Clinical Policy: Pancreas Transplantation

Reference Number: LA.CP.MP.102 Revision Log
Date of Last Revision: ~~43~~/235~~/22~~ 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.[1] The SPK procedure is the most commonly performed transplant procedure, and has the highest post-operative graft survival rates.

Policy/Criteria

I. It is the policy of Louisiana Healthcare Connections that ~~a~~ *pancreas transplant*ation is **medically necessary** when meeting all of the following*:*

A. Member/enrollee has one of the following

1. Diagnosis of diabetes mellitus requiring insulin (members/enrollees with requirements for insulin over one unit/kg should be closely evaluated as they may be less likely to benefit from pancreas transplant compared to those with lower insulin doses)
2. Diagnosis of exocrine pancreatic insufficiency
3. A requirement for the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons

B. Does not have ANY of the following contraindications:[2,8]

~~**A.**~~**C.** ~~Medical therapy for condition does not exist or has failed;~~

~~**B.**~~**D.** ~~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 with high risk of recurrence or death related to cancer;
2. Glomerular filtration rate < 40 mL/min/1.73m^2 unless being considered for multi-organ transplant;
3. Stroke, acute coronary syndrome, or myocardial infarction (excluding demand ischemia) within 30 days;
4. Acute liver failure, or cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multi-organ transplant;

~~5. Acute renal failure with rising creatinine or on dialysis and low likelihood of recovery;~~

~~5.~~

6. Septic shock;
7. ~~Chronic~~ Active~~Acute~~ infection with highly virulent and/or resistant microbes that are poorly controlled pre-transplant;
8. Active tuberculosis infection;

9. HIV infection with detectable viral load;
10. Progressive cognitive impairment;
11. Inability to adhere to the regimen necessary to preserve the transplant, even with caregiver support;
12. Active substance use or dependence including current tobacco use, vaping, marijuana ~~smoking,~~ (unless prescribed by a licensed practitioner) or~~or~~ IV drug use without convincing evidence of risk reduction behaviors, (unless urgent transplant timelines are present, in which case a commitment to reducing behaviors is acceptable) ~~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;
13. Chronic, non-healing wounds;
14. Significant comorbidities, such as advanced cardiopulmonary, cardiovascular, cerebrovascular, or peripheral vascular disease;
~~12.~~
~~13.~~15. Other severe uncontrolled medical condition expected to limit survival after transplant;

~~D.~~C. Request is for one of the following procedures and meets the corresponding criteria:

1. Pancreas Transplant Alone (*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~~ or 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;
   ~~b.~~c. Has been medically managed by an endocrinologist for at least 12 months;[RJ1]
2. Simultaneous Pancreas Kidney Transplant *(SPK)*, meets all:
   a. Meets above criteria for PTA
   ~~a.~~b. 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.~~c. Glomerular filtration rate (GFR) ≤ 20mL/min (does not have to be the most recent value) [RJ2]*or* creatinine clearance (CrCl) < 20mL/min;
3. Pancreas After Kidney Transplant *(PAK)*, meets all:
   a. Meets above criteria for PTA
   ~~a.~~b. Underwent successful kidney transplant without significant chronic rejection of kidney transplant;
   ~~b.~~c. 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 Louisiana Healthcare Connections 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 Louisiana Healthcare Connections that *pancreas re-transplantations* are considered **medically necessary** after one failed primary pancreas transplant.

IV. It is the policy of Louisiana Healthcare Connections that current evidence does not support the use of pancreas transplant procedures 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 characterized by hyperglycemia that results from defects in insulin secretion, insulin action, or both.[3] According to the Centers for Disease Control and Prevention estimations, approximately 37.3 million people or 11.3% of the United States population has diabetes with approximately 8.5 million undiagnosed cases.[4] Chronic hyperglycemia existing in diabetic patients facilitates long term organ damage, especially to the eyes, kidneys, nerves, and blood vessels.[3]

The prevalent type 2 diabetes is caused by a resistance to insulin action and an inadequate compensatory insulin secretory response.[3] Type 1 diabetes is caused by immune mediated destruction of the insulin secreting pancreatic β cells.[5] 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.[3,5,6]

Pancreas transplantation allows for the possibility to restore glucose regulated endogenous secretion, decrease the progression of diabetic complications, and improve quality of life in patients with diabetes.[1,7] Pancreas transplantation is the only proven method to restore normoglycemia in type 1 diabetic patients.[8] Simultaneous pancreas kidney transplant (SPK), pancreas after kidney transplant (PAK), and pancreas transplant alone (PTA) are primarily performed on patients with type 1 diabetes.[8] SPK is an established procedure for diabetic patients with advanced chronic kidney disease or end stage kidney disease and accounts for approximately 90% of pancreas transplants performed in the United States.[9]

A 2011 study by Gruessner[10] reviewed the outcomes of SPK, PAK, and PTA transplantations according to follow-up data collected by the International Pancreas Transplant Registry. Patient survival rates were reported to be over 95% after one year and over 83% at five years post-transplant. The highest graft survival rates were observed in SPK transplants at 86% for pancreas and 93% for kidney graft function one year post-transplant. PAK procedures displayed graft function at 80%, while PTA had graft function at 78% one year after transplantation.[10] Graft survival rate is defined as total freedom from insulin therapy, normal fasting blood glucose concentrations, and normal or only slightly elevated hemoglobin A1C values.[11] The study

demonstrated that pancreas transplantation offers excellent outcomes for patients with labile diabetes due to the improvement in patient survival and graft function shown in all three categories over the course of 24 years.[10]

Patients undergoing pancreas transplantation, especially SPK transplant, require extensive immunosuppression regiments.[1] It is theorized that pancreas transplant recipients require higher levels of immunosuppression therapy than other solid organ transplants due to the immunogenicity of the pancreas or the autoimmune status of the recipient.[12]

During pancreatic islet autotransplantation, Islet β cells are transferred into the liver through the portal vein of the recipient.[1] Pancreatic islet autotransplantation is performed following a pancreatectomy in patients with severe chronic pancreatitis. Chronic pancreatitis is a debilitating disease which causes diarrhea, weight loss, poor quality of life, and severe abdominal pain that is difficult to alleviate with pharmacological treatment or other therapeutic measures.[1,13] Due to the excessive pain observed in patients with chronic pancreatitis, pain control is a primary goal of pancreatectomy and pancreatic islet autotransplantation.[13]

Coding Implications

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~~**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 2020, approximately 34.2 million people or 10.5% of the U.S. population have diabetes, with an approximate 7.3 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]**~~

~~**Pancreas transplantation allows for the possibility to restore glucose regulated endogenous secretion, decrease the progression of diabetic complications, and improve quality of life in patients with diabetes.[1,7] Pancreas transplantation is the only proven method to restore normoglycemia in type 1 diabetic patients.[8] Simultaneous pancreas kidney transplant**~~

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~~Patients undergoing pancreas transplantation, especially the SPK procedure, require extensive immunosuppression regiments; pancreas transplant 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]~~

~~During pancreatic islet autotransplantation, Islet β cells are transferred into the liver through the portal vein of the recipient.[1] Pancreatic islet autotransplantation is performed following a pancreatectomy in patients with severe chronic pancreatitis. Chronic pancreatitis is a debilitating disease which causes diarrhea, weight loss, poor quality of life, and severe abdominal pain that is difficult to alleviate with pharmacological treatment or other therapeutic measures.[1,13] Due to the excessive pain observed in patients with chronic pancreatitis, pain control is a primary goal of pancreatectomy and pancreatic islet autotransplantation.[13]~~

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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
50328	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each
50329	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral 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

* All non-covered codes are reviewed for medical necessity for members under 21 years old

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

* All non-covered codes are reviewed for medical necessity for members under 21 years old

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	Revision Date	Approval Date
Converted corporate to local policy.	3/21	
Removed contraindication of "severely limited functional status with poor rehabilitation potential." Replaced "Psychiatric or psychological condition associated with the inability to cooperate or comply with medical therapy" and the contraindication regarding non-compliance with medical therapy with "Inability to adhere to the regimen necessary to preserve the transplant, even with caregiver support." Changed "Review Date" in header to "Date of Last Revision," and "Date" in the revision log header to "Revision Date." Added "and may not support medical necessity" to coding implications.	2/22	2/22
Annual review. References reviewed and updated. Updated description and background with no clinical significance. Updated all	5/22	8/13/22

Reviews, Revisions, and Approvals	Revision Date	Approval Date
contraindications in criteria I.C. "Experimental/investigational" verbiage replaced in criteria IV. statement with descriptive language. Specialist reviewed. Added "and may not support medical necessity" to coding implications.		
Annual review. Removed criterion I.A. stating that medical treatment does not exist or has failed. Removed C-peptide values and BMI requirements from Criteria I.B.1 and I.B.2. Noted in I.B.1. that member/enrollees with requirements for insulin over one unit/kg should be closely evaluated as they may be less likely to benefit from pancreas transplant compared to those with lower insulin doses Added indication in I.B.2 for exocrine pancreatic insufficiency. Added indication I.B.3. for requirement for the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons; Changed "chronic" to "active" in infection contraindication in I.C.7. Removed acute renal failure contraindication. Criteria I.C.12. updated to exclude marijuana use when prescribed by a licensed practitioner and include required commitment to reducing substance use behaviors if urgent transplant timelines are present. Added chronic, non-healing wounds as contraindication in Criteria I.C.13. Added contraindication of significant comorbidities in Criteria I.C.14. Clarified in I.C.1.b that problems with insulin could be clinical or clinical and emotional. Added in I.C.2.c. that the GFR does not have to be the most recent value. Added Criteria I.D.1.c. requirement for being medically managed by an endocrinologist for at least 12 months for pancreas transplant alone. Added requirements for SPK and PAK that PTA criteria also needs to be met for those procedures. ICD-10 codes removed. Added CPT codes 50328 and 50329. Background updated with no impact on criteria. References reviewed and updated.	~~3~~4/23	

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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. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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