

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Pancreas transplantation is a treatment option for patients with Type 1 diabetes mellitus and, in some cases, brittle diabetes with significant metabolic instability. The primary goal is to improve glycemic control and overall quality of life. Successful pancreas transplantation can eliminate the need for exogenous insulin, reduce or eliminate the need for renal dialysis, and prevent or delay complications related to diabetes, including diabetic nephropathy, retinopathy, neuropathy, vasculopathy, and macrovascular disease. Diabetic nephropathy is a common complication in both Type 1 and Type 2 diabetes and is a leading cause of end-stage renal disease (ESRD) (Alhamad & Stratta 2024; Bloom 2025; Robertson 2026).

Pancreas Transplant Alone (PTA): Performed in patients with labile diabetics, hypoglycemic unawareness, and frequent episodes of diabetic ketoacidosis episodes, but without ESRD. The goal is to limit or prevent complications resulting from poor glycemic control.

Simultaneous Pancreas-Kidney (SPK) Transplantation: Performed in patients with Type I diabetes and ESRD. Both organs are typically procured from the same deceased donor. The objectives are to restore endogenous insulin secretion, slow or stop progression of diabetic complications, protect renal function, and improve quality of life.

Pancreas After Kidney (PAK) Transplantation: Performed in Type I diabetic patients with end stage renal disease who have already received a kidney transplant (usually from a living donor). A pancreas transplant is performed subsequently to restore glycemic control.

RELATED POLICIES

MCP-459: Pre-Transplant and Transplant Evaluations

MCP-045: Kidney Transplantation

MCP-441: Allogeneic Pancreatic Islet Cell Transplantation with Lantidra (donislecel-juj)

COVERAGE POLICY

All transplants require prior authorization from the Corporate Transplant Department. Solid organ transplant requests will be reviewed by the Corporate Senior Medical Director or qualified clinical designee. All other transplants will be reviewed by the Corporate Senior Medical Director or covering Medical Director. If the criteria are met using appropriate NCD and/or LCD guidelines, State regulations, and/or MCP policies the Corporate Senior Medical Director's designee can approve the requested transplant.

Office visits with participating Providers do NOT require prior authorization. Providers should see the Member in office visits as soon as possible and without delay. Failure to see the Member in office visits may be considered a serious quality of care concern.

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Please see *MCP-459 Pre-Transplant and Transplant Evaluation* for pre-transplant criteria and transplant evaluation criteria that must be met prior to solid organ transplant.

Solid Organ Pancreas Transplant Procedures Criteria

Pancreas Transplant Alone (PTA), Simultaneous Pancreas-Kidney Transplantation (SPK), and Pancreas After Kidney (PAK) organ transplantation from a donor may be **considered medically necessary** in adult Members that have met ALL the following:

1. All pre-transplant and transplant evaluation criteria are met as stipulated in *MCP-459 Pre-Transplant and Transplant Evaluation*
2. Member has been optimally managed for at least 12 months by an endocrinologist or pancreas transplant surgeon
3. Documentation of insulin dependent Type 1 diabetes showing abnormal beta cell functioning as evidenced by ONE of the following:
 - a. Beta cell autoantibody positive
 - b. Fasting C-peptide undetectable (e.g., $\leq 110\%$ of the laboratory's lower limit of normal and with a concurrently obtained fasting glucose $\leq 225\text{mg/dl}$)
4. Documented history of frequent, medically uncontrolled, labile (brittle) insulin dependent diabetes mellitus, with recurrent, acute, and severe life-threatening metabolic complications that have required previous hospitalization (e.g., ketoacidosis, hypoglycemia, or hyperglycemia attacks)
5. Consistent failure of aggressive insulin management (e.g., insulin pump, adjusting amounts and frequencies of injected insulin, multiple daily blood glucose levels, and strict diet and exercise)
6. Transplant procedure is ONE of the following procedures, with Member meeting ALL the subsequent specific transplant type criteria:
 - a. **For Pancreas Transplant Alone, Partial Pancreas Transplant from a Living Donor, or Pancreas Re-Transplantation after a failed primary pancreas transplant:** ALL the following criteria are met:
 - i. The presence of at least one secondary complication that has not progressed to end-organ failure such as proliferative diabetic retinopathy, neuropathy, gastroparesis, accelerated atherosclerosis
 - ii. Creatinine clearance glomerular filtration rate of $\geq 80\text{ml/min}$
 - iii. No significant proteinuria
 - b. **For Simultaneous Pancreas-Kidney Transplant:** ALL the following criteria are met:
 - i. The presence of at least one secondary complication that has not progressed to end-organ failure such as proliferative diabetic retinopathy, neuropathy, gastroparesis, accelerated atherosclerosis
 - ii. The Member has renal insufficiency with uremia or impending/ current end stage renal disease (ESRD) with poor renal function and ONE of the following:
 - a) Currently receiving dialysis
 - b) Anticipated dialysis within 6 months
 - c) Demonstrates 50% or more decline in renal function over the past 12 months
 - c. **For Pancreas After Kidney Transplant:** ALL the following criteria are met:
 - i. The presence of at least one secondary complication that has not progressed to end-organ failure such as proliferative diabetic retinopathy, neuropathy, gastroparesis, accelerated atherosclerosis
 - ii. The Member has a living organ donor for the kidney transplant procedure otherwise SPK should be considered
 - iii. Previously successful kidney transplant as evidenced by stable function of previous renal allograft
 - iv. Stable adequate kidney function as evidenced by creatinine clearance glomerular filtration rate of $\geq 45\text{ml/min}$
 - v. No significant proteinuria

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Limitations and Exclusions

Any of the following are considered **experimental, investigational, and unproven** due to insufficient evidence in the peer reviewed published literature:

1. Pancreas transplantation for Type 2 diabetes mellitus
2. Use of bioartificial pancreas devices

DOCUMENTATION REQUIREMENTS: Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Systematic Reviews and Meta-Analyses

Giri et al. (2025) completed a systematic review of 45 retrospective studies evaluating the impact of pancreas transplantation on secondary diabetic complications in individuals with type 1 diabetes mellitus (T1D). Most studies assessed simultaneous pancreas- kidney transplantation (SPK), with fewer evaluating pancreas transplant alone (PTA). Across the evidence base, pancreas transplantation was consistently associated with improvement or stabilization of diabetic retinopathy, peripheral neuropathy, and cardiovascular disease. For diabetic retinopathy studies reported either improvement or stabilization following SPK or PTA, zone interpretation was limited by small sample sizes and heterogeneous assessment methods. For diabetic neuropathy, most studies demonstrated benefit, with improvements in objective measures such as nerve conduction studies, vibration perception thresholds, and corneal confocal microscopy. For cardiovascular disease SPK was associated with reduced cardiovascular events, improved cardiac function, and favorable changes in metabolic risk factors. Evidence regarding peripheral vascular disease was mixed, with older studies showing higher amputation rates and SK recipients and more recent data showing lower long-term complications rates compared with kidney only transplant recipients with T1DM. Overall the review concludes that SPK and PTA improve or stabilize major diabetes related complications in individuals with type 1 diabetes, although the evidence is limited by retrospective designs and variability in outcome measures.

Amara et al. (2022) completed a systematic review on pancreas transplantation for type 2 diabetes. Pancreas transplantation in adults with type 2 diabetes (T2D) demonstrates consistently favorable outcomes, with 1-year *patient survival* of 86% to 100%, 3-year survival from 80.1%-98.6% and 5-year survival of 74.1% to 85%, across the 22 studies. *Pancreas graft survival* is similarly strong, with 1-year graft survival of 81.0% to 100%, and 5-year survival from 70%-100%, including OPTN-based cohorts reporting ~70% at 5-years. *Kidney graft survival* in SPK recipients was favorable, with 1-year kidney graft survival of 85.7% to 100%, and 5-year survival of 74% to 75.2%. Glycemic control improved substantially after transplant, with multiple studies reporting HbA1c values <6-6.5% for years, including median values of 5.4 to 5.67% at 1-3 years and mean values of 6.17-6.75% at 3-5 years. Comparative analysis showed that pancreas graft survival in T2D patients is comparable to type 1 diabetes in 15 of 16 studies. and SPK recipients often experience better long-term survival and kidney graft outcomes than T2D kidney-alone recipients when pancreas graft functions early. However, the evidence base is limited by substantial heterogeneity in T2D definitions, inconsistent graft failure criteria, retrospective single-center designs, small sample sizes, and variable follow-up durations. Overall, the findings support pancreas transplantation as a potential option for carefully selected, insulin dependent T2D patients with limited insulin resistance and advanced kidney disease.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

The First World Consensus Conference on Pancreas Transplantation (Boggi et al. 2021) conducted a comprehensive review of 597 studies and issued 110 recommendations addressing indications, outcomes, and best practices for pancreas transplantation. The consensus concluded that simultaneous pancreas-kidney (SPK) transplantation improves survival and quality of life in individuals with insulin-dependent diabetes, including appropriately selected patients with Type 2 diabetes, as reflected in the graded recommendation that there is no evidence to prioritize graft allocation to type 1 over type 2 diabetes for SPK (grade 2B). Jury deliberations also found that pancreas-after-kidney (PAK) transplantation is feasible in selected patients with type 2 diabetes and that PAK improves quality of life in type 1 diabetes. Additionally, the consensus determined that pancreas transplant alone (PTA) improves quality of life and

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may improve survival in individuals with severe hyperglycemia, hypoglycemia unawareness, autonomic neuropathy, or brutal diabetes. Although most recommendations are graded 2B or 2C due to the inherent limitations of conducting randomized trials and transplant surgery, the consensus emphasized that the advantages of pancreas transplantation clearly outweigh the disadvantages and characterize the procedure as low-volume and high-complexity rather than experimental.

National and Specialty Organizations

The American Diabetic Association (ADA) Standards of Care in Diabetes 2026, identify pancreas transplantation (including simultaneous pancreas-kidney and pancreas-after- kidney procedures) as surgical options for select individuals with type 1 diabetes, noting that successful pancreas transplantation can normalize glucose levels and reduce the risk of microvascular complications. Because pancreas transplantation requires lifelong immunosuppression with potential adverse effects, the ADA recommends reserving this procedure for individuals with type 1 diabetes undergoing simultaneous kidney transplantation, following kidney transplantation, or for those with recurrent ketoacidosis or severe hypoglycemia despite optimized glycemic management

The **Organ Procurement and Transplantation Network (OPTN)** and United Network for Organ Sharing (UNOS) provide operational guidelines and policies for transplant centers, organ procurement organizations, and histocompatibility laboratories across the United States. OPTN provides detailed guidance on organ-specific transplantation practices, living donation, and patient safety protocols. UNOS is responsible for managing the national transplant waiting list, facilitating the matching of donors and recipients, and maintaining the comprehensive database of all organ transplant data in the country. Additionally, UNOS ensures adherence to organ allocation policies, supports patients and their families, and provides education for both transplant professionals and the general public on organ donation and transplantation.

The 2020 **Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation** recommend that patients with type 1 diabetes and end stage kidney disease be considered for SPK due to potential benefits in survival and diabetes-related outcomes compared to kidney-alone transplantation (Chaden et al. 2020).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48551	Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery
48552	Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each
48554	Transplantation of pancreatic allograft
48556	Removal of transplanted pancreatic allograft
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous

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	anastomosis, each
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50370	Removal of transplanted renal allograft

HCCPS (Healthcare Common Procedure Coding System)

Code	Description
S2065	Simultaneous pancreas kidney transplantation
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor (s), procurement, transplantation, and related complications; including drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and post-transplant care in the global definition

CODING DISCLAIMER: Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

06/10/2026	Policy reviewed. Updated Summary of Medical Evidence and References. No changes to coverage criteria.
06/11/2025	Policy reviewed. Updated Summary of Medical Evidence and References. No changes to coverage criteria.
06/12/2024	Policy reviewed. Updated summary of Medical Evidence and References. Coverage criteria revised with removal of transplant evaluation, continuation of therapy, and general contraindication coverage criteria as it is now stipulated in MCP 459 Pre-Transplant and General Transplant Evaluation. No change to pancreas specific transplant criteria.
06/14/2023	Policy reviewed, moved islet cell transplant to separate policy, updated neurological exam criteria, updated "marijuana" to "cannabis," removed section under lab studies related to serology. Updated Overview, Summary of Evidence, and References. Policy reviewed in May 2023 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the areas of Surgery, Transplant.
06/08/2022	Policy reviewed, no changes to criteria; included section on marijuana use; updated Overview, Summary of Medical Evidence and Reference sections.
06/09/2021	Policy reviewed, updated references. Added CPT codes: 48551, 48552, 50323, 50325, 50327.
04/23/2020	Policy updated with medically necessary criteria for autologous pancreatic islet cell transplantation when used as an adjunct to a total or near total pancreatectomy in patients with chronic pancreatitis. Updated references, guidelines; added three new 2020 CPT codes (0584T, 0585T, 0586T) and one new ICD-10 code (K86.0-K86.1) for chronic pancreatitis. Policy reviewed in January 2020 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the areas of Surgery, Transplant.
09/18/2019	Policy reviewed, updated references only.
09/13/2018	Policy reviewed, updated references only.
06/22/2017	Policy reviewed, no changes.
12/14/2016	Policy reviewed, no changes.
05/26/2015	Policy updated with new pretransplant criteria and one new exclusion for bioartificial pancreas devices; Summary of Medical Evidence section was condensed.
10/31/2012	Policy updated (criteria for pre-transplant evaluation and HIV/AIDS patients). Summary of Medical Evidence was updated.
08/25/2010	Policy updated; some of the contraindications were moved from absolute to relative contraindications. The pancreas transplant alone (PTA) section includes a new requirement of glomerular filtration rate (GFR) of > 80ml/min and minimal proteinuria (based on recent studies that demonstrated improved outcomes). Document reviewed by an AMR board certified physician in General Surgery and Transplant Surgery.
08/28/2007	Policy reviewed by a board-certified Endocrinologist and Pancreas Transplant Surgeon. Pancreas transplant alone criteria added.
06/14/2006	New policy.

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