



# Pancreas transplantation

Clinical Policy ID: CCP.1201

Recent review date: 3/2026

Next review date: 7/2027

Policy contains: Diabetes; pancreas alone; pancreas–kidney.

*AmeriHealth Caritas Next has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Next's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of medically necessary, and the specific facts of the particular situation are considered, on a case by case basis, by AmeriHealth Caritas Next when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Next's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Next's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Next will update its clinical policies as necessary. AmeriHealth Caritas Next's clinical policies are not guarantees of payment.*

## Coverage policy

Pancreas transplantation is clinically proven and, therefore, may be medically necessary in members with type 1 diabetes mellitus when the following criteria are met (Kidney Disease: Improving Global Outcomes Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation, 2020; Paty, 2013; Sung, 2015; American Diabetes Association, Standards of Care in Diabetes, 2026):

- For simultaneous pancreas–kidney transplantation using deceased donor pancreas and kidney or deceased donor pancreas and live donor kidney, members must meet all the criteria for kidney transplantation.
- For pancreas transplantation after a previous kidney transplantation (pancreas-after-kidney) in members with stable kidney graft function (estimated glomerular filtration rate > 40 mL/min/1.73 m<sup>2</sup>).
- For pancreas transplantation alone using deceased donor whole organ in members who meet all of the following criteria:
  - Diagnosis of type 1 diabetes mellitus and one of the following:
    - Be beta cell autoantibody-positive.

- Demonstrate insulinopenia, defined as a fasting C-peptide level of  $\leq 110\%$  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 of  $\leq 225$  mg/dL.
- A history of severely disabling and potentially life-threatening complications due to recurrent ketoacidosis or severe hypoglycemia despite optimized glycemic management and education (American Diabetes Association, 2026).
- Optimally and intensively managed by an endocrinologist for at least 12 months with the most medically recognized advanced insulin formulations and delivery systems.
- Satisfactory kidney function (estimated glomerular filtration rate  $> 40$  mL/min/1.73 m<sup>2</sup>) (Kidney Disease: Improving Global Outcomes, 2024, Recommendation 1.1.1).
- Adequate cardiac status (no uncorrectable, symptomatic New York Heart Association Functional Class III or IV heart disease; left ventricular ejection fraction less than 30%; no active symptomatic cardiac disease that has not been evaluated and managed by a cardiologist per current guidelines; non-invasive coronary artery disease screening performed for candidates at high risk or with poor functional capacity) (Kidney Disease: Improving Global Outcomes, 2020).
- Documentation of adherence with medical management (Kidney Disease: Improving Global Outcomes, 2020).
- An acceptable psychosocial risk for transplantation surgery and the lifelong need for immunosuppression as determined by a qualified health care professional experienced in the psychosocial aspects of transplantation (Kidney Disease: Improving Global Outcomes, 2020).
- Otherwise a suitable candidate for transplantation.

Pancreas transplantation in members with type 2 diabetes mellitus is clinically proven and, therefore, may be medically necessary when all of the following criteria are met (Weems, 2014 Kidney Disease: Improving Global Outcomes, 2020; Organ Procurement and Transplantation Network/United Network for Organ Sharing Policy Notice, 2018):

- Simultaneous pancreas–kidney transplantation using deceased donor pancreas and kidney or deceased donor pancreas and live donor kidney is performed.
- Body habitus examined by a transplant surgeon and, if obesity is present, weight loss interventions have been offered prior to transplantation. Candidates should not be excluded from transplantation based on body mass index alone (Kidney Disease: Improving Global Outcomes, 2020, Organ Procurement and Transplantation Network, 2018).
- Insulin dependence.
- Low total insulin requirements ( $< 1$  U/kg of ideal body weight per day).
- Imminent or established renal failure (dialysis dependent or pre-dialysis advanced diabetic nephropathy with estimated glomerular filtration rate  $\leq 20$  mL/min/1.73 m<sup>2</sup>).
- Fasting C-peptide less than 10 ng/mL.
- No uncorrectable, symptomatic New York Heart Association Functional Class III or IV heart disease (ejection fraction less than 30%, severe coronary artery disease, or severe valvular disease).
- Non-invasive coronary artery disease screening completed for asymptomatic candidates at high risk or with poor functional capacity.
- Peripheral arterial disease evaluated per history and physical examination.
- History of medical and dietary adherence (Kidney Disease: Improving Global Outcomes, 2020).

Pancreas re-transplantation is clinically proven and, therefore, may be medically necessary upon individual case review.

## Limitations

Requests for pancreas transplantation in members with the following conditions require secondary review:

- Chronic liver disease.
- Clinical evidence of severe cerebrovascular or peripheral vascular disease (e.g., ischemic ulcers, previous amputation secondary to vascular disease). Adequate peripheral arterial supply should be determined by standard evaluation in the vascular laboratory, including Doppler examination and plethysmographic readings of systolic blood pressure.
- Past psychosocial abnormality.
- Body mass index  $\geq 30$  kg/m<sup>2</sup> but  $< 35$  kg/m<sup>2</sup>.
- Structural genitourinary abnormality or recurrent urinary tract infection.
- Substance use history (other than persistent substance use).
- Treated malignancy (simultaneous pancreas–kidney transplantation is considered medically necessary in persons with malignant neoplasm if the neoplasm has been adequately treated and the risk of recurrence is small).
- Uncontrolled hypertension.

Absolute contraindications to pancreas transplantation include, but are not limited to acquired immune deficiency syndrome diagnosis with CD4 count  $< 200$  cells/mm<sup>3</sup> (Centers for Disease Control and Prevention, 2022) unless all of the following criteria are met:

- CD4 count greater than 200 cells/mm<sup>3</sup> for more than six months.
- Human immunodeficiency virus type 1 RNA undetectable.
- Consistent anti-retroviral therapy for more than three months.
- Absence of acquired immune deficiency syndrome complications (e.g., opportunistic infection, Kaposi's sarcoma, or other neoplasm).
- Criteria met for pancreas or pancreas–kidney transplantation.
- Active drug use and alcohol dependence.
- Active hepatitis or cirrhosis.
- Active or recent malignancy.
- Active peptic ulcer.
- Body mass index  $\geq 35$  kg/m<sup>2</sup> (bariatric surgery should be considered).
- Demonstrated patient non-adherence to medical recommendations (e.g., failure to comply with prescribed drug regimens).
- Ongoing or recurring infections that are not effectively treated.
- Potential complications from immunosuppressive medications unacceptable to the patient.
- Psychiatric disease that may compromise patient compliance.
- Serious cardiac or other ongoing insufficiencies that create an inability to tolerate surgery.
- Serious conditions unlikely to be improved by transplantation as life expectancy can be finitely measured.

All other uses of pancreas transplantation are not medically necessary.

## Alternative covered services

- Exogenous insulin therapy.
- Hemodialysis.
- Peritoneal dialysis.

## Background

The pancreas is an organ behind the stomach with digestive (exocrine) and hormonal (endocrine) functions. The digestive enzymes secreted by the exocrine (via ducts) portion help break down protein, fats, carbohydrates, and acids ingested in the duodenum, and secretes bicarbonate to neutralize stomach acid. The endocrine gland portion (via bloodstream) secretes glucagon, insulin and somatostatin to regulate release of insulin and glucagon needed for metabolism and other cellular functions. Diabetes develops as a result of a poorly functioning pancreas, or cells not effectively using insulin, or both (Longnecker, 2021).

Every year about 80,000 people are diagnosed with chronic pancreatitis that can occur over several years and become life threatening. The debilitation from the disease results in frequent hospitalizations, increasing narcotic use for pain control, and a resultant decrease in quality of life. Islet cell transplant is critical for patients with immense pain who have failed other treatments. The autologous islet cell transplant procedure consists of extracting islet cells from the pancreas and reintroducing them into the patients liver via the portal vein where the cells continue to produce insulin to regulate glucose. This process removes the diseased organ's debilitating symptoms and creates a new pathway for the production of insulin, thus eliminating the risk of becoming a diabetic (PRWeb 2021).

The primary cause of pancreatic disease is type 1 diabetes mellitus, followed by type 2 diabetes mellitus, chronic pancreatitis, cancer, and cystic fibrosis (Kandaswamy, 2015). A pancreas transplantation provides an endogenous, self-regulated source to achieve physiologic insulin regulation without inducing adverse effects associated with administration of exogenous insulin. The goal of pancreas transplantation is to produce a lasting normoglycemic state that enhances quality of life. The procedure may involve the whole pancreas, a pancreas segment, a large group of pancreatic islet cells, or be in combination with a kidney transplant.

The U.S. Food and Drug Administration (2009) does not regulate the transplantation of human organs containing blood vessels, such as kidney, liver, heart, lung or pancreas. However, it does regulate allogeneic islet cell transplantation as somatic cell therapy. Clinical studies to determine safety and effectiveness outcomes of allogeneic islet cell transplantation must be conducted under an investigational new drug regulation.

## Findings

Clinical guidelines and other forms of peer review literature including systematic reviews and meta-analysis for supports the clinical utility of pancreas transplantation across multiple outcome domains. Simultaneous pancreas-kidney transplantation confers a long-term survival advantage, with registry data demonstrating graft durability exceeding 25 years and patient survival rates of 96% at one year and 89% at five years. Successful transplantation normalizes glycemic control, reduces microvascular complications, and improves peripheral vascular outcomes. For islet cell transplantation, both allogeneic and autologous approaches provide clinically meaningful metabolic benefit: even when full insulin independence is not sustained, partial graft function produces near-target hemoglobin A1c levels, markedly reduces severe hypoglycemic episodes, and improves diabetes-specific quality of life. The eligible candidate population has broadened as evidence has accumulated; carefully selected patients with type 2 diabetes mellitus achieve five-year outcomes comparable to those with type 1 diabetes mellitus, and chronologic age alone does not preclude benefit. Candidacy evaluation requires rigorous pretransplant renal and cardiovascular assessment, particularly for pancreas transplant alone recipients in whom kidney failure develops in approximately 10% within five years.

### Guidelines

The Kidney Disease: Improving Global Outcomes Transplant Work Group (2009) established foundational recommendations for the care of kidney transplant recipients, including guidance on immunosuppression,

infection prophylaxis, and cardiovascular risk management that applies to simultaneous pancreas-kidney recipients. The guideline emphasized structured long-term follow-up and multidisciplinary evaluation of transplant candidates. Paty (2013) provided an evidence-based framework for pancreas transplant candidate selection, underscoring the role of comprehensive metabolic, cardiovascular, and psychosocial assessment in identifying patients most likely to benefit from transplantation. Together, these two guidelines established the baseline evaluation standards that inform current candidate selection protocols.

Updated guidance on chronic kidney disease management from the Kidney Disease: Improving Global Outcomes (2024) guideline introduced refined thresholds for transplant planning. Practice Points 5.4.1 through 5.4.5 recommend initiating preemptive transplant planning when the estimated glomerular filtration rate declines below 15-20 mL/min/1.73 m<sup>2</sup> or when the estimated risk of kidney replacement therapy exceeds 40% within two years, as determined by validated risk models such as the Kidney Failure Risk Equation. The guideline emphasized shared decision-making and individualized assessment rather than reliance on a single laboratory threshold. For pediatric populations, preemptive kidney transplantation is identified as the treatment of choice, with transplant evaluation recommended when estimated glomerular filtration rate falls to 5-15 mL/min/1.73 m<sup>2</sup>. These thresholds provide actionable criteria for identifying simultaneous pancreas-kidney transplant candidates before the onset of dialysis dependence.

The Kidney Disease: Improving Global Outcomes (2025) anemia guideline addressed the management of anemia in patients with chronic kidney disease, including transplant recipients and transplant candidates. The guideline recommended erythropoiesis-stimulating agents as first-line therapy over hypoxia-inducible factor prolyl hydroxylase inhibitors, with a hemoglobin ceiling of 11.5 g/dL during erythropoiesis-stimulating agent therapy. For transplant candidates, the guideline highlighted the allosensitization risk associated with red blood cell transfusions, citing an odds ratio of 2.38 for developing panel-reactive antibody levels greater than 80% following transfusion. Avoidance of unnecessary transfusions through adequate anemia management is therefore a critical component of transplant candidacy preservation, as elevated panel-reactive antibody levels are associated with prolonged wait times and inferior graft outcomes.

The Organ Procurement and Transplantation Network/United Network for Organ Sharing (2018) modified the waiting time criteria for kidney-pancreas candidates aged 18 years and older by removing the prior body mass index threshold of 28 kg/m<sup>2</sup> or less and the fasting C-peptide requirement of 2 ng/mL or less, along with the associated sliding-scale mechanism. The revised policy simplified qualification to three requirements: registration on the kidney-pancreas waiting list, qualification for kidney waiting time, and current insulin therapy. The prior criteria disproportionately affected minority populations, as higher body mass index prevalence among Black and Hispanic populations more frequently excluded these individuals from listing. C-peptide level was also determined to be an unreliable predictor of pancreas transplant outcomes. This policy change expanded equitable access to simultaneous pancreas-kidney transplantation for patients with type 2 diabetes mellitus who are insulin-dependent.

The American Diabetes Association (2026) standards of care addressed the role of autologous islet cell transplantation in the management of chronic pancreatitis. The guideline supports total pancreatectomy with islet autotransplantation as a treatment option for patients with refractory chronic pancreatitis who have failed medical and endoscopic management, recognizing the procedure's capacity to preserve endocrine function and reduce opioid dependence. This endorsement from a major diabetes management authority reinforces the clinical validity of autologous islet cell transplantation as a distinct indication from allogeneic islet transplantation for type 1 diabetes mellitus.

### Systematic reviews

Two systematic reviews examined quality of life outcomes following islet cell transplantation. Speight (2010) conducted a systematic review of patient-reported outcomes after islet and pancreas transplantation in type 1

diabetes mellitus and found improvements in diabetes-specific quality of life measures, including reductions in hypoglycemia fear and diabetes-related distress. Gariani (2024) conducted a systematic review of seven studies (n = 205) evaluating quality of life after islet transplantation alone or islet-after-kidney transplantation, with study quality assessed by Newcastle-Ottawa Scale (mean 6.9 out of nine). All four studies that measured hypoglycemia fear using the Hypoglycemia Fear Survey reported statistically significant reductions in total scores ( $p < 0.05$  in each), and all three studies measuring diabetes-specific quality of life satisfaction reported significant improvement ( $p < 0.05$  or  $p < 0.01$ ). Diabetes distress scores decreased significantly in both studies that assessed them ( $p < 0.05$ ). Generic quality of life instruments such as the 36-Item Short Form Health Survey showed less consistent results, with only two of four studies reporting significant improvements in composite scores. Disease-specific instruments were more sensitive to change than generic instruments. These converging findings across a 14-year span indicate that islet transplantation produces durable, measurable improvements in diabetes-specific quality of life, particularly in the reduction of hypoglycemia fear and diabetes-related distress.

Bramis (2012) conducted a systematic review of total pancreatectomy with islet autotransplantation for chronic pancreatitis, examining outcomes including pain relief, insulin independence, and metabolic function. The review established that autologous islet cell transplantation following total pancreatectomy can preserve endocrine function in a meaningful proportion of recipients and reduce the burden of chronic pancreatitis-related pain. Unlike allogeneic islet transplantation for type 1 diabetes mellitus, autologous islet cell transplantation does not require immunosuppression, which eliminates an important source of morbidity and extends the eligible patient population to include those who would not tolerate long-term immunosuppressive therapy.

Amara (2022) conducted a systematic review of 39 studies examining pancreas transplantation in type 2 diabetes mellitus and found favorable outcomes in patient survival, graft survival, and glycemic control. The review documented that five-year patient and graft survival after simultaneous pancreas-kidney transplantation was comparable between participants with type 1 diabetes mellitus and those with type 2 diabetes mellitus across the included case series. The growing proportion of pancreas transplant recipients with type 2 diabetes mellitus, combined with the favorable survival data, supports the expansion of candidacy criteria to include carefully selected patients with type 2 diabetes mellitus.

Gariani (2025) conducted a systematic review of 25 studies (n = 1,373) evaluating the impact of islet transplantation on chronic complications of type 1 diabetes mellitus, with study quality assessed by Newcastle-Ottawa Scale (mean 7.0 out of nine). Among 13 studies examining diabetic nephropathy, islet-after-kidney recipients demonstrated slower estimated glomerular filtration rate decline compared to kidney transplant alone recipients over long-term follow-up, and four studies reported stabilization or reduction in urinary albumin excretion. Among five studies (116 participants) examining diabetic retinopathy, two studies found no retinopathy progression over one to nine years, and transient worsening occurred in fewer than 10% of participants. Among 10 studies examining diabetic neuropathy, the general trend was toward stabilization or modest improvement in peripheral nerve function, with sensory nerves showing more improvement than motor nerves. Macrovascular findings across five studies included reduced carotid intima-media thickness in islet transplant alone recipients at 12 and 50 months and improved cardiac function in islet-after-kidney recipients. However, no significant reduction in major macrovascular events was observed in a comparison of 61 islet transplant alone recipients with 610 matched controls. Mortality data from three studies showed no significant survival advantage for islet-after-kidney over kidney transplant alone (hazard ratio 0.73; 95% confidence interval [CI], 0.30-1.89;  $p = 0.36$ ), though islet transplant alone recipients demonstrated a significant reduction in all-cause mortality compared to matched type 1 diabetes mellitus controls. The microvascular stabilization observed across multiple complication domains indicates that functioning islet grafts confer protective effects beyond glycemic control alone.

### Meta-analyses

Hughes (2026) conducted a systematic review and meta-analysis of 17 studies (n = 1,332) examining long-term metabolic outcomes following pancreatectomy with autologous islet cell transplantation. The pooled rate of insulin independence at one year or longer of follow-up was 34% (95% CI, 29%-40%), with moderate heterogeneity (I-squared = 59%). Participants with chronic pancreatitis achieved insulin independence at a rate of 33% (95% CI, 29%-38%), while those with non-chronic pancreatitis indications such as trauma or neoplasm achieved 68% (95% CI, 27%-93%). Pooled hemoglobin A1c was 6.9% (95% CI, 6.4%-7.3%), and pooled fasting C-peptide was 1.0 ng/mL (95% CI, 0.76-1.25 ng/mL), indicating clinically meaningful endocrine function even among participants who did not achieve full insulin independence. The pooled severe hypoglycemic event rate was 11% (95% CI, 9.2%-14%), with no heterogeneity across studies (I-squared = 0%). Leave-one-out sensitivity analysis confirmed that the pooled insulin independence estimate remained stable (range 32%-36%) when individual studies were excluded, and funnel plot assessment detected no significant publication bias. The near-target hemoglobin A1c levels and low rate of severe hypoglycemic events, even in participants requiring some exogenous insulin, demonstrate that partial graft function provides substantial metabolic benefit after autologous islet cell transplantation.

### Other evidence

#### *Survival*

Pancreas alone and simultaneous pancreas-kidney transplants have one-year and five-year survival rates of 96% and 89%, respectively (National Health Service, 2020). Three large cohort studies documented long-term outcomes following simultaneous pancreas-kidney transplantation: Esmeijer (2020) reported superior long-term survival with a 30-year follow-up, Parajuli (2020) documented more than 25 years of pancreas graft survival, and Sung (2015) conducted a survival analysis that reassessed outcomes from registry data. There is sufficient evidence to support the use of simultaneous pancreas-kidney transplantation either simultaneously or sequentially in patients with uremia and type 1 diabetes mellitus who have been carefully selected. Successful transplantation does not jeopardize patient survival, may improve kidney survival, and achieves normalization of glucose control.

#### *Renal Function*

There is sufficient evidence to support pancreas transplantation alone (deceased or living-donor segmental) in patients with type 1 diabetes mellitus and preserved renal function to eliminate the problems of hypoglycemic unawareness and severe metabolic lability associated with diabetes. Two Organ Procurement and Transplantation Network/United Network for Organ Sharing database analyses underscore the importance of monitoring kidney function before and after pancreas transplantation alone. Kidney failure developed in approximately 10% of participants at five years of follow-up, and kidney function before transplant was the most important predictor of end-stage renal disease (Kim, 2014; Nata, 2013). These findings reinforce the need for rigorous pretransplant renal assessment and ongoing post-transplant surveillance of kidney function in pancreas transplant alone recipients.

#### *Glycemic control and metabolic outcomes*

Andacoglu (2019) performed a glycemic control comparison following pancreas transplantation at a high-volume center, reviewing both type 1 and type 2 diabetes mellitus recipients. Increased complication rates such as higher body mass index, higher short-term insulin requirements, and a higher rate of enteric conversion were found in the type 2 diabetes mellitus cohort. Both cohorts had similar positive glycemic control results at the five-year mark. Hau (2020) found both short- and long-term metabolic benefits associated with simultaneous pancreas-kidney transplantation for both type 1 and type 2 diabetes mellitus recipients. The comparable five-year glycemic outcomes across diabetes types support the clinical rationale for extending transplant candidacy to carefully selected patients with type 2 diabetes mellitus.

### *Vascular outcomes*

Sucher (2019) reported improved outcomes of peripheral vascular diseases following simultaneous pancreas-kidney transplantation. Peripheral vascular disease is a major source of morbidity in patients with long-standing diabetes mellitus, and the observed improvements after transplantation provide additional evidence of clinical benefit beyond glycemic normalization.

### *Islet cell transplantation: allogeneic long-term data*

Allogeneic islet cell transplantation holds significant potential advantages over whole-gland transplantation, particularly its less invasive surgical approach, but its long-term graft survival has not reached the standard of whole-organ pancreas transplantation. Twenty-year data from the Edmonton cohort showed insulin independence of 61% at one year and 8% at 20 years. However, even participants who resumed insulin often retained partial graft function, with improved glycemic control and marked reduction in severe hypoglycemic episodes (Vantighem, 2019a; Vantighem, 2019b). The persistence of partial graft function over two decades, with its attendant glycemic and hypoglycemia benefits, indicates that allogeneic islet cell transplantation provides durable clinical value even when full insulin independence is not maintained.

### *Age considerations*

Growing evidence suggests chronologic age alone should not exclude a patient from candidacy for pancreas transplantation. One large case series found that while complications may occur, older recipients (age 55 and older) of pancreas transplantation had comparable long-term patient and graft survival rates to those of younger recipients (Scalea, 2016). A United Network for Organ Sharing database analysis of 21,328 pancreas transplant recipients found that older participants (age 45 and older) may have higher pancreas graft failure, but patient survival was not significantly different from that of younger participants (age 18 to 29) (Siskind, 2014). The absence of a significant patient survival difference by age supports individualized candidacy evaluation over rigid age-based exclusion criteria.

### *Type 2 diabetes mellitus candidacy*

The rate of pancreas transplantation among individuals with type 2 diabetes mellitus has increased significantly. Currently 18.6% of persons with simultaneous transplants, 4.8% with kidney transplant after pancreas transplant, and 15.3% with pancreas transplant after kidney transplant have type 2 diabetes mellitus (Kandaswamy, 2015). Based on the evidence available to date, the following criteria have been proposed for type 2 diabetes mellitus candidates for simultaneous pancreas-kidney transplantation (Weems, 2014):

- Younger than age 55 years
- Body mass index less than 30 kg/m-squared
- Insulin dependence
- Low total insulin requirements (less than 1 U/kg of ideal body weight per day)
- Presence of renal failure (dialysis-dependent or pre-dialysis advanced diabetic nephropathy with glomerular filtration rate less than or equal to 20 mL/min/1.73 m-squared)
- Fasting C-peptide less than 10 ng/mL
- Low cardiac and vascular disease risk
- History of medical and dietary compliance

Yet there remains an absence of unified and defined criteria for candidacy. Results from a small number of case series suggest five-year patient and graft survival after simultaneous pancreas-kidney transplantation is comparable between participants with type 1 diabetes mellitus and those with type 2 diabetes mellitus.

In 2026, the findings section was reorganized. Three new systematic reviews were added: a review of quality of life outcomes following islet transplantation in type 1 diabetes mellitus (Gariani, 2024), a review of the impact of islet transplantation on chronic complications of type 1 diabetes mellitus (Gariani, 2025), and a meta-analysis of metabolic outcomes following pancreatectomy with autologous islet cell transplantation (Hughes, 2026). Three new guidelines were incorporated: the Kidney Disease: Improving Global Outcomes 2024 chronic kidney disease guideline with updated transplant planning thresholds, the Kidney Disease: Improving Global Outcomes 2025 anemia guideline addressing erythropoiesis-stimulating agent use and transfusion-related allosensitization risk, and the Organ Procurement and Transplantation Network/United Network for Organ Sharing 2018 policy removing body mass index and C-peptide restrictions from kidney-pancreas waiting time criteria. Policy changes were warranted.

## References

On February 8, 2026, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “pancreas transplantation” “pancreas-kidney transplant” (MeSH) and “islets of Langerhans transplantation” “end stage renal disease” (MeSH). We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Amara D, Hansen KS, Kupiec-Weglinski SA, et al. Pancreas transplantation for type 2 diabetes: A systematic review, critical gaps in the literature, and a path forward. *Transplantation*. 2022;106(10):1916-1934. Doi: 10.1097/TP.0000000000004113.

American Diabetes Association. 4. Comprehensive medical evaluation and assessment of comorbidities: Standards of medical care in diabetes-2020. *Diabetes Care*. 2020;43(Suppl 1):S37-s47. Doi: 10.2337/dc20-S004.(a)

American Diabetes Association. 9. Pharmacologic approaches to glycemic treatment: Standards of medical care in diabetes-2020. *Diabetes Care*. 2020;43(Suppl 1):S98-s110. Doi: 10.2337/dc20-S009.(b)

Andacoglu OM, Himmler A, Geng X, Ahn J, Ghasemian S, Cooper M, Abrams P. Comparison of glycemic control after pancreas transplantation for type 1 and type 2 diabetic recipients at a high volume center. *Clin Transplant*. 2019;33(8):e13656. Doi: 10.1111/ctr.13656.

Bramis K, Gordon-Weeks AN, Friend PJ, et al. Systematic review of total pancreatectomy and islet autotransplantation for chronic pancreatitis. *Br J Surg*. 2012;99(6):761-766. Doi: 10.1002/bjs.8713.

Centers for Disease Control and Prevention. About HIV/AIDS. <https://www.cdc.gov/hiv/basics/whatishiv.html>. Reviewed June 30, 2022.

Esmeijer K, Hoogeveen EK, van den Boog PJM, et al. Superior long-term survival for simultaneous pancreas-kidney transplantation as renal replacement therapy: 30-year follow-up of a nationwide cohort. *Diabetes Care*. 2020;43(2):321-328. Doi: 10.2337/dc19-1580.

Gariani K, Peloso A, Galani V, et al. Effect of islet alone or islets after kidney transplantation on quality of life in type 1 diabetes: a systematic review. *Transplantation Reviews*. 2024;38:100870. doi:10.1016/j.trre.2024.100870

Gariani K, Peloso A, Haidar F, et al. Impact of islet transplantation on type 1 diabetes-related complication: a systematic review. *Transplant International*. 2025;38:15091. doi:10.3389/ti.2025.15091

Hau HM, Jahn N, Brunotte M, et al. Short and long- term metabolic outcomes in patients with type 1 and type 2 diabetes receiving a simultaneous pancreas kidney allograft. *BMC Endocr Disord*. 2020;20(1):30. Doi: 10.1186/s12902-020-0506-9.

Hughes DL, Di Bella C, Quaratino B, et al. Long term metabolic outcomes following pancreatectomy and autologous islet transplantation: systematic review and meta-analysis. *J Surg Oncol*. 2026:1-11. doi:10.1002/jso.70193

Kandaswamy R, Skeans MA, Gustafson SK, et al. OPTN/SRTR 2013 Annual Data Report: Pancreas. *Am J Transplant*. 2015;15 Suppl 2:1-20. Doi: 10.1111/ajt.13196.

Kidney Disease: Improving Global Outcomes Transplant Work Group. KDIGO clinical practice guideline for the care of kidney transplant recipients. *Am J Transplant*. 2009;9 Suppl 3:S1-155. Doi: 10.1111/j.1600-6143.2009.02834.x.

Kidney Disease: Improving Global Outcomes. KDIGO 2024 clinical practice guideline for the evaluation and management of chronic kidney disease. *Kidney Int*. 2024;105(Suppl 4S):S117-S314.

Kidney Disease: Improving Global Outcomes. KDIGO 2025 clinical practice guideline for anemia in chronic kidney disease. Public review draft. November 2024.

Kim SJ, Smail N, Paraskevas S, et al. Kidney function before pancreas transplant alone predicts subsequent risk of end-stage renal disease. *Transplantation*. 2014;97(6):675-680. Doi: 10.1097/01.TP.0000437556.87109.45.

Longnecker DS. American Pancreatic Association. Anatomy and histology of the pancreas. *Pancreapedia: Exocrine pancreas knowledge base*. 2021. <https://www.pancreapedia.org/reviews/anatomy-and-histology-of-pancreas>. Doi: 10.3998/panc.2021.01.

Nata N, Huang E, Kamgar M, et al. Kidney failure requiring kidney transplantation after pancreas transplant alone. *Clin Transpl*. 2013;45-52. <http://www.ncbi.nlm.nih.gov/pubmed/25095491>. Published 2013.

NHS Blood and Transplant. Annual report on pancreas and islet transplantation: Report for 2019/2020 (1 April 2010-31 March 2020). <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/19868/nhsbt-pancreas-and-islet-transplantation-annual-report-2019-2020.pdf>. Published September 2020.

Organ Procurement and Transplantation Network/United Network for Organ Sharing. Proposal to change waiting time criteria for kidney-pancreas candidates. Policy notice. Approved by the OPTN Board on June 12, 2018.

Parajuli S, Bath NM, Aziz F, et al. More than 25 years of pancreas graft survival after simultaneous pancreas and kidney transplantation: Experience from the world's largest series of long-term survivors. *Transplantation*. 2020;104(6):1287-1293. Doi: 10.1097/tp.0000000000002960.

Paty BW, Koh A, Senior P. Pancreas and islet transplantation. *Can J Diabetes*. 2013;37 Suppl 1:S94-96. Doi: 10.1016/j.jcjd.2013.01.028.

PRWeb. AHN performs its first islet cell transplants to treat chronic pancreatitis: Advanced capability compliments network's unique islet cell isolation lab at AGH, making organization one of a select group across

the country offering comprehensive care for debilitating condition. <https://www.prweb.com/releases/ahn-performs-its-first-islet-cell-transplants-to-treat-chronic-pancreatitis-844118706.html>. Published October 5, 2021.

Scalea JR, Redfield RR, 3rd, Arpali E, et al. Pancreas transplantation in older patients is safe, but patient selection is paramount. *Transpl Int*. 2016;29(7):810-818. Doi: 10.1111/tri.12754.

Siskind E, Maloney C, Akerman M, et al. An analysis of pancreas transplantation outcomes based on age groupings--an update of the UNOS database. *Clin transplant*. 2014;28(9):990-994. Doi: 10.1111/ctr.12407.

Speight J, Reaney MD, Woodcock AJ, Smith RM, Shaw JA. Patient-reported outcomes following islet cell or pancreas transplantation (alone or after kidney) in Type 1 diabetes: A systematic review. *Diabet Med*. 2010;27(7):812-822. Doi: 10.1111/j.1464-5491.2010.03029.x.

Sucher R, Rademacher S, Jahn N, et al. Effects of simultaneous pancreas-kidney transplantation and kidney transplantation alone on the outcome of peripheral vascular diseases. *BMC Nephrol*. 2019;20(1):453. Doi: 10.1186/s12882-019-1649-7.

Sung RS, Zhang M, Schaubel DE, et al. A Reassessment of the survival advantage of simultaneous kidney-pancreas versus kidney-alone transplantation. *Transplantation*. 2015;99(9):1900-1906. Doi: 10.1097/tp.0000000000000663.

U.S. Food and Drug Administration. Guidance for industry. Considerations for allogeneic pancreatic islet cell products. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-allogeneic-pancreatic-islet-cell-products>. Published September 2009.

Vantyghem MC, Chetboun M, Gmyr V, et al. Ten-year outcome of islet alone or islet after kidney transplantation in type 1 diabetes: A prospective parallel-arm cohort study. *Diabetes Care*. 2019;42(11):2042-2049. Doi: 10.2337/dc19-0401.

Vantyghem MC, de Koning EJP, Pattou F, Rickels MR. Advances in beta-cell replacement therapy for the treatment of type 1 diabetes. *Lancet*. 2019;394(10205):1274-1285. Doi: 10.1016/s0140-6736(19)31334-0.

Weems P, Cooper M. Pancreas transplantation in type II diabetes mellitus. *World Journal of Transplantation*. 2014;4(4):216-221. Doi: 10.5500/wjt.v4.i4.216.

## Policy updates

10/2015: initial review date and clinical policy effective date: 4/2016

2/2017: Policy references updated.

2/2018: Policy references updated. Coverage expanded per American Diabetes Association (2018) guideline.

2/2019: Policy references updated. Policy ID changed.

2/2020: Policy references updated.

2/2021: Policy references updated.

2/2022: Policy references updated.

3/2023: Policy references updated.

3/2024: Policy references updated.

3/2025: Policy references updated.

3/2026: Policy reference is updated. Coverage expanded due to guidelines.

## Related Codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1201. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code Description
<b>Pancreas Transplantation Codes</b>	
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or islet cells
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48551	Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including splenectomy, duodenotomy, CBD ligation, Y graft arterial anastomosis
48552	Backbench reconstruction of donor pancreas, venous anastomosis, each
48554	Transplantation of pancreas allograft
48556	Removal of transplanted pancreatic allograft
48999	Unlisted procedure, pancreas
<b>Kidney Transplantation Codes</b>	
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy, open, from living donor
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation
50325	Backbench standard preparation of living donor renal allograft prior to transplantation
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; arterial anastomosis, each
50329	Backbench reconstruction of cadaver or living donor renal allograft; ureteral anastomosis, each
50340	Recipient nephrectomy (separate procedure; removal of native kidney)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50370	Removal of transplanted renal allograft
50380	Renal autotransplantation, reimplantation of kidney
50547	Laparoscopic donor nephrectomy
<b>Simultaneous Pancreas-Kidney Transplantation</b>	
S2065	Simultaneous pancreas kidney transplantation
<b>Islet Cell Transplantation</b>	
G0341	Percutaneous islet cell transplant, includes portal vein catheterization and infusion

G0342	Laparoscopic islet cell transplant, includes portal vein catheterization and infusion
G0343	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion