



Manual: IU Health Plans
Department: Utilization Management
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Health Plans

X Medicare Advantage

X Commercial

Transplant: Pancreas Alone and Pancreas/Kidney Policy

I. Purpose

Indiana University Health Plans (IU Health Plans) considers clinical indications when making a medical necessity determination for Transplant: Pancreas Alone and Pancreas/Kidney.

II. Scope

This policy applies to all IU Health Plans and Utilization Management staff having decision-making responsibilities where authorization is required for Fully Insured and Medicare Advantage (MA) plans.

III. Exceptions

1. All other medical and surgical therapies that might be expected to yield both short-and long- term survival comparable to that of transplantation must have been tried or considered.
2. Members must complete stringent physical and psychological evaluation to determine eligibility for transplant. Transplants will not be covered for members who have other serious medical problems or are not psychologically willing to undergo the stressful surgery and postoperative care necessary.

IV. Definitions

Pancreas transplantation is performed to induce an insulin-independent, euglycemic state in diabetic patients. The procedure is generally limited to those patients with severe secondary complications of diabetes, including kidney failure. However, pancreas transplantation is sometimes performed on patients with labile diabetes and hypoglycemic unawareness.

Members with diabetes are divided into three main categories for pancreas transplantation:

1. Members with end-stage renal failure and undergoing simultaneous kidney transplantation (SPK)
2. Members who have already had a successful kidney transplant in the past (Pancreas

- after kidney: PAK)
3. Members in the pre-uremic stage (Pancreas transplant alone: PTA).

V. Policy Statements

IU Health Plans considers pancreas and pancreas/kidney transplants medically necessary when the member meets the institution's selection criteria for pancreas or pancreas/ kidney transplantation for **ONE of the following indications**:

1. Pancreas Transplant Alone (PTA) is considered medically necessary for carefully selected members who meet **all of the following** criteria:
 - a. The member has no medical, cognitive, or other psychiatric condition that is likely to interfere with their ability to manage the sequelae of the transplant, including complex medication regimens
 - b. Members must have a diagnosis of Type I Diabetes
 - c. Member must be positive for autoantibodies directed against pancreatic Beta cells, which include anti-islet cell, anti-insulin, and/or anti-glutamic acid decarboxylase autoantibodies
 - d. Member must be insulin dependent, adherent to treatment and refractory to intensive insulin therapy, with documented severe and/or life-threatening metabolic complications requiring urgent medical care and/or hospitalizations, including **ONE of the following**:
 - i. Hypoglycemia unawareness
 - ii. Recurring severe hypoglycemic attacks
 - iii. Recurring severe ketoacidosis
 - iv. Recurring, severe and/or persistent hyperglycemia requiring medical attention
 - e. Members must have been optimally and intensively managed by an endocrinologist for at least 12 months with the most medically recognized advanced insulin formulations and delivery systems
 - f. No active alcohol or illicit drug abuse
2. Simultaneous Pancreas/Kidney Transplant (SPK) is considered medically necessary for carefully selected members with end-stage renal disease from diabetic nephropathy who meet **ALL of the following** criteria:
 - a. End-stage renal disease requiring chronic dialysis or glomerular filtration rate less than 20 ml/min/1.73m² or less than 30 ml/min/1.73m² with uremia
 - b. Type 1 diabetes refractory to intensive insulin therapy as described above under the Specific Criteria for Pancreas Transplant Alone (PTA) or type 1 diabetes with **ONE or more** progressive complications of diabetes, including the following:
 - i. Diabetic retinopathy
 - ii. Diabetic neuropathy
 - iii. Diabetic gastroparesis
 - iv. Arteriosclerotic vascular disease
3. Pancreas Transplant after Kidney Transplantation (PAK) is considered medically necessary for members with insulin dependent diabetes who meet **ALL of the following** criteria:
 - a. Member has undergone successful kidney transplant
 - b. There is absence of significant chronic rejection of the transplanted kidney

- c. The transplanted kidney is stable and functioning well with a minimum creatinine clearance of 30 ml/min and the absence of significant proteinuria, and
 - d. All of the criteria are met for PTA or SPK.
4. Pancreas re-transplantation is considered medically necessary for selected members case by case based on treating physician's recommendations after a failed primary pancreas transplant.
 5. For Partial Pancreatic Tissue or Islet Cell Transplantation refer to MP062 Pancreatectomy with Autologous Islet Cell Transplantation
 6. Pancreas/pancreas-kidney transplantation in HIV+ members are considered medically necessary when all of the following conditions are met:
 - a. The member has a life expectancy of at least five years
 - b. CD4 count ≥ 200 cells/mL for at least six months
 - c. Undetectable HIV viremia (< 50 copies/mL) for six months
 - d. Demonstrated adherence to highly active antiretroviral therapy (HAART) regimen for \geq six months
 - e. Available anti-retroviral treatment options post-transplant

Codes:

CPT Codes

Code	Description
S2065	Simultaneous pancreas kidney transplantation
48160	Pancreatectomy, total or subtotal, with transplantation of pancreas or pancreatic islet cells
48550	Donor pancreatectomy
48551	Backbench preparation of cadaver donor pancreas
48552	Backbench reconstruction of cadaver donor pancreas; venous anastomosis
48554	Transplantation of pancreatic allograft
48556	Removal of previously transplanted donor pancreas when not functional
50300	Donor nephrectomy from cadaver donor
50320	Donor nephrectomy from a living donor
50340	Recipient nephrectomy
50365	Renal allotransplantation with recipient nephrectomy
50370	Removal of transplanted renal allograft
50380	Renal auto-transplantation, reimplantation of kidney

VII. Procedures

None

VIII. Rationale

Simultaneous Pancreas-Kidney Transplantation (SPK)

Evidence for SPK primarily consists of case series, institutional experiences, registry reports, evaluations of diabetes-related complications, and quality-of-life studies. Collectively, the data demonstrate that SPK effectively restores insulin production and kidney function, may enhance quality of life, and slows or reverses secondary complications of diabetes.

A 2020 study by Parajuli et al. examined 291 SPK recipients from 1986 to 1993. As of 2018, 39 individuals (13.4%) had functional pancreas allografts 25 years post-transplant. Most had type 1 diabetes and diabetic nephropathy, though no specific baseline factors predicted long-term graft survival.

In 2022, Cao et al. conducted a meta-analysis on SPK outcomes for patients with end-stage kidney disease and type 2 diabetes. Pooled survival rates were 98% at 1 year, 95% at 3 years, and 91% at 5 years. Pancreas graft survival rates were 91%, 86%, and 81% for the same intervals, respectively.

The American Diabetes Association (ADA) 2023 guidelines recommend pancreas transplantation for individuals with type 1 diabetes undergoing simultaneous or subsequent kidney transplantation, or those experiencing recurrent ketoacidosis or severe hypoglycemia despite intensive glycemic management.

Simultaneous Cadaver-Donor Pancreas and Living-Donor Kidney Transplant (SPLK)

Evidence supports the effectiveness of living-donor kidney transplants due to shorter waiting times, expanded donor pools, and better renal graft outcomes. SPLK offers advantages such as a single surgical procedure and improved long-term kidney function compared to sequential living-donor kidney transplants followed by pancreas after kidney (PAK) transplants.

Pancreas Transplant Alone (PTA)

PTA has been shown in case series to significantly improve quality of life by eliminating the need for insulin, frequent glucose monitoring, and restrictive diets, while preventing acute complications like hypoglycemia and hyperglycemia.

A 2022 study by Boggi et al. followed 66 PTA recipients with type 1 diabetes for 10 years. Survival rates were 92.4%, with 57.4% achieving optimal graft function (normoglycemia and insulin independence). Another 3% had good graft function, including improved HbA1c and reduced insulin use.

Pancreas After Kidney Transplant (PAK)

Controlled studies comparing PAK and PTA are limited. Case series and registry data support PAK in selected patients with successful kidney transplants. According to the International Pancreas Transplant Registry (IPTR), the 1-year graft survival rate for PAK is 77.5%, defined as insulin independence, normal fasting glucose, and near-normal HbA1c.

Living-Donor Segmental Pancreas Transplantation

Small case series suggest that living-donor segmental pancreas transplants have lower rejection rates and better long-term outcomes than deceased-donor grafts. IPTR data through 2020 show that of

33,541 pancreas transplants, only 137 (0.4%) were from living donors, most of which were solitary pancreas transplants.

National and International Transplant Data

Between January and October 2023, the Organ Procurement and Transplant Network (OPTN) recorded 88 PTA and 679 SPK transplants in the U.S. For PTA, the 1-year survival rate was 91%, and the 5-year rate was 79.6%. For SPK, 1-year survival was 97.5%, and 5-year survival was 88.9%. IPTR (2022) data show similar outcomes worldwide, with 1-year patient survival rates of 96.9% for SPK, 96.3% for PAK, and 98.3% for PTA.

A 2023 Spanish study by Ventura-Aguiar et al. analyzed 301 pancreas transplant recipients, including SPK (80.1%), PAK (18.6%), and PTA (1.3%). The estimated graft survival rates were 87.8% at 1 year, 84.9% at 3 years, and 83.0% at 5 years, while patient survival rates were 98.7%, 96.1%, and 94.4%, respectively.

Pancreas Retransplantation

Uncontrolled studies suggest that pancreas retransplantation can improve outcomes following graft failure. Gasteiger et al. (2018) reported 1-year graft survival of 79% and patient survival of 96% after 52 pancreas retransplantations. Parajuli et al. (2019) found that SPK recipients who underwent pancreas retransplantation had better kidney graft survival rates (76% vs. 52%) compared to those who did not.

According to the OPTN, repeat PTA recipients between 2008 and 2015 had a 1-year survival rate of 96.4% and a 5-year survival rate of 83.7%. Repeat SPK recipients had a 1-year survival rate of 100% and a 5-year survival rate of 71%.

IX. References/Citations

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X. Forms/Appendices

None

XI. Responsibility

Medical Director

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