans affiliated with Centene Corporation that *pancreas re-transplantation* are considered **medically necessary** after one failed primary pancreas transplant.

IV. It is the policy of health plans affiliated with Centene Corporation 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. Allogeneic 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 autotransplantation 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 that support coverage criteria

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

CPT Codes that do not support coverage criteria

CPT® Codes	Description
0584T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous
0585T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic
0586T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open

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
E10.21-E10.29	Type 1 diabetes mellitus with kidney complications
K86.0	Alcohol-induced chronic pancreatitis
K86.1	Other chronic pancreatitis
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
Z94.0	Kidney transplant status
Z94.83	Pancreas transplant status

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed. Reviewed by specialist 4/16.	02/16	04/16
References reviewed and updated	03/17	03/17
Removed "islet cell transplantation" from III. References reviewed and updated. ICD-10 and HCPCS codes added.	01/18	02/18
Minor wording changes to description for clarity	05/18	
Added "early prostate cancer with a low Gleason score," as an exception to malignancy contraindication, I.b. Removed "and/or islet cell" from IV. A. References reviewed and updated. Specialist reviewed.	01/19	02/19
References reviewed and updated. In I.D.2.b for SPK, changed GFR "<20" to GFR "≤ 20". Added 2020 CPT codes that do not support coverage criteria (0584T, 0585T, 0586T) Added ICD-10 Z94.83	01/20	02/20

Reviews, Revisions, and Approvals	Date	Approval Date
Edited malignancy contraindication to not specify within 2 years, or low Gleason score, and added exceptions early stage prostate cancer, cancer that has been completely resected, or that has been treated and poses acceptable future risk. Clarified that BMI maximal allowable value in I.B. 2 is (i.e., ≤ 30 to 35 kg/m2, depending on transplant center).	05/20	05/20

References

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCD's

and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.