

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 used to treat Type 1 diabetes. The goal is to improve overall quality of life for the recipient. Successful transplantation can eliminate the need for exogenous insulin, renal dialysis, and the associated primary and secondary complications that result from diabetes mellitus (e.g., nephropathy/renal failure, retinopathy, neuropathy, and vasculopathy). Nephropathy is a frequent major complication associated with type 1 and type 2 diabetes and often ends in end-stage renal disease. (Alhamad & Stratta 2023; Bloom 2021; Robertson 2023; ¹⁻² DynaMed n.d.). There are several types of pancreas transplantation:

Pancreas Transplant Alone (PTA). Performed in labile diabetics with hypoglycemic unawareness and frequent ketoacidotic episodes without end stage renal disease. The goal is to limit or prevent complications that could cause permanent disability that may result from uncontrolled glucose levels (e.g., retinopathy, neuropathy, nephropathy, and vasculopathy).

Simultaneous Pancreas Kidney (SPK) Transplantation. Performed in Type I diabetes with end stage renal disease. Both organs come from the same living or deceased donor. The objectives are to restore glucose-regulated endogenous insulin secretion, arrest progression of complications, protect kidney damage from hyperglycemia and improve quality of life.

Pancreas After Kidney (PAK) Transplantation. Performed in Type I diabetic patients with end stage renal disease. Two operations are required. Treatment of choice for candidates with a living donor for a kidney transplant.

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.

Transplant Evaluation

Please see MCP-323 Pre-Transplant Evaluation for additional criteria and information.

Components of the transplant evaluation include:

1. History and physical examination; **AND**

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2. Psychosocial evaluation and clearance:
 - a. No behavioral health disorder by history or psychosocial issues:
 - If history of behavioral health disorder, no severe psychosis or personality disorder;
 - Mood/anxiety disorder must be excluded or treated;
 - Member understands surgical risk and post procedure compliance and follow-up required.

AND

- b. Adequate family and social support.

AND

3. EKG; **AND**

4. Chest x-ray; **AND**

5. Cardiac clearance in the presence of any of the following:
 - a. Chronic smokers; **OR**
 - b. Members > 50 years age; **OR**
 - c. Those with a clinical or family history of heart disease or diabetes.

AND

6. Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease; **AND**
7. Neurological exam and clearance for transplant including **ONE** of the following:
 - a. Normal neurologic exam; **OR**
 - b. Non-life limiting neurological impairment that does not preclude transplant and not caused by hematologic malignancy (e.g., diabetic peripheral neuropathy); **OR**
 - c. Abnormal neurological exam with positive findings including **ONE** of the following:
 - Lumbar puncture normal cytology; **OR**
 - Lumbar puncture with cytological exam abnormal, however central nervous system disease treated prior to clearance.

AND

8. A Performance Status that includes **ONE** of the following:
 - a. Karnofsky score 70-100%; **OR**
 - b. Eastern Cooperative Oncology Group (ECOG) Grade 0-2.

AND

9. Lab studies that include:
 - a. Complete blood count; kidney profile (blood urea nitrogen, creatinine); electrolytes; calcium; phosphorous; albumin; liver function tests; and coagulation profile (prothrombin time, and partial thromboplastin time);*
 - b. Serologic screening for: Human immunodeficiency virus (HIV); Epstein Barr virus (EBV); Hepatitis virus B (HBV); Hepatitis C (HCV); cytomegalovirus (CMV); RPR and/or FTA:.*
 - If HIV positive **ALL** of the following must be met:
 - i. CD4 count >200 cells/mm-3 for >6 months; **AND**
 - ii. HIV-1 RNA (ribonucleic acid) undetectable; **AND**
 - iii. On stable anti-retroviral therapy >3 months; **AND**
 - iv. No other complications from acquired immunodeficiency syndrome (AIDS) (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).
 - c. Urine drug screen (UDS) if Member is current or gives a history of past drug abuse.

AND

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10. Colonoscopy (if indicated or if Member is age ≥ 45) with complete workup and treatment of abnormal results as indicated (an initial screening colonoscopy after initial negative screening requires a follow-up colonoscopy every 10 years);*

AND

11. Gynecological examination with Pap smear for women ages ≥ 21 to ≤ 65 years of age or if indicated (not indicated in women who have had a total abdominal hysterectomy [TAH] or a total vaginal hysterectomy [TVH]) within the last three years with complete workup and treatment of abnormal results as indicated.*

Within the last 12 months:

1. Dental examination or oral exam showing good dentition and oral care or no abnormality on panorex or plan for treatment of problems pre- or post-transplant; **AND**
2. Mammogram (if indicated or $>$ age 40) with complete workup and treatment of abnormal results as indicated; **AND**
3. Prostate specific antigen (PSA) if history of prostate cancer or previously elevated PSA with complete workup and treatment of abnormal results as indicated.*

* Participating Centers of Excellence may waive these criteria.

Transplant Criteria

Pancreas alone, simultaneous pancreas-kidney transplantation, and pancreas after kidney organ transplantation from a donor **may be considered medically necessary** in adult members that have met **ALL** of the following:

1. All transplant evaluation criteria are met; **AND**
2. Optimally managed for at least 12 months by an endocrinologist or pancreas transplant surgeon; **AND**
3. Documentation of insulin dependent Type 1 diabetes showing abnormal beta cell functioning:
 - a. Beta cell autoantibody positive; **OR**
 - b. Fasting C-peptide undetectable (e.g., $\leq 110\%$ of the laboratory's lower limit of normal and with a concurrently obtained fasting glucose $\leq 225\text{mg/dl}$);

AND

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); **AND**
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).

AND

6. The requesting transplant recipient should not have any of the following **absolute contraindications**:
 - a. Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery; **OR**
 - b. Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer); **OR**
 - c. Systemic and/or uncontrolled infection; **OR**
 - d. AIDS (CD4 count $< 200\text{cells/mm}^3$); **OR**
 - e. Unwilling or unable to follow post-transplant regimen as evidenced by **ONE** of the following:
 - Documented history of non-compliance; **OR**
 - Inability to follow through with medication adherence or office follow-up.

OR

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- f. Chronic illness with one year or less life expectancy; **OR**
- g. Limited, irreversible rehabilitation potential; **OR**
- h. Active untreated substance abuse issues (requires documentation supporting that Member is free from addiction for minimally 6 months if previous addiction was present); **OR**
- i. No adequate social or family support.

AND

7. The requesting transplant recipient should be evaluated carefully and potentially treated if any of the relative contraindications below are present. (Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation.)
- a. Smoking, documentation supporting free from smoking for 6 months; **OR**
 - b. Active peptic ulcer disease; **OR**
 - c. Active gastroesophageal reflux disease; **OR**
 - d. CVA with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months; **OR**
 - e. Obesity with body mass index of $>30 \text{ kg/m}^2$ may increase surgical risk; **OR**
 - f. Chronic liver disease such as Hepatitis B/C/D, or cirrhosis which increases the risk of death from sepsis and hepatic failure requires consultation by a gastroenterologist or hepatologist; **OR**
 - g. Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation.

AND

8. **One of the following pancreas transplantation specific requirements by transplantation type must also be met:**
- a. **For Pancreas Transplant Alone, Partial Pancreas Transplant from a Living Donor, or Pancreas Re-Transplantation after a failed primary pancreas transplant; ALL of the following:**
 - i. The presence of minimally one secondary complication that has not progressed to end-organ failure such as proliferative diabetic retinopathy, neuropathy, gastroparesis, accelerated atherosclerosis; **AND**
 - ii. Creatinine clearance glomerular filtration rate of $\geq 80 \text{ ml/min}$; **AND**
 - iii. No significant proteinuria.
 - b. **For Simultaneous Pancreas-Kidney Transplant, ALL of the following:**
 - i. The presence of minimally one secondary complication that has not progressed to end-organ failure such as proliferative diabetic retinopathy, neuropathy, gastroparesis, accelerated atherosclerosis; **AND**
 - 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 on dialysis; **OR**
 - b. Anticipated date of the member requiring dialysis would be within the next 6 months or demonstrates 50% or more decline in renal function in the past year.
 - c. **For Pancreas After Kidney Transplant, all of the above main criteria are met and ALL of the following criteria:**
 - i. The presence of minimally one secondary complication that has not progressed to end-organ failure such as proliferative diabetic retinopathy, neuropathy, gastroparesis, accelerated atherosclerosis; **AND**
 - ii. The Member has a living organ donor for the kidney transplant procedure otherwise SPK should be considered; **AND**
 - iii. Previously successful kidney transplant as evidenced by stable function of previous renal allograft; **AND**
 - iv. Stable adequate kidney function as evidenced by creatinine clearance glomerular filtration rate of $\geq 45 \text{ ml/min}$; **AND**
 - v. No significant proteinuria.

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Continuation of Therapy

When extension of a previously approved transplant authorization is requested, review using updated clinical information is appropriate.

1. If Molina Healthcare has authorized prior requests for transplantation, **ALL** of the following information is required for medical review:
 - a. Presence of no absolute contraindication as listed above; **OR**
 - b. History and physical within the last 12 months; **OR**
 - c. Kidney profile within the last 12 months; **OR**
 - d. Cardiac update if history of cardiac disease within two years (\geq 50 years of age); **OR**
 - e. Psychosocial evaluation or update within the last 12 months; **OR**
 - f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.
2. If authorized prior requests for transplantation were obtained from another insurer, **ALL** of the following information is required for medical review:
 - a. Authorization letter/documentation from previous insurer; **OR**
 - b. Presence of no absolute contraindication as listed above; **OR**
 - c. History and physical within the last 12 months; **OR**
 - d. Cardiac update if history of cardiac disease within two years (\geq 50 years of age); **OR**
 - e. Psychosocial evaluation or update within the last 12 months; **OR**
 - f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.

For Members with Significant or Daily Cannabis Use

1. Documentation of compliance with a physician prescribed and managed program of abstinence, and a reasonable expectation that the Member will be abstinent from cannabis use during the transplant and immediate post-transplant time period. Daily use is an absolute contraindication for both transplant and pre-transplant evaluation unless there is a state mandate applicable for medical cannabis use and transplants, and there is documentation of Member compliance with a physician prescribed plan of care for prescribed cannabis use.
2. If the Member's cannabis use is in compliance with a formal, State-based program for managed medical cannabis, the request should include:
 - Documentation of the Plan of Care for medical cannabis (including the medical decision making that supports the use of medical marijuana); **AND**
 - Transplant Provider agreement with the Plan of Care (including agreement to be accountable for managing the Member's use of medical cannabis).

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 transplant in Type II diabetes
2. 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

PTA is a potential treatment for brittle type I diabetes mellitus in suitable candidates who have not yet developed advanced nephropathy, while SPK and PAK are treatments considered for select patients with type 1 diabetes and

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end-stage kidney disease.

Boggi et al. (2021) published a consensus statement on pancreas transplantation after convening the First World Consensus Conference on Pancreas Transplantation. Reviewers identified 597 studies to produce the guidelines. The panel released 110 recommendations and 49 jury deliberations. The jury deliberations report generally positive outcomes for select patients with type I diabetes treated with SPK, PAK, and PTA in terms of improved quality of life and, in some cases for SPK and PAK, long-term survival. None of the consensus statements achieved grade 1A due to lack of meta-analysis of prospective and randomized trials on the topics. The consensus acknowledges that pancreas transplantation is a rarely performed procedure which has never gained widespread acceptance in practice. Ultimately, the consensus concedes that in pancreas transplantation, there are many issues for which practice is not strongly supported by current evidence.

The **American Diabetes Association (ADA)** Standards of Care in Diabetes (Elsayed et al. 2023) identifies PTA, SPK, and PAK as treatment options in select patients, noting that successful pancreas transplantation can both normalize glucose levels and minimize potential microvascular complications of type I diabetes. However, because transplants require lifelong immunosuppression post-operatively, pancreas transplantation should be reserved for those also undergoing PAK or SPK, or for those with recurrent ketoacidosis or severe hypoglycemia despite aggressive medical management.

The **Organ Procurement and Transplantation Network (OPTN)** has published [policies](#) that govern operation of United Network for Organ Sharing (UNOS) member transplant hospitals, organ procurement organizations, and histocompatibility laboratories in the United States. Organ-specific [guidance](#) is available from OPTN as well as guidance on living donation, and patient safety. The focus of UNOS is to manage the national transplant waiting list and match donors to recipients (24 hours a day, 365 days a year). In addition, UNOS manages the database of all organ transplant data in the United States; monitors organ matches to ensure that allocation policies are followed; assists patients and their family members; and educates transplant professionals and the public on various aspects of organ donation.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	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

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50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
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

HCPCS Codes

HCPCS	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

06/14/2023	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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