Clinical UM Guideline

adopted

Subject: Pancreas Transplantation and Pancreas Kidney Transplantation
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Description/Scope

This document addresses pancreas alone or a pancreas/kidney transplant which involves the removal of human organs from a *deceased or living donor* with the implantation into a single recipient.

Position Statement

Note: *Members must meet the disease specific criteria as well as the General Individual Selection criteria below for the transplantation to be considered medically necessary.*

Medically Necessary:

Simultaneous deceased-donor pancreas/kidney transplant (SPK) is considered **medically necessary** for individuals with insulin dependent diabetes mellitus (IDDM) who have end-stage renal disease.

Simultaneous deceased-donor pancreas and living-donor kidney transplant (SPLK) is considered **medically necessary** for individuals with insulin dependent diabetes mellitus who have end-stage renal disease.

Pancreas transplant alone (PTA) either deceased or living-donor segmental is considered **medically necessary** for individuals who have insulin dependent diabetes mellitus with severe disabling and documented life threatening hypoglycemic unawareness due to labile diabetes which persists despite optimal medical management.

Pancreas after kidney transplant (PAK) is considered **medically necessary** for individuals with insulin dependent diabetes mellitus.

One pancreas alone, one pancreas after kidney or one simultaneous pancreas/kidney (SPK or SPLK) re-transplantation after failure of the primary graft is considered **medically necessary** provided the individual meets the transplant criteria above.

Investigational and Not Medically Necessary:

Pancreas transplantation is considered **investigational and not medically necessary** for all other applications.

A third or subsequent pancreas alone, pancreas after kidney or SPK or SPLK transplantation is considered **investigational and not medically necessary** in all cases.

Note: For multi-organ transplant requests, criteria must be met for each organ requested. In those situations, an individual may present with a concurrent medical condition which would be considered an exclusion or a comorbidity that would preclude a successful outcome, but would be treated with the other organ transplant. Such cases will be reviewed on an individual basis for coverage determination to assess the member's candidacy for transplantation.

General Individual Selection Criteria

In addition to having the clinical indications above, the member must not have a contraindication as defined by the American Society of Transplantation in Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation (2001) listed below.

Absolute Contraindications- for Transplant *Recipients* include, but are not limited to, the following:

A. Metastatic cancer
B. Ongoing or recurring infections that are not effectively treated
C. Serious cardiac or other ongoing insufficiencies that create an inability to tolerate transplant surgery
D. Serious conditions that are unlikely to be improved by transplantation as life expectancy can be finitely measured
E. Demonstrated patient noncompliance, which places the organ at risk by not adhering to medical recommendations
F. Potential complications from immunosuppressive medications are unacceptable to the patient
G. Acquired immune deficiency syndrome (AIDS) (diagnosis based on Centers for Disease Control and Prevention [CDC] definition of CD4 count, 200 cells/mm^3) unless the following are noted:
    1. CD4 count greater than 200 cells/mm^3 for greater than 6 months
    2. HIV-1 RNA undetectable
    3. On stable anti-retroviral therapy greater than 3 months
    4. No other complications from AIDS (for example, opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi's sarcoma or other neoplasm)
    5. Meeting all other criteria for pancreas or pancreas/kidney transplantation.

Steinman, Theodore, et al. Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation. Transplantation. Vol. 71, 1189-1204, No. 9, May 15, 2001.

Rationale

Simultaneous Pancreas-Kidney Transplantation (SPK)
The level of evidence consists primarily of case series or summaries of institutional experience with SPK and pancreas after kidney (PAK) transplants, transplant registry reports, evaluations of secondary complications of diabetes and their relationship to SPK/PAK, and measures of Quality of Life (QOL) associated with these procedures. Collectively, this evidence has established that SPK is effective in normalizing insulin production and kidney function, may improve quality of life, and slows, halts or reverses the progression of secondary diabetic complications.

Data on long-term survival after SPK were published by Parajuli and colleagues in 2020. The authors reported on 291 individuals who received an SPK between 1986 and 1993. A total of 39 of 291 individuals (13.4%) had a functional pancreas allograft as of October 31, 2018, which was at least 25 years after transplantation. All of these had the same indication for SPK; namely, long-standing diabetic nephropathy and all but one had been diagnosed with type 1 diabetes. Nine additional individuals had pancreas graft survival of at least 25 years but were not available at the 2018 follow-up. No baseline characteristics predicted pancreas graft survival of at least 25 years.

A meta-analysis of studies on outcomes after SPK in individuals with end-stage kidney disease and type 2 diabetes was published in 2022 by Cao and colleagues. The authors identified nine cohort studies published through May 2021 and six of these were included in a meta-analysis of survival rates. Pooled survival rates at 1 year, 3 years and 5 years were 98% (95% confidence interval [CI], 96% to 100%), 95% (95% CI, 91% to 99%) and 91% (95% CI, 87% to 96%), respectively. Pooled pancreas graft survival rates at 1 year, 3 years and 5 years were 91% (95% CI, 86% to 95%), 86% (95% CI, 78% to 94%) and 81% (95% CI, 78% to 84%), respectively.

The American Diabetes Association (ADA) 2023 recommendations on pancreas transplantation, and pancreas kidney transplantation are as follows:

Successful pancreas and islet transplantation can normalize glucose levels and mitigate microvascular complications of type 1 diabetes. However, people receiving these treatments require lifelong immunosuppression to prevent graft rejection and/or recurrence of autoimmune islet destruction. Given the potential adverse effects of immunosuppressive therapy, pancreas transplantation should be reserved for people with type 1 diabetes undergoing simultaneous renal transplantation, following renal transplantation, or for those with recurrent ketoacidosis or severe hypoglycemia despite intensive glycemic management.

Simultaneous Cadaver-Donor Pancreas and Living-Donor Kidney Transplant (SPLK)
The evidence from the peer-reviewed literature supports the efficacy and use of a well-matched living-donor kidney. Such transplants offer the potential benefits of shorter waiting time, expansion of the organ donor pool, and improved short-term and long-term renal graft function. SPLK has the advantage of being a single procedure in contrast to the standard living-donor kidney transplant followed by PAK; in addition, SPLK in general leads to better early and long-term renal graft function.

Pancreas Transplant Alone (PTA)
Successful pancreas transplantation has been demonstrated in multiple case series studies to be efficacious in significantly improving the quality of life of people with type 1 diabetes, primarily by eliminating the need for exogenous insulin, frequent daily blood glucose measurements, and many of the dietary restrictions imposed by the disorder. Transplantation can also eliminate the acute complications commonly experienced by individuals with type 1 diabetes (e.g., hypoglycemia and hyperglycemia).

In 2022, Boggi and colleagues reported on 66 individuals with type 1 diabetes who underwent PTA and had at least 10 years of follow-up. A total of 61 of 66 individuals survived 10 years after PTA, for a survival rate of 92.4%. Among the 5 individuals who died, causes of death were infectious disease in 2 cases and cardiovascular disease in the other 3 cases. Of the 61 individuals who were alive at the 10-year follow-up, 35 (57.4%) had optimal graft function, defined as normoglycemia and insulin independence. An additional 2 individuals had good graft function, which included HbA1c levels below 7%, no severe hypoglycemia, more than a 50% reduction in insulin use and restoration of clinically significant C-peptide production.

Pancreas After Kidney Transplant (PAK)
There is a paucity of data from controlled studies comparing pancreas after kidney and pancreas transplant alone. Studies comparing the two procedures are case series or summaries of transplant centers' experience, rather than randomized studies, and, for the most part, involve small study samples, retrospective design, and relatively short follow-up considering the rate of late graft failure. Data from the International Pancreas Transplant Registry provides sufficient evidence to support the efficacy of PAK in carefully selected diabetics who have previously received a successful kidney transplant. The 1-year graft survival rate (defined as total freedom from insulin therapy, normal fasting blood glucose concentrations, and normal or only slightly elevated HbA1c) is 77.5%.

Living-Donor Segmental Pancreas Transplantation
Evidence from small case series studies focusing on the limited number of living-related donor segmental pancreas transplants indicates that these grafts have a lower rejection rate and may provide a more satisfactory long-term outcome than grafts from deceased donors.

A 2022 report from the International Pancreas Transplant Registry (IPTR) reported that of 33,541 pancreas transplants through 2020 of the three major types (SPK, PAK and PTA), only 137 (0.4%) were from living donors. Of these 137 transplants, most (n=88) were solitary pancreas transplants.

National and International Transplant Data
According to the Organ Procurement Transplant Network (OPTN), in 2022, there were 100 PTA transplants and 756 SPK transplants performed in the US. Survival data are available from the OPTN through November 18, 2022. After PTA, the 1-year patient survival rate was 91.0% (95% CI, 88.7% to 92.8%) and the 5-year patient survival was 79.6% (95% CI, 77.0% to 82.0%). After SPK, 1-year patient survival was 97.5% (95% CI, 96.9% to 98.0%) and 5-year patient survival was 88.9% (95% CI, 87.7% to 89.9%).

The IPTR (2022) reported that, worldwide, the patient survival rate at 1 year for primary deceased-donor transplants occurring between 2016 and 2020 was 96.9% for SPK recipients, 96.3% for PAK recipients and 98.3% for PTA recipients.

Pancreas Retransplantation
The effects of pancreas retransplantation on health outcomes (recipient survival, graft survival, morbidity) are reported from uncontrolled analyses in the literature. For example, Gasteiger and colleagues (2018) reported on 52 pancreas retransplantations performed at a single center. After a median follow-up of 65 months, the 1-year graft survival rate was 79%. The 1-year and 5-year patient survival rates were 96% and 89%, respectively.

A 2019 study by Parajuli and colleagues found better health outcomes in individuals who underwent pancreas retransplantation after graft failure; these individuals had undergone SPK transplants. After a mean follow-up post-SPK of 8-9 years, the death-censored kidney graft failure rate was 24% among individuals with pancreas retransplantation and 48% among those without pancreas retransplantation.

According to the OPTN, for individuals who underwent repeat PTA between 2008 and 2015, the 1-year survival rate was 96.4% (95% CI, 92.1% to 98.4%) and the 5-year survival rate was 83.7% (95% CI, 78.1% to 87.9%). For individuals who underwent repeat SPK, the 1-year survival rate was 100% (95% CI, 100% to 100%) and the 5-year survival rate was 71% (95% CI, 55.4% to 82.0%).

Background/Overview

PTA is a standard treatment option for individuals with IDDM who have failed insulin-based management leading to frequent and acute metabolic complications. SPK is a standard treatment option for individuals with IDDM with end-stage renal disease.

The annual incidence of type 1 diabetes has been rising worldwide. It is estimated that the prevalence of type 1 diabetes in the United States is approximately 1 in 300 by age 18. Over one-third of individuals with IDDM eventually develop end-stage renal disease (ESRD), the treatment for which is either dialysis with glucose control or kidney transplantation. Dialysis is not considered a favorable long-term option due to low 5-year survival rates of approximately 33%. Renal transplantation has demonstrated superiority over renal dialysis, with 5-year survival rates approximately 83% for individuals receiving cadaveric grafts and 92% for recipients of living-related transplants. However, adequate glycemic control is necessary to prevent recurrence of disease in the transplanted kidney. Although stringent glucose control for diabetics is possible, it can be difficult to achieve for many individuals, since it requires multiple injections of insulin every day combined with frequent self-monitoring of blood glucose levels. In addition, individuals on intensive insulin therapy have an elevated risk of severe hypoglycemia. Thus, pancreas transplantation has been investigated as a method of restoring glucose homeostasis in individuals with IDDM. For individuals who are candidates for a kidney transplant, a simultaneous pancreas transplant can restore glucose homeostasis and can provide the additional benefits that accompany being insulin-independent for many years.

For type 1 diabetics experiencing glucose control problems or progressive diabetic complications, pancreas transplantation may be performed alone (PTA), simultaneously with a kidney transplant (SPK), or after a successful kidney transplant (PAK). PTA is performed in nonuremic or preuremic individuals; SPK is performed in uremic individuals; and PAK is performed in individuals who have undergone successful kidney transplantation to correct previous uremia. Since kidney failure is one of the major diabetic complications, most potential pancreas graft recipients are uremic. PAK is generally reserved for individuals with a suitable replacement kidney from a living related donor, which is associated with increased kidney graft survival, as compared with a cadaver kidney. However, PAK is an infrequently performed procedure. Thus, most pancreas transplantation procedures involve SPK grafting; consequently, relatively few studies are available that detail the outcome of PAK. Additionally, only a few controlled clinical trials have investigated the risk and benefits of pancreas transplant alone as compared with intensive conventional therapy. One recent nonrandomized controlled study suggests that the relative increase in post-surgical mortality may not be balanced by an improvement in survival over the next 4 years. Study limitations identified include retrospective design and the fact that the transplants were performed at multiple transplant centers with varying experience, technique and immunosuppressive approaches, any of which can

influence postoperative mortality. However, further studies are underway to investigate whether the benefits of surgery outweigh the risks in this population.

Pancreas transplantation involves the surgical removal of a segmental pancreas from a living donor or a whole pancreas from a deceased donor, and the implantation of the pancreas into a recipient. Pancreas transplantation has been used in an attempt to restore endogenous insulin secretion and normal glucose metabolism for individuals with insulin-dependent diabetes. It should be noted that pancreas transplantation is also associated with a significant incidence of adverse effects, including episodes of graft rejection, pancreatitis, dehydration and infectious, vascular and urologic complications. The use of immunosuppressive agents also increases the risk for developing infections, lymphomas and other malignancies.

Definitions

End Stage Renal Disease (ESRD): Persistent decline in renal function as documented by falling creatinine clearance in an individual diagnosed with a renal disease whose natural history is progression to renal impairment requiring renal replacement (dialysis or transplant).

Kidney: One of a pair of organs situated in the body cavity near the spinal column that remove waste products of metabolism from the blood and excrete them in urine. In humans they are bean-shaped organs about 4½ inches (11½ centimeters) long.

Pancreas: A tongue-shaped glandular organ lying below and behind the stomach that secretes insulin, glucagon (both regulate blood sugar) and digestive enzymes.

Segmental pancreas: A portion or section of the pancreas.

Simultaneous deceased-donor pancreas and living-donor kidney transplant (SPLK): The concurrent surgical removal of a deceased-donor pancreas and a living-donor kidney for implantation into a recipient in one surgical procedure.

Simultaneous deceased-donor pancreas/kidney transplant (SPK): The concurrent surgical removal of a pancreas and a kidney from the same deceased donor, and the implantation of the pancreas and kidney into a recipient. This procedure is done for individuals with insulin-dependent diabetes and end-stage renal failure.

Type 1 diabetes: A form of diabetes that usually develops during childhood or adolescence and is characterized by a severe deficiency of insulin secretion resulting from atrophy of the islets of Langerhans and causes hyperglycemia and a marked tendency toward ketoacidosis. Also called insulin-dependent diabetes, insulin-dependent diabetes mellitus, juvenile diabetes, juvenile-onset diabetes, type 1 diabetes mellitus.

Uremia: Accumulation in the blood of constituents normally eliminated in the urine that produces a severe toxic condition and usually occurs in severe kidney disease.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Pancreas transplant (PTA, PAK, SPK)
When services may be Medically Necessary when criteria are met:

CPT

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

HCPCS

S2065	Simultaneous pancreas kidney transplantation

ICD-10 Procedure

0FYG0Z0	Transplantation of pancreas, allogeneic, open approach
0FYG0Z1	Transplantation of pancreas, syngeneic, open approach

ICD-10 Diagnosis

E08.00-E13.9	Diabetes mellitus
N18.1-N18.9	Chronic kidney disease (CKD)
P70.2	Neonatal diabetes mellitus
T86.890-T86.899	Complications of other transplanted tissue [when specified as pancreas transplant]
Z79.4	Long term (current) use of insulin

When services are Investigational and Not Medically Necessary:
For the procedure codes listed above when criteria are not met; for all other diagnoses not listed, for third or subsequent transplantations, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

Kidney Transplant (related to pancreas transplant, SPK, SPLK)
When services may be Medically Necessary when criteria are met:

CPT

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
50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor

ICD-10 Procedure

0TY00Z0	Transplantation of right kidney, allogeneic, open approach
0TY00Z1	Transplantation of right kidney, syngeneic, open approach
0TY10Z0	Transplantation of left kidney, allogeneic, open approach
0TY10Z1	Transplantation of left kidney, syngeneic, open approach

ICD-10 Diagnosis

E08.21-E08.29	Diabetes mellitus due to underlying condition with kidney complications
E09.21-E09.29	Drug or chemical induced diabetes mellitus with kidney complications
E10.21-E10.29	Type 1 diabetes mellitus with kidney complications
E11.21-E11.29	Type 2 diabetes mellitus with kidney complications
E13.21-E13.29	Other specified diabetes mellitus with kidney complications
P70.2	Neonatal diabetes mellitus
T86.10-T86.19	Complications of kidney transplant
Z79.4	Long term (current) use of insulin

When services are Investigational and Not Medically Necessary:
For the procedure and diagnosis codes listed above for kidney transplantation in association with pancreas transplantation when criteria are not met, for third or subsequent transplantations, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

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Peer Reviewed Publications:

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17. Maahs DM, West NA, Lawrence JM, Mayer-Davis EJ. Chapter 1: Epidemiology of Type 1 Diabetes. Endocrinol Metab Clin North Am. 2010; 39(3):481-497.
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Government Agency, Medical Society, and Other Authoritative Publications:

1. American Diabetes Association. Standards of medical care in diabetes--2023. Available at: https://diabetesjournals.org/care/issue/46/Supplement_1. Accessed on December 13, 2022.
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Websites for Additional Information

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Index

Document History

Status	Date	Action
Reviewed	02/16/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.
Reviewed	02/17/2022	MPTAC review. Rationale and References sections updated.
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Reviewed	05/07/2015	MPTAC review. Updated Description, Rationale, Background, and References sections.
Reviewed	05/15/2014	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Websites.
Revised	05/09/2013	MPTAC review. Clarified medically necessary statements. Clarified investigational and not medically necessary statement for third or subsequent pancreas or simultaneous pancreas/kidney transplants. Updated Rationale, References, and Websites.

Reviewed	05/10/2012	MPTAC review. Rationale, Reference and Website section updated.
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Reviewed	05/21/2009	MPTAC. References updated.
Reviewed	05/15/2008	MPTAC review. References updated.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	05/17/2007	MPTAC review. Rationale and references updated.
	09/14/2006	Added “End Stage Renal Disease (ESRD)” to Definitions.
Reviewed	06/08/2006	MPTAC review. References updated.
	11/21/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Reviewed	07/14/2005	MPTAC review.
Revised	04/28/2005	
