Clinical Policy: Pancreas Transplantation

Reference Number: CP.MP.102
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Revision Log
Coding Implications

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

This policy describes the medical necessity requirements for pancreas transplantation procedures. Multiple types of pancreas transplants are effective therapeutic options for arresting the progression of complications of diabetes mellitus and improving the quality of life for diabetic patients, including simultaneous pancreas kidney transplant (SPK), pancreas after kidney transplant (PAK), pancreas transplant alone (PTA), and islet cell transplant.[1]

Note: For criteria related to Lantidra, please see CP.MP.250 Lantidra (donislecel): Allogeneic Pancreatic Islet Cellular Therapy

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that pancreas transplantation is **medically necessary** when meeting all of the following:

A. Member/enrollee has one of the following:
   1. Diagnosis of diabetes mellitus type I requiring insulin;
   2. Diagnosis of exocrine pancreatic insufficiency;
   3. A requirement for the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons;

B. Request is for one of the following procedures and meets the corresponding criteria:
   1. Pancreas Transplant Alone (PTA), meets all:
      a. Recurrent, severe, and potentially life-threatening metabolic complications that required medical attention, as documented by chart notes, emergency department visits, or hospitalizations, including any of the following:
         i. Severe hypoglycemia unawareness;
         ii. Recurring severe hypoglycemic attacks;
         iii. Marked hyperglycemia;
         iv. Recurring severe ketoacidosis;
      b. Clinical and/or emotional problems with exogenous insulin therapy that are so severe as to be incapacitating or consistent failure of insulin-based management to prevent acute complications;
      c. Has been medically managed by an endocrinologist for at least 12 months;
   2. Simultaneous Pancreas Kidney Transplant (SPK), meets all:
      a. Meets above criteria for PTA;
      b. End-stage renal disease (ESRD), as defined by both:
         i. Presence of uremia;
         ii. Requires dialysis or is expected to require dialysis in the next 12 months;
      c. Glomerular filtration rate (GFR) $\leq$ 20mL/min *or* creatinine clearance (CrCl) < 20mL/min, *or* dialysis dependent;
   3. Pancreas After Kidney Transplant (PAK), meets all:
      a. Meets above criteria for PTA;
      b. Underwent successful kidney transplant without significant chronic rejection of

kidney transplant;
    c. Stable kidney transplant function, as defined by both:
        i. Stable creatinine clearance ≥ 30 mL/min;
        ii. Absence of significant proteinuria specified as greater than 500mg/day;

C. Does not have ANY of the following contraindications:[2,8]
    1. Malignancy with high risk of recurrence or death related to cancer;
    2. Glomerular filtration rate < 40 mL/min/1.73m^2 unless being considered for multi-organ transplant;
    3. Stroke or acute coronary syndrome within 30 days;
    4. Myocardial infarction within six months, excluding demand ischemia;
    5. Acute liver failure, or cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multi-organ transplant;
    6. Septic shock;
    7. Active infection with highly virulent and/or resistant microbes that are poorly controlled pre-transplant;
    8. Active tuberculosis infection;
    9. HIV infection with detectable viral load unless all of the following are noted:
        a. CD4 cell count >200 cells/mm3;
        b. Absence of active AIDS-defining opportunistic infection (unless treated efficaciously or prevented) or malignancy;
        c. Member/enrollee is currently on effective ART (antiretroviral therapy);
    10. Progressive cognitive impairment;
    11. Inability to adhere to the regimen necessary to preserve the transplant, even with caregiver support;
    12. Active substance use or dependence including current tobacco use, vaping, marijuana use (unless prescribed by a licensed practitioner), or IV drug use without convincing evidence of risk reduction behaviors (unless urgent transplant timelines are present, in which case a commitment to reducing behaviors is acceptable). Serial blood and urine testing may be used to verify abstinence from substances that are of concern;
    13. Chronic, non-healing wounds;
    14. Significant comorbidities, such as advanced cardiopulmonary, cardiovascular, cerebrovascular, or peripheral vascular disease;
    15. Other severe uncontrolled medical condition expected to limit survival after transplant;

II. It is the policy of health plans affiliated with Centene Corporation that autologous islet cell transplants are considered **medically necessary** as an adjunct procedure to a total or near total pancreatectomy for severe, refractory pancreatitis.

III. It is the policy of health plans affiliated with Centene Corporation that pancreas re-transplantations are considered **medically necessary** after one failed primary pancreas transplant.

IV. It is the policy of health plans affiliated with Centene Corporation that current evidence does not support the use of pancreas transplant procedures for any of the following indications:
A. Re-transplantations after two or more failed primary pancreas transplantations;
B. Allogeneic islet cell transplantation or xenotransplantation;
C. SPK transplantation for patients with amputation due to peripheral obstructive vascular disease;
D. For the treatment of all other conditions than those specified above.

Background

The American Diabetes Association defines diabetes mellitus as a group of metabolic diseases

characterized by hyperglycemia that results from defects in insulin secretion, insulin action, or both.[3] According to the Centers for Disease Control and Prevention estimations, approximately 38.4 million people or 11.6% of the United States population has diabetes with approximately 8.7 million undiagnosed cases.[4] Chronic hyperglycemia existing in diabetic patients facilitates long term organ damage, especially to the eyes, kidneys, nerves, and blood vessels.[3]

The prevalent type 2 diabetes is caused by a resistance to insulin action and an inadequate compensatory insulin secretory response.[3] Type 1 diabetes is caused by immune mediated destruction of the insulin secreting pancreatic β cells.[5] Islet cell autoantibodies, insulin autoantibodies, autoantibodies to glutamic acid decarboxylase, zinc transporter 8 (ZnT8A), and autoantibodies to the tyrosine phosphatase IA-2 and IA-2β are serological markers of the pancreatic β cell destruction observed in type 1 diabetes.[3,5,6]

Pancreas transplantation allows for the possibility to restore glucose regulated endogenous secretion, decrease the progression of diabetic complications, and improve quality of life in patients with diabetes.[1,7] Pancreas transplantation is the only proven method to restore normoglycemia in type 1 diabetic patients.[8] Simultaneous pancreas kidney transplant (SPK), pancreas after kidney transplant (PAK), and pancreas transplant alone (PTA) are primarily performed on patients with type 1 diabetes.[8] SPK is an established procedure for diabetic patients with advanced chronic kidney disease or end stage kidney disease and accounts for approximately 90% of pancreas transplants performed in the United States.[9]

A 2011 study by Gruessner[10] reviewed the outcomes of SPK, PAK, and PTA transplantations according to follow-up data collected by the International Pancreas Transplant Registry. Patient survival rates were reported to be over 95% after one year and over 83% at five years post-transplant. The highest graft survival rates were observed in SPK transplants at 86% for pancreas and 93% for kidney graft function one-year post-transplant. PAK procedures displayed graft function at 80%, while PTA had graft function at 78% one year after transplantation.[10] The study demonstrated that pancreas transplantation offers excellent outcomes for patients with labile diabetes due to the improvement in patient survival and graft function shown in all three categories over the course of 24 years.[10]

Patients undergoing pancreas transplantation, especially SPK transplant, require extensive immunosuppression regiments.1 It is theorized that pancreas transplant recipients require higher levels of immunosuppression therapy than other solid organ transplants due to the immunogenicity of the pancreas or the autoimmune status of the recipient.11

During pancreatic islet autotransplantation, Islet β cells are transferred into the liver through the portal vein of the recipient.[1] Pancreatic islet autotransplantation is performed following a pancreatectomy in patients with severe chronic pancreatitis. Chronic pancreatitis is a debilitating disease which causes diarrhea, weight loss, poor quality of life, and severe abdominal pain that is difficult to alleviate with pharmacological treatment or other therapeutic measures.[1,12] Due to the excessive pain observed in patients with chronic pancreatitis, pain control is a primary goal of pancreatectomy and pancreatic islet autotransplantation.[12]

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are

included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT Codes that support coverage criteria

CPT Codes	Description
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas of 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 anastomosis, each
50328	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial 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

CPT Codes that do not support coverage criteria

CPT Codes	Description
0584T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous

0585T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic
0586T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open

HCPCS Codes	Description
S2065	Simultaneous pancreas kidney transplantation

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by specialist 4/16.	02/16	04/16
Background updated to reflect current data. References reviewed and updated. Replaced "member" with "member/enrollee" in all instances. Under contraindication I.C. removed "malignancy metastasized to or extending beyond the margins of the kidney and/or pancreas" as this is inclusive to contraindication #1.	02/21	02/21
Removed contraindication of "severely limited functional status with poor rehabilitation potential." Replaced "Psychiatric or psychological condition associated with the inability to cooperate or comply with medical therapy" and the contraindication regarding non-compliance with medical therapy with "Inability to adhere to the regimen necessary to preserve the transplant, even with caregiver support." Changed "Review Date" in header to "Date of Last Revision," and "Date" in the revision log header to "Revision Date."	08/21	08/21
Annual review. References reviewed and updated. Updated description and background with no clinical significance. Removed requirement in I.A. that medical therapy does not exist or has failed. Updated all contraindications in criteria I.C. "Experimental/investigational" verbiage replaced in criteria IV. statement with descriptive language. Specialist reviewed.	02/22	02/22
Annual review. Removed criterion I.A. stating that medical treatment does not exist or has failed. Removed C-peptide values and BMI requirements from Criteria I.B.1 and I.B.2. Noted in I.B.1. that member/enrollees with requirements for insulin over one unit/kg should be closely evaluated as they may be less likely to benefit from pancreas transplant compared to those with lower insulin doses Added indication in I.B.2 for exocrine pancreatic insufficiency. Added indication I.B.3. for requirement for the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons; Changed "chronic" to "active" in infection contraindication in I.C.7. Removed acute renal failure contraindication. Criteria I.C.12. updated to exclude marijuana use when prescribed by a licensed practitioner and include required commitment to reducing substance use behaviors if urgent transplant timelines are present. Added chronic, non-healing wounds as contraindication in Criteria I.C.13. Added contraindication of significant comorbidities in Criteria I.C.14. Clarified in I.C.1.b that problems with insulin could be clinical or clinical and emotional. Added in I.C.2.c. that	02/23	02/23

the GFR does not have to be the most recent value. Added Criteria I.D.1.c. requirement for being medically managed by an endocrinologist for at least 12 months for pancreas transplant alone. Added requirements for SPK and PAK that PTA criteria also needs to be met for those procedures. ICD-10 codes removed. Background updated with no impact on criteria. References reviewed and updated.		
Added note to policy to see CP.MP.250 Lantidra (donislecel): Allogeneic Pancreatic Islet Cellular Therapy for criteria related to Lantidra.	08/23	08/23
Annual review. Expanded criteria I.B. to I.B.a. through c. Updated description and background with no clinical significance. Coding reviewed. References reviewed and updated. Reviewed by external specialist	02/24	02/24
Annual review. In I.B.3. changed "myocardial infarction within 30 days" to "myocardial (within 6 months)" and reworded the information about "stroke or acute coronary syndrome". Added I.C.1.a.ii "Recurring severe hypoglycemic attacks". Background updated. Added CPT code 50328. References reviewed and updated.	01/25	01/25
Annual review. Under criteria I.A.1. specified “type I” and removed “(members/enrollees with requirements…). Under I.B.1.a. replaced “require” with “required” and “room” with “department”. Reworded criteria under I.B.1.b. with no impact on criteria. Under I.B.2.c. removed “(does not have to be…) and added “or dialysis dependent”. Under. I.B.3.c.ii. added “specified as greater than 500mg/day”. Moved contraindications under I.B. to I.C. References reviewed and updated. Reviewed by internal and external specialist.	01/26	01/26

References

1. Robertson, RP, Rickels, M. Pancreas and islet transplantation in diabetes mellitus. UpToDate. www.uptodate.com. Published April 03, 2024. Accessed November 3, 2025.
2. Leard LE, Holm AM, Valapour M, et al. Consensus document for the selection of lung transplant candidates: An update from the International Society for Heart and Lung Transplantation. *J Heart Lung Transplant*. 2021;40(11):1349 to 1379. doi:10.1016/j.healun.2021.07.005
3. American Diabetes Association. Diagnosis and classification of diabetes mellitus. *Diabetes Care.* 2014;37 Suppl 1:S81 to S90. doi:10.2337/dc14-S081
4. Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. https://www.cdc.gov/diabetes/php/data-research/methods.html?CDC_AAref_Val=. Published May 15, 2024. Accessed November 3, 2025.
5. Atkinson MA, Eisenbarth GS, Michels AW. Type 1 diabetes. *Lancet*. 2014;383(9911):69 to 82. doi:10.1016/S0140-6736(13)60591-7
6. Chiang JL, Kirkman MS, Laffel LM, Peters AL; Type 1 Diabetes Sourcebook Authors. Type 1 diabetes through the life span: a position statement of the American Diabetes Association. *Diabetes Care*. 2014;37(7):2034 to 2054. doi:10.2337/dc14-1140
7. Mittal S, Johnson P, Friend P. Pancreas transplantation: solid organ and islet. *Cold Spring Harb Perspect Med*. 2014;4(4):a015610. Published 2014 Apr 1. doi:10.1101/cshperspect.a015610
8. Alhamed T, Stratta RJ. Pancreas-kidney transplantation in diabetes mellitus: Patient selection

and pretransplant evaluation. UpToDate. www.uptodate.com. Published January 19, 2023. Accessed November 3, 2025.
9. Alhamed T, Stratta RJ. Pancreas-kidney transplantation in diabetes mellitus: Benefits and complication. UpToDate. www.uptodate.com. Published January 20, 2023. Accessed November 3, 2025.
10. Gruessner AC. 2011 update on pancreas transplantation: comprehensive trend analysis of 25,000 cases followed up over the course of twenty-four years at the International Pancreas Transplant Registry (IPTR). *Rev Diabet Stud*. 2011;8(1):6 to 16. doi:10.1900/RDS.2011.8.6
11. Redfield RR, Scalea JR, Odorico JS. Simultaneous pancreas and kidney transplantation: current trends and future directions. *Curr Opin Organ Transplant*. 2015;20(1):94 to 102. doi:10.1097/MOT.0000000000000146
12. Kesseli SJ, Smith KA, Gardner TB. Total pancreatectomy with islet autologous transplantation: the cure for chronic pancreatitis?. *Clin Transl Gastroenterol*. 2015;6(1):e73. Published 2015 Jan 29. doi:10.1038/ctg.2015.2
13. National coverage determination: Pancreas transplants (260.3). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published April 26, 2006. Accessed November 3, 2025.
14. Organ Procurement and Transplant Network. OPTN Organ Procurement and Transplant Network Policies. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf. Published January 10, 2024. Effective October 1, 2025 Accessed November 3, 2025.
15. American Diabetes Association Professional Practice Committee. 2. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes-2024. *Diabetes Care.* 2024;47(Suppl 1):S20-S42. doi:10.2337/dc24-S002
16. Bahar SG, Devulapally P. Pancreas Transplantation. In: *StatPearls*. Treasure Island (FL): StatPearls Publishing; March 14, 2023
17. Clinic C. Protein In Urine (Proteinuria): Causes, Symptoms & Treatment. Cleveland Clinic. Published January 15, 2019. https://my.clevelandclinic.org/health/symptoms/16428-proteinuria

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting

may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCD's and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.