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Allogeneic Pancreas Transplant

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Related Policies (if applicable)
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Disclaimer

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Texas ONLY: For policies (IFM, Student, Small Group, Mid-Market, Large Group, fully-insured Municipalities/Counties/Schools, State Employee Plans, PPO, HMO, POS) delivered, issued for delivery, or renewed on or after January 1, 2024, TIC Chapter 1380 (§§ 1380.001 – 1380.003 [SB 1040 Human Organ Transplant]) prohibits coverage of a human organ transplant or post-transplant care if the transplant operation is performed in China or another country known to have participated in forced organ harvesting; or the human organ to be transplanted was procured by a sale or donation originating in China or another country known to have participated in forced organ harvesting. The commissioner of state health services may designate countries who are known to have participated in forced organ harvesting. Forced organ harvesting is defined as the removal of one or more organs from a living person by means of coercion, abduction, deception, fraud, or abuse of power or a position of vulnerability.

Coverage

The following pancreatic transplantation procedures **may be considered medically necessary** when specific indications or criteria are met:

- A combined (or simultaneous) pancreas-kidney transplant for insulin-dependent diabetic mellitus (IDDM) individuals with uremia; or
- A pancreas transplant after a prior kidney transplant in individuals with IDDM; or
- A pancreas transplant alone in individuals with severely disabling and potentially life-threatening complications due to hypoglycemia unawareness and labile IDDM that persists despite optimal medical management (refer to **NOTE 1** below); or
- Pancreatic retransplantation after a failed primary pancreas transplant for individuals who continue to meet the criteria for a pancreas transplantation.

NOTE 1: Candidates for a pancreas transplant alone should meet **ONE** of the following severities of illness criteria:
- Documented severe hypoglycemia unawareness as evidenced by chart notes or emergency department visits; or
- Documented potentially life-threatening labile diabetes, as evidenced by chart notes or hospitalization for diabetic ketoacidosis.

All other individual pancreatic transplantation procedures/situations **are considered experimental, investigational and/or unproven**, including but not limited to:
- Pancreatic retransplantation (PR) after two or more failed pancreas transplants;
- Transplantation of a segment of a pancreas from a living related donor (i.e., head or tail sections).

Policy Guidelines

General
Potential contraindications for solid organ transplant that are subject to the judgment of the transplant center include the following:
- Known current malignancy, including metastatic cancer,
- Recent malignancy with high risk of recurrence,
- Untreated systemic infection making immunosuppression unsafe, including chronic infection,
- Other irreversible end-stage disease not attributed to kidney disease,
- History of cancer with a moderate risk of recurrence,
- Systemic disease that could be exacerbated by immunosuppression,
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

Multiple Transplant
Although there are no standard guidelines for multiple pancreas transplants, the following information may aid in case review:
- If there is early graft loss resulting from technical factors (e.g., venous thrombosis), a retransplant may generally be performed without substantial additional risk.
- Long-term graft losses may result from chronic rejection, which is associated with increased risk of infection following long-term immunosuppression, and sensitization, which increases

the difficulty of finding a negative cross-match. Some transplant centers may wait to allow reconstitution of the immune system before initiating retransplant with an augmented immunosuppression protocol.

Description

Transplantation of a healthy pancreas is a treatment for patients with insulin-dependent diabetes. Pancreas transplantation can restore glucose control and prevent, halt, or reverse the secondary complications from diabetes.

Background

Solid Organ Transplantation

Solid organ transplantation offers a treatment option for patients with different types of end-stage organ failure that can be lifesaving or provide significant improvements to a patient's quality of life. (2) Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Patients are prioritized for transplant by mortality risk and severity of illness criteria developed by Organ Procurement and Transplantation Network and United Network of Organ Sharing.

Allogeneic Pancreas Transplant

In 2023, 46,630 transplants were performed in the United States (U.S.) procured from more than 16,000 deceased donors and 6,900 living donors. (3) Pancreas-kidney transplants were the fifth most common procedure, with 812 transplants performed in 2023. Pancreas-alone transplants were the sixth most common procedure, with 102 transplants performed in 2023.

Pancreas transplantation occurs in several different scenarios such as:

1. A diabetic patient with renal failure who may receive a simultaneous cadaveric pancreas plus kidney transplant; or
2. A diabetic patient who may receive a cadaveric or living-related pancreas transplant after a kidney transplantation (pancreas after kidney); or
3. A nonuremic diabetic patient with specific severely disabling and potentially life-threatening diabetic problems who may receive a pancreas transplant alone.

Data from the United Network for Organ Sharing and the International Pancreas Transplant Registry indicate that the proportion of simultaneous pancreas plus kidney transplant recipients worldwide who have type 2 diabetes has increased over time, from 6% of transplants between 2005 and 2009 to 9% of transplants between 2010 and 2014. (4) Between 2010 and 2014, approximately 4% of pancreas after kidney transplants and 4% of pancreas alone transplants were performed in patients with type 2 diabetes. In 2022, patients with type 2 diabetes accounted for 22.4% of all pancreas transplants, according to data from the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients. (1)

Regulatory Status
Solid organ transplants are a surgical procedure and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA).

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation Title 21, parts 1270 and 1271. Solid organs used for transplantation are subject to these regulations.

Rationale

This medical policy was created in 1990 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through June 24, 2024.

Medial policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Much of the published literature consists of retrospective data reported by single centers and registry data. The extant RCTs compare immunosuppression regimens and surgical techniques and therefore do not compare pancreas transplantation with insulin therapy, or simultaneous pancreas and kidney (SPK) transplant with insulin therapy and hemodialysis.

Pancreas Transplant After Kidney Transplant

Clinical Context and Therapy Purpose

The purpose of a pancreas after kidney (PAK) transplant in individuals who have insulin-dependent diabetes is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with insulin-dependent diabetes.

Interventions

The therapy being considered is a PAK transplant.

PAK transplantation permits patients with insulin-dependent diabetes to benefit from a living-related kidney graft, if available, and to benefit from a subsequent pancreas transplant that is likely to improve quality of life compared with a kidney transplant alone. Patients with insulin-dependent diabetes for whom a cadaveric kidney graft is available, but a pancreas graft is not simultaneously available, benefit similarly from a later pancreas transplant.

Comparators

The following therapy is currently being used to make decisions about insulin-dependent diabetes: insulin therapy.

Outcomes

The general outcomes of interest are overall survival (OS), disease progression, graft failure, and adverse events. In the short-term (post-surgery), follow-up monitors for graft failure. Long-term follow-up has extended to 10 years as survival improves.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Within each category of study design, studies with larger sample sizes and longer duration were preferred.
- Studies with duplicative or overlapping populations were excluded.

Registry Studies and Retrospective Studies

As reported by Gruessner and Gruessner (2016), according to United Network for Organ

Sharing (UNOS) and International Pancreas Transplant Registry data, patient survival rates after PAK conducted from 2010 to 2014 were 97.9% after 1 year and 94.5% after 3 years. (4) This compares with 1-year (96.4%) and 3-year (93.1%) patient survival rates for transplants conducted from 2005 to 2009.

Parajuli et al. (2019) described a single center's experience with 635 pancreas and kidney transplant patients (611 SPK, 24 PAK). (5) Transplants were performed between 2000 and 2016. The mean length of time between kidney transplant and pancreas transplant was 23.8 months in the PAK group. Pancreas rejection rates at 1-year post-transplant were 4% and 9% with PAK and SPK respectively (p=0.39). During the entire study period, PAK patients were more likely to experience pancreas rejection (38% vs. 16%; p=0.005). Kidney and pancreas graft survival rates did not differ between groups at 1 year or at last follow-up. Pancreas graft survival rates for PAK and SPK at 1 year were 100% and 89%, respectively (p=0.09). Death-censored pancreas graft failure rates for PAK and SPK at last follow-up were 13% and 25%, respectively (p=0.17). Patient survival at last follow-up was similar between groups (71% with PAK vs. 68% with SPK; p=0.79).

Bazerbachi et al. (2013) reviewed a single center's experience with PAK and SPK. (6) Between 2002 and 2010, 172 pancreas transplants were performed in diabetic patients (123 SPK and 49 PAK). The median length of time between kidney transplant and pancreas transplant in the PAK group was 4.8 years. Graft and patient survival rates were similar for both groups. Death-censored pancreas graft survival rates for SPK and PAK were 94% and 90% at 1 year, 92% and 90% at 3 years, and 85% and 85% at 5 years (p=0.93), all respectively. Patient survival rates (calculated from the time of pancreas transplantation) in the SPK and PAK groups were 98% and 100% after 1 year, 96% and 100% after 3 years, and 94% and 100% after 5 years (p=0.09), respectively.

Fridell et al. (2009) reported on a retrospective review of a single center's experience with PAK and SPK since 2003, when current induction or tacrolimus immunosuppressive strategies became standard. (7) Of the 203 cases studied, 61 (30%) were PAK and 142 (70%) were SPK. One-year patient survival rates were 98% PAK and 95% SPK (p=0.44). Pancreas graft survival rates at 1 year were 95% and 90%, respectively (p=0.28). The authors concluded that in the modern immunosuppressive era, PAK should be considered as an acceptable alternative to SPK in candidates with an available living kidney donor.

Kleinclauss et al. (2009) retrospectively reviewed data from 307 diabetic kidney transplant recipients from a single center and compared renal graft survival rates in those who subsequently received a pancreatic transplant with those who did not. (8) The comparative group was analyzed separately based on whether patients were medically eligible for pancreas transplant but chose not to proceed for financial or personal reasons or were ineligible for medical reasons. The ineligible (n=57) group differed significantly at baseline from both the PAK group (n=175) and the eligible group (n=75) with respect to age, type of diabetes, and dialysis experience; kidney graft survival rates at 1, 5, and 10 years were lower in the ineligible group (75%, 54%, and 22%, respectively, p<0.001) than in the other groups (for the PAK group, 98%, 82%, and 67% vs. for the eligible group, 100%, 84%, and 62%). The authors concluded that the subsequent transplant of a pancreas after a living donor kidney transplant does not adversely affect patient or kidney graft survival rates.

Section Summary: Pancreas Transplant after Kidney Transplant

Data from national and international registries have found relatively high patient survival rates after PAK (e.g., a 3-year survival rate of 94.5%). Single-center retrospective analyses have found similar patient survival and death-censored pancreas graft survival rates after PAK and SPK transplants.

Simultaneous Pancreas Plus Kidney Transplants for Patients with Uremia

Clinical Context and Therapy Purpose

The purpose of an SPK transplant in individuals who have insulin-dependent diabetes with uremia is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who have insulin-dependent diabetes with uremia.

Interventions

The therapy being considered is an SPK transplant.

Comparators

The following therapy is currently being used to make decisions about insulin-dependent diabetes with uremia: insulin therapy.

Outcomes

The general outcomes of interest are OS, disease progression, graft failure, and adverse events. In the short term (post-surgery), follow-up monitors for graft failure. Long-term follow-up has extended to 10 years as survival improves.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Within each category of study design, studies with larger sample sizes and longer duration were preferred.

- Studies with duplicative or overlapping populations were excluded.

Registry Studies and Retrospective Studies
The U.S.-based Organ Procurement and Transplant Network (OPTN) has reported a 1-year patient survival rate of 97.5% (95% confidence interval [CI], 96.9% to 98%) for primary SPK procedures performed between 2008 and 2015. (9) Three- and 5-year patient survival rates were 94.8% (95% CI, 93.9% to 95.5%) and 88.9% (95% CI, 87.5% to 89.9%), respectively.

An analysis of U.K. registry data by Barlow et al. (2017) compared outcomes in patients with type 1 diabetes and end-stage renal disease who had SPK transplants (n=1739) versus live donor kidney transplants (n=370). (10) In multivariate analysis, there was no significant association between type of transplant and patient survival (hazard ratio, 0.71; 95% CI, 0.47 to 1.06; p=0.095). Simultaneous pancreas plus kidney recipients with a functioning pancreas graft had significantly better OS than those with a living donor kidney transplant (p<0.001).

Simultaneous pancreas plus kidney transplants have been found to reduce mortality in patients with type 1 diabetes. van Dellen et al. (2013) in the U.K. reported on a retrospective analysis of data on 148 SPK patients and a wait-list control group of 120 patients. (11) All patients had type 1 (insulin-dependent) diabetes. (The study also included 33 patients who had PAK and 11 patients who had pancreas transplant alone [PTA].) Overall mortality (mortality at any time point) was 30% (30/120) for the waiting list and 9% (20/193) for transplanted patients; the difference between groups was statistically significant (p<0.001). The 1-year mortality rate was 13% (n=16) on the waiting list and 4% (n=8) for the transplant group (p<0.001).

Sampaio et al. (2011) published an analysis of data from the UNOS database. (12) Outcomes for 6141 patients with type 1 diabetes and 582 patients with type 2 diabetes who underwent SPK were similar for both groups in adjusted analyses. After adjusting for other factors (e.g., body weight; dialysis time; cardiovascular comorbidities), type 2 diabetes was not associated with an increased risk of pancreas or kidney graft failure or mortality compared with type 1 diabetes.

Section Summary: Simultaneous Pancreas Plus Kidney Transplants for Patients with Uremia
Data from national and international registries have found relatively high patient survival rates after SPK transplants (e.g., a 3-year survival rate of 94.8% and a 5-year survival rate of 88.9%). A retrospective analysis found a higher survival rate in patients with type 1 diabetes who had an SPK transplant than in those on a waiting list.

Pancreas Transplant Alone for Patients with Severe Complications
Clinical Context and Therapy Purpose
The purpose of a pancreas transplant in individuals who have insulin-dependent diabetes with severe diabetic complications is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals who have insulin-dependent diabetes with severe diabetic complications.

Although pancreas transplantation is generally not considered a life-saving treatment for individuals with insulin-dependent diabetes, in a small subset of patients who experience life-threatening complications from diabetes, pancreas transplantation could be considered life-saving. PTA has also been investigated in patients following total pancreatectomy for chronic pancreatitis. In addition to the immune rejection issues common to all allograft transplants, autoimmune destruction of beta cells has been observed in the transplanted pancreas, presumably from the same mechanism responsible for type 1 diabetes. (13)

Most patients undergoing PTA are those with either hypoglycemic unawareness or labile diabetes. However, other exceptional circumstances may exist where patients with nonuremic type 1 diabetes have significant morbidity risks due to secondary complications of diabetes (e.g., peripheral neuropathy) that exceed those of the transplant surgery and subsequent chronic immunosuppression. Because virtually no published evidence addresses outcomes of medical management in this very small group of exceptional diabetic patients, it is not possible to generalize about which circumstances represent appropriate indications for PTA. Case-by-case consideration of each patient's clinical situation may be the best option for determining the balance of risks and benefits.

Interventions
The therapy being considered is PTA.

Comparators
The following therapy is currently being used to make decisions about insulin-dependent diabetes with severe diabetic complications: insulin therapy.

Outcomes
The general outcomes of interest are OS, disease progression (e.g., end-stage renal disease), graft failure, and adverse events (e.g., hypoglycemia, labile diabetes). In the short-term (post-surgery), follow-up monitors for graft failure. Long-term follow-up has extended to 5 years as survival improves.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

- Within each category of study design, studies with larger sample sizes and longer duration were preferred.
- Studies with duplicative or overlapping populations were excluded.

Registry Studies and Retrospective Studies

Pancreas transplant graft survival has improved over time. According to International Pancreas Transplant Registry data, 1-year graft function increased from 51.5% in 1987 to 1993 to 77.8% for 2006 to 2010 ($p<0.001$). (14) One-year immunologic graft loss remained higher (6.0%) after PTA than after PAK (3.7%) or SPK (1.8%). According to UNOS and the International Pancreas Transplant Registry data, for the period from 2010 to 2014, the patient survival rate for PTA was 96.3% after 1 year and 94.9% after 3 years. (4) This compares with 1-year and 3-year patient survival rates of 97.5% and 93.3% for 2005 to 2009, respectively. According to Gruessner (2011), in carefully selected patients with type 1 diabetes and severely disabling and potentially life-threatening complications due to hypoglycemia unawareness and persistent labile diabetes despite optimal medical management, the benefits of PTA were judged to outweigh the risk of performing pancreas transplantation with subsequent immunosuppression. (14)

Boggi et al. (2021) reported results of a single-center cohort study of 66 patients with type 1 diabetes who received PTA. (15) After 10 years of follow-up, patient survival was 92.4%. Of these patients surviving to 10 years, 57.4% had optimal graft function (defined as normoglycemia and insulin independence) and 3.2% had good graft function (defined as HbA1c <7%, no severe hypoglycemia, >50% reduction in insulin requirements, and restoration of clinically significant C-peptide production). Four patients (6.0%) developed end-stage renal failure (stage 5, estimated glomerular filtration rate [eGFR] < 15 ml/min/1.73 m^2), and 2 additional patients (3.0%) showed stage 4 kidney failure (eGFR 15 to 30 ml/min/1.73 m^2) at the 10-year posttransplant assessment.

Noting that nephrotoxic immunosuppression may exacerbate diabetic renal injury after PTA, Scalea et al. (2008) reported on a single institutional review of 123 patients who received 131 PTA for the development of renal failure. (16) Mean graft survival was 3.3 years (range, 0-11.3 years), and 21 patients were lost to follow-up. At mean follow-up of 3.7 years, the mean eGFR was 88.9 mL/min/1.73 m^2 pretransplantation and 55.6 mL/min/1.73 m^2 posttransplantation. All but 16 patients had a decrease in eGFR. Thirteen developed end-stage renal disease, which required kidney transplantation at a mean of 4.4 years. The authors suggested that patients should be made aware of the risk and only the most appropriate patients should be offered PTA.

Section Summary: Pancreas Transplant Alone for Patients with Severe Complications

Data from international and national registries have found that graft and patient survival rates after PTA have improved over time. For the period of 2010 to 2014, 1- and 3-year survival rates had improved to 96.3% and 94.9%, respectively.

Pancreas Retransplantation

Clinical Context and Therapy Purpose

The purpose of a pancreas retransplant in individuals who have had a prior pancreas transplant and still meet criteria for a pancreas transplant is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who have had a prior pancreas transplant and still meet criteria for a pancreas transplant.

Interventions

The therapy being considered is a pancreas retransplant.

The approach to retransplantation varies by cause of failure. Surgical and technical complications such as venous thrombosis are the leading cause of pancreatic graft loss among diabetic patients. Graft loss from chronic rejection may result in sensitization, increasing both the difficulty of finding a cross-matched donor and the risk of rejection of a subsequent transplant. Each transplant center has guidelines based on experience; some centers may wait to allow reconstitution of the immune system before initiating retransplant with an augmented immunosuppression protocol.

Comparators

The following therapy is currently being used to make decisions about a failed pancreas transplant: insulin therapy.

Outcomes

The general outcomes of interest are OS, graft progression, transplant failure, and adverse events. In the short-term (post-surgery), follow-up monitors for graft failure. Long-term follow-up has extended over time to 5 years as survival improves.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Within each category of study design, studies with larger sample sizes and longer duration were preferred.
- Studies with duplicative or overlapping populations were excluded.

Registry Studies and Retrospective Studies

Parajuli et al. (2019) compared outcomes among SPK patients who did or did not receive pancreas retransplantation after isolated pancreas graft failure. (17) Among 109 SPK patients with pancreas graft failure, 25 underwent pancreas retransplantation and 84 did not. The mean follow-up time after pancreas graft failure was longer among patients who underwent pancreas retransplantation (7.6 years vs. 4.6 years). Rates of death-censored kidney graft failure at last follow-up were lower among patients who underwent pancreas retransplantation (24% vs. 48%; p=0.04). However, given the retrospective nature of the study, selection bias may have influenced the observed outcomes. Patient survival was not significantly different between groups. Among patients who underwent retransplantation, 1-year pancreas graft survival was 84%.

The retrospective observational study by Gasteiger et al. (2018) assessed the outcomes of pancreas retransplantation for patients with pancreas graft failure (defined as a return to insulin dependence). (18) The study evaluated pancreas retransplantations performed between 1997 and 2013 at a single Austrian medical university. Fifty-two pancreas retransplantations were identified, and the median follow-up was 65.0 (range, 0.8 to 174.3) months. At 5 years, the overall patient survival rate was 89%; the survival rate for patients who underwent simultaneous kidney-pancreas retransplantation was 90% (18/20), and the survival rate for those who received only a pancreas retransplantation was 88% (28/32). Graft survival rates were 79% at 1 year and 69% at 5 years. The 5-year graft survival rate was higher following SPK retransplantation than pancreas retransplantation alone: 80% for SPK (16/20) versus 63% (20/32) for pancreas alone (p=0.226). During the entire follow-up, 42% (22/52) of the grafts were lost. Two factors significantly associated with long-term graft survival were early surgical complications (odds ratio, 3.29; 95% CI, 1.09 to 9.99; p=0.035) and acute rejection (odds ratio, 4.49; 95% CI, 1.59 to 12.68; p=0.005). The authors note that because pancreas transplantation is not a life-saving operation, the risks and benefits of the procedure must be carefully considered.

The OPTN has reported data on transplants performed between 2008 and 2015. (9) Patient survival rates after repeat PTA were similar to survival rates after primary transplants. For example, the 1-year survival rate was 90.9% (95% CI, 88.7% to 92.8%) after a primary pancreas transplant and 96.4% (95% CI, 92.1% to 98.4%) after a repeat pancreas transplant. The number of patients transplanted were not reported, but OPTN data stated that 663 patients were alive 1 year after primary transplant and 154 after repeat transplants. The 3-year patient survival rate was 87.5% (95% CI, 85.1% to 89.6%) after primary transplants and 91.2% (95% CI, 86.2% to 94.4%) after repeat transplants. The 5-year patient survival rate was 79.9% (95% CI, 77.4% to 82.2%) after primary transplants and 83.7% (95% CI, 78.2% to 88.0%) after repeat transplants. The 1-year graft survival rate was 81.8% (95% CI, 78.9% to 84.3%) after primary pancreas transplant and 77.7% (95% CI, 70.8% to 83.1%) after repeat transplant.

Data are similar for patients receiving SPK transplants, but follow-up data are only available on a small number of patients who had repeat SPK transplants, so estimates of survival rates in this group are imprecise. Three-year patient survival rate was 94.8% (95% CI, 93.9% to 95.5%) after primary SPK transplant and 87.9% (95% CI, 73.4% to 94.8%) after a repeat SPK transplant.

The number of patients living 3 years after transplant was 2871 after a primary combined procedure and 36 after a repeat combined procedure.

Several centers have published outcomes after pancreas retransplantation and generally reported comparable graft and patient survival rates after initial transplants and retransplants. (19-22) The largest and most recent studies are further described here. Fridell et al. (2015) reported on 441 initial transplants and 20 late transplants. (20) One-year graft survival rates were 92% after initial transplant and 90% after retransplant (p=0.48). Similarly, 1-year patient survival rates were 96% after initial transplants and 95% after retransplants (p=0.53). However, Rudolph et al. (2015), who assessed the largest number of patients, reported higher graft survival rates, but not patient survival rates, after primary transplant. (22) A total of 2145 pancreas transplants were performed, 415 (19%) of which were retransplants. The death-censored graft survival rate at 1 year was 88.2% in initial transplants and 75.0% in retransplants (p<0.001). Patient survival rates at 1 year were 91.3% after initial transplants and 88.2% after retransplants (p=0.06).

Section Summary: Pancreas Retransplantation

National and international data reported from specific transplant centers have generally reported similar graft and patient survival rates after pancreas retransplantation compared with initial transplantation. There is insufficient data regarding health outcomes associated with third and subsequent pancreas transplant to allow strong conclusions.

Potential Contraindications

Pancreas Transplant in Human Immunodeficiency Virus (HIV)-Positive Transplant Recipients

Current OPTN policy permits HIV-positive transplant candidates. (23)

The American Society of Transplantation (2019) published a guideline on solid organ transplantation in HIV-infected patients. (24) For kidney-pancreas transplants, the following criteria for transplantation are suggested:

- Cluster of differentiation 4 count >200 cells/mL for at least 3 months (insufficient data to recommend for or against transplantation in patients with counts >100 cells/mL and no history of opportunistic infection);
- Undetectable HIV viral load while receiving antiretroviral therapy;
- Documented compliance with a stable antiretroviral therapy regimen;
- Absence of active opportunistic infection and malignancy;
- Absence of chronic wasting or severe malnutrition;
- Appropriate follow-up with providers experienced in HIV management and ready access to immunosuppressive medication therapeutic drug monitoring.

The guideline authors note that patients with a previous history of progressive multifocal leukoencephalopathy, chronic interstitial cryptosporidiosis, primary central nervous system lymphoma, or visceral Kaposi's sarcoma were excluded from studies of solid organ transplantation in HIV-infected patients. Patients with HIV and concomitant controlled hepatitis B infection may be considered for transplant. Caution is recommended in hepatitis C-coinfected patients who have not been initiated on direct acting antiviral therapy.

Age

Recipient age older than 50 years has been considered a relative contraindication for a pancreas transplant. Several analyses of outcomes by patient age group have prompted general agreement among experts that age should not be a contraindication; however, age-related comorbidities must be considered when selecting patients for transplantation.

In the largest study of pancreas outcomes by recipient age, Siskind et al. (2014) assessed data from the UNOS database. (25) Investigators included all adults who received SPK or PTA transplants between 1996 and 2012 (N=20,854). This included 3160 patients between the ages of 50 and 59 years, and 280 patients aged 60 years or older. Overall, Kaplan-Meier survival analysis found statistically significant differences in patient survival (p<0.001) and graft survival (p<0.001) by age category. Graft survival was lowest in the 18-to-29 age group at 1, 5, and 10 years, which the authors noted might be due to early immunologic graft rejection as a result of more robust immune responses. However, 10- and 15-year graft survival was lowest in the 60 and older age group. Patient survival rates decreased with increasing age, and the differential between survival in older and younger ages increased with longer follow-up intervals. Lower survival rates in patients 50 and older could be due in part to comorbidities at the time of transplantation. Also, as patients age, they are more likely to die from other causes. Still, patient survival rates at 5 and 10 years are relatively high, as shown in Table 1.

Table 1. Patient Survival by Age Group

Year After Transplant	Age 18-29, %	Age 30-39, %	Age 40-49, %	Age 50-59, %	Age 60+, %
1 year	95.4	96.0	94.9	93.3	91.0
5 years	86.3	87.8	85.7	81.6	71.4
10 years	73.5	76.8	71.8	61.5	42.5

Adapted from Siskind et al. (2014). (25)

Among previous studies on pancreas outcomes in older patients, Shah et al. (2013) reviewed data on 405 patients who underwent PTA transplants between 2003 and 2011. (26) One-year patient survival was 100% for patients younger than age 30 years, 98% for patients aged 30 to 39 years, 94% for patients aged 40 to 49 years, 95% for patients aged 50 to 59 years, and 93% for patients aged 60 years or older. There was no statistically significant difference in patient survival by age (p=0.38). Findings were similar for 1-year graft survival; there was no statistically significant difference in outcomes by age of transplant recipients (p=0.10).

A study by Afaneh et al. (2011) reviewed data on 17 individuals at least 50 years old and 119 individuals younger than 50 years who had a pancreas transplant at a single institution in the United States. (27) The 2 groups had similar rates of surgical complications, acute rejection, and nonsurgical infections. Overall patient survival was similar. Three- and 5-year survival rates were 93% and 90%, respectively, in the younger group, and 92% and 82%, respectively, in the older group. Schenker et al. (2011) compared outcomes in 69 individuals at least 50 years old with 329 individuals younger than 50 years who had received pancreas transplants. (28) Mean duration of follow-up was 7.7 years. One-, 5-, and 10-year patient and graft survival rates were similar for the groups. For example, the 5-year patient survival was 89% in both groups. The 5-year pancreas graft survival was 76% in the older group and 72% in the younger group. The authors of both studies, as well as the authors of a commentary accompanying the Schenker et al. (2011) article, (29) agreed that individuals aged 50 years and older are suitable candidates for pancreas transplantation.

Living Donor Pancreas Transplantation

Living donor segmental pancreas transplants (LDSPTx) have been performed selectively to offer a preemptive transplant option for simultaneous pancreas-kidney recipients and to perform a single operation decreasing the cost of pancreas after kidney transplant. For solitary pancreas transplants, this option historically provided a better immunologic match. Although short-term donor outcomes have been documented, there are no long-term studies. (30)

Kirchner et al. (2016) studied post-donation outcomes in 46 segmental pancreas living donors, looking at surgical complications, risk factors for development of diabetes mellitus and quality of life. (30) Between January 1, 1994 and May 1, 2013, 46 LDSPTx were performed. Intraoperatively, 5 (11%) donors received transfusion. Overall, 9 (20%) donors underwent splenectomy. Postoperative complications included: 6 (13%) peripancreatic fluid collections and 2 (4%) pancreatitis episodes. Post-donation, diabetes mellitus requiring oral hypoglycemics was diagnosed in 7 (15%) donors and insulin-dependent diabetes mellitus in 5 (11%) donors. Quality of life was not significantly affected by donation. Mean graft survival was 9.5 (±4.4) years from donors without and 9.6 (±5.4) years from donors with post-donation diabetes mellitus.

In 2018, Henderson et al. reported on the landscape of living multiorgan donation in the United States using the Scientific Registry of Transplant Recipients (SRTR). (31) Kidney-pancreas donation comprised the most common form of simultaneous multiorgan donation, with 48 cases identified in the SRTR since 1994. The first living donor simultaneous pancreas-kidney transplant was reported in the US in 1994. Much of the literature on donor outcomes after living pancreas-kidney donation has focused on short-term perioperative complications, rather than long-term complications. Significant perioperative complications related to pancreatectomy, such as pancreatitis, abscess, or fistula, have been reported in less than 5% of living donors in case series, while reoperation and splenectomy due to bleeding, ischemia, or abscess have been noted in 5% to 20%. Data on long-term outcomes are limited, but a recent study of 45 living pancreas donors that included 69% simultaneous kidney donations found that over a mean post-donation follow-up period of 16.3 years, 26.7% filled prescriptions for diabetes treatments, compared with 5.9% of kidney-alone living donors (odds ratio, 4.13; 95% confidence interval, 1.91-8.93; P = 0.0003). These findings suggest a more than fourfold increase in the incidence of diabetes after living kidney-pancreas donation, a concern that warrants longer follow-up and investigation to adequately understand risks to the donor.

Choi et al. (2016) reported on a single center experience of 20 cases of pancreas transplantation from living donors. (32) Six cases (30%) were PTA, and the rest (70%) were SPK. Relations of donor and recipient were parents in 7 (35%), siblings in 6 (30%), spouse in 6 (30%), and cousin in 1 (5%). Graft survival in SPK at 1, 3, 5, and 10 years was 91.7%, 83.3%, 83.3%, and 83.3%, respectively, and that in PTA recipients was 50%, 33.3%, 16.7%, and 16.7%, respectively ($p = 0.005$). Causes of graft failure in SPK were thrombosis (one case) and rejection (one case), whereas those in PTA were noncompliance (two cases), thrombosis (one case), reflux pancreatitis (one case), and chronic rejection (one case). In terms of pancreas exocrine drainage, two grafts (25%) maintained their function in bladder drainage, while all grafts maintained in enteric drainage $p < 0.05$). Seven (35%) donors experienced minor pancreatic juice leakage and one underwent reoperation due to postoperative hematoma. Most donors maintained normoglycemia and normal renal function. However, two donors developed DM (at 1- and 90-months post-donation) and were treated with oral hypoglycemic agents. Efforts to reduce complications and improve donor safety are required before pancreas transplantation from living donors can be considered an acceptable and safe treatment.

Summary of Evidence:

For individuals who have insulin-dependent diabetes who receive a pancreas transplant after a kidney transplant, the evidence includes retrospective studies and registry studies. Relevant outcomes are overall survival (OS), change in disease status, and treatment-related mortality and morbidity. Data from national and international registries have found relatively high patient survival rates with a pancreas transplant after a kidney transplant (e.g., a 3-year survival rate of 94.5%). Single-center retrospective studies have found similar patient survival and death-censored pancreas graft survival rates with a pancreas transplant after a kidney transplant or a simultaneous pancreas and kidney (SPK) transplant. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have insulin-dependent diabetes with uremia who receive SPK transplants, the evidence includes retrospective studies and registry studies. Relevant outcomes are OS, change in disease status, and treatment-related mortality and morbidity. Data from national and international registries have found relatively high patient survival rates after SPK transplant. A retrospective analysis found a higher survival rate in patients with type 1 diabetes who had an SPK transplant versus those on a waiting list. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have insulin-dependent diabetes and severe complications who receive pancreas transplant alone, the evidence includes registry studies. Relevant outcomes are OS, change in disease status, and treatment-related mortality and morbidity. Data from international and national registries have found that graft and patient survival rates after pancreas transplant alone have improved over time (e.g., 3-year survival of 94.9%). The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had a prior pancreas transplant who still meet criteria for a pancreas transplant who receive pancreas retransplantation, the evidence includes retrospective studies and registry studies. Relevant outcomes are OS, change in disease status, and treatment-related mortality and morbidity. National data and specific transplant center data have generally found similar graft and patient survival rates after pancreas retransplantation compared with initial transplantation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. For third and subsequent pancreas transplant, there is still insufficient data regarding health outcomes to allow strong conclusions to be made.

For individuals receiving a living donor pancreas transplantation, the evidence is primarily retrospective reports and patient-registry data. Donor and recipient selection criteria for living donor pancreas transplantation have not been clearly defined, and long-term clinical outcomes for the donor and recipient have not been reported. In the short-term, there is limited evidence supporting normalizing insulin production for selected recipients, however concerns remain regarding negative metabolic impact to donors. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

Organ Procurement and Transplantation Network (OPTN)

The Organ Procurement and Transplantation Network (OPTN) updated its comprehensive list of transplant-related policies, most recently in September 2024. (33)

For pancreas registration:
"Each candidate registered on the pancreas waiting list must meet one of the following requirements:

- Be diagnosed with diabetes,
- Have pancreatic exocrine insufficiency,
- Require the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons."

For combined kidney plus pancreas registration: "Each candidate registered on the kidney-pancreas waiting list must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency."

Medicare National Coverage

An allogeneic pancreas transplant is covered under Medicare when performed in a facility approved by Medicare as meeting institutional coverage criteria. (34) The Centers for Medicare & Medicaid Services made the following national coverage decision on pancreas transplant for Medicare recipients. (35)

"A. General

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.

B. Nationally Covered Indications

Effective … 1999, whole organ pancreas transplantation is nationally covered by Medicare when performed simultaneously with or after a kidney transplant. If the pancreas transplant occurs after the kidney transplant, immunosuppressive therapy begins with the date of discharge from the inpatient stay for the pancreas transplant.

Effective … 2006, pancreas transplants alone (PA) are reasonable and necessary for Medicare beneficiaries in the following limited circumstances:

1. PA will be limited to those facilities that are Medicare-approved for kidney transplantation.
2. Patients must have a diagnosis of type I diabetes:
    - Patient with diabetes must be beta-cell autoantibody-positive; or
    - Patient must demonstrate insulinopenia defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose ≤225 mg/dL;
3. Patients must have a history of medically-uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization. Aforementioned complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;
4. Patients 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;
5. Patients must have the emotional and mental capacity to understand the significant risks associated with surgery and to effectively manage the lifelong need for immunosuppression; and,
6. Patients must otherwise be a suitable candidate for transplantation."

Nationally noncovered indications include "Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial)."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned	Completion

		Enrollment	Date
Ongoing			
NCT01047865	Recurrence of T1D in Pancreas Transplantation	400	May 2025
NCT01957696	A Prospective, Observational Study in Pancreatic Allograft Recipients: The Effect of Risk Factors, Immunosuppressive Level and the Benefits of Scheduled Biopsies – On Surgical Complications, Rejections and Graft Survival	80	Oct 2028
Unpublished			
NCT00238693	Transplant Registry: Patients Who May Require Transplantation and Those Who Have Undergone Transplantation of Liver, Kidney and/or Pancreas	13,767	Aug 2018
NCT03921593	Prospective Longitudinal Observational Study on Insulin Dependent Diabetic Patients Undergoing Any Form of Solid Organ Pancreas Transplantation Aimed to Clarify Quality of Life Changes After Pancreas Transplantation	110	Mar 2022

NCT: national clinical trial; No: number.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	48550, 48551, 48552, 48554
HCPCS Codes	S2065

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2024	Document updated with literature review. Coverage unchanged. Added/updated references 1, 3, 23, and 30-35.
03/15/2024	Document updated with literature review. Minor editorial refinement to existing Coverage although no change in intent. Moved content on islet cell transplant to policy SUR703.057. Removed Note 2. No new references: others updated. Title changed from: Pancreas and Related Organ Tissue Transplantation.
1/1/2023	Document updated with literature review. Coverage unchanged. Added/updated the following references: 3, 5, 16, 24, 31, 32, 34, 63, 64, 68, 76, 79, 80, 84, 87-89.
1/1/2022	Reviewed. No changes.
3/15/2021	Document updated with literature review. The following change was made to Coverage: Clarified that all other individual pancreatic transplantation procedures/situations are considered experimental, investigational and/or unproven, other than those specifically identified as conditionally medically necessary. Added references: 1-3, 7, 11, 15, 18-19, 25, 33, 36-51, 53-56, 58-65, and 78-79.
3/1/2019	Document updated with literature review. Coverage unchanged. References 6, 10, 15, 17, 19, 27, 37, and 36 were added and two references removed.
12/1/2017	Reviewed. No changes.
2/15/2017	Document updated with literature review. For pancreas transplantation, the following was changed: 1) Coverage statement on pancreas retransplantation was modified that it applies to patients who meet criteria for pancreas transplantation; 2) Experimental, investigational and/or

	unproven statement on individual pancreatic transplantation was modified by adding, “including but not limited to.” For pancreatic transplantation, Description, Rationale, and References significantly reorganized. For islet cell transplantation, the following was changed: Experimental, investigational and/or unproven statement on allogeneic pancreas islet cell transplantation was modified by adding, “for patients with type I diabetes mellitus. For islet cell transplantation, the following was added: “Islet cell transplantation is considered experimental, investigational and/or unproven in all other situations.”
8/15/2015	Reviewed. No changes.
3/1/2014	Document updated with literature review. The following was added to the criteria for combined (or simultaneous) pancreas-kidney transplantation: for insulin dependent diabetes mellitus. The following was removed: pancreas transplantation coverage for HIV positive patients. Description and Rationale significantly revised. CPT/HCPCS code(s) updated.
1/1/2005	Document updated.
8/1/2002	Document updated.
2/1/2002	Codes Added/Deleted
5/1/1998	Document updated.
5/1/1996	Document updated.
4/1/1996	Document updated.
7/1/1994	Document updated.
4/1/1993	Document updated.
1/1/1992	Document updated.
3/1/1991	Document updated.
5/1/1990	New medical document.