Clinical Policy: Pancreas Transplantation

Reference Number: NC.CP.MP.102
Date of Last Revision: 04/2024

Coding Implications
Revision Log

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]

Policy/Criteria

I. It is the policy of Carolina Complete Health that a pancreas transplant is **medically necessary** when meeting Criterion A **OR** B along with Criterion C and D*:*

A. Severely disabling and potentially life-threatening complications due to hypoglycemic unawareness and labile insulin-dependent diabetes (Type I DM) that persists in spite of optimal medical management and;
1. Diagnosis of diabetes mellitus requiring insulin (members/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);
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;
4. There is adequate renal function as defined by the evaluating center that the probability of ESRD after transplant is considered low.

B. Diagnosis of Type II DM that persists in spite of optimal medical management and:
1. Uses between 10-100 units of insulin per day and BMI is less than 32;
2. There is adequate renal function as defined by the evaluating center that the probability of ESRD after transplant is considered low.

C. Does not have ANY of the following contraindications:
1. Malignancy with high risk of recurrence or death related to cancer;
2. Stroke, acute coronary syndrome, or myocardial infarction (excluding demand ischemia) within 30 days;
3. Acute liver failure or cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multi-organ transplant;
4. Septic shock;
5. Active infection with highly virulent and/or resistant microbes that are poorly controlled pre-transplant;
6. Active tuberculosis infection;
7. HIV infection with detectable viral load except where optimal management can be demonstrated by a physician with generally recognized expertise in HIV care;

8. Progressive cognitive impairment;
9. Inability to adhere to the regimen necessary to preserve the transplant, even with caregiver support;
10. Active substance use or dependence including current tobacco use, vaping, marijuana smoking (unless prescribed by a licensed practitioner), or IV drug use without convincing evidence of risk of reduction behaviors (unless urgent transplant timelines are present, in which case commitment to reduce behaviors is acceptable). Serial blood and urine testing may be used to verify abstinence from substances that are of concern;
11. Chronic, non-healing wounds;
12. Significant comorbidities, such as advanced cardiopulmonary, cardiovascular, cerebrovascular, or peripheral vascular disease;
13. Other severe uncontrolled medical condition expected to limit survival after transplant;

**Note: Each of the above represent relative as opposed to absolute contraindications and each case will be evaluated on the individual merits and medical necessity*

D. Request is for one of the following procedures and meets the corresponding criteria:

1. *PTA*, meets all:
    a. Recurrent, severe, and potentially life-threatening metabolic complications that require medical attention, as documented by chart notes, emergency room visits, or hospitalizations, including any of the following:
        i. Severe hypoglycemia unawareness;
        ii. Marked hyperglycemia;
        iii. Recurring severe ketoacidosis;
    b. Clinical and 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;

    **Note: Medical management by an endocrinologist for at least 12 months is preferred.*
2. *SPK* with end-stage renal disease (ESRD), as evidenced by uremia;
    a. Meets above criteria for PTA;
3. *PAK transplant*, 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 $\geq$ 30 mL/min,
        ii. Absence of significant proteinuria.

II. It is the policy of Carolina Complete Health 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 Carolina Complete Health that *pancreas re-transplantation* are considered **medically necessary** after one failed primary pancreas transplant.

IV. It is the policy of Carolina Complete Health 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 37.3 million people or 11.3% of the United States population has diabetes with approximately 8.5 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] Graft survival rate is defined as total freedom from insulin therapy, normal fasting blood glucose concentrations, and normal or only slightly elevated hemoglobin A1C values.[11] 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.[12]

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.[1,13] Due to the excessive pain observed in patients with chronic pancreatitis, pain control is a primary goal of pancreatectomy and pancreatic islet autotransplantation.[13]

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. 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	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
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy

HCPCS Codes	Description
S2065	Simultaneous pancreas kidney transplantation

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy adapted for use by North Carolina Health Plan (Carolina Complete Health), per state feedback and requirements: replaced requirement for failure or non-existence of medical treatment for condition and indication of DM 1 and definitions of insulin dependence per specific C peptide values/C peptide values and BMI with the indication of severe complications due to hypoglycemic unawareness and labile Type 1 DM. Replaced contraindications of malignancy in past 2 years or metastasized malignancy with "active, potentially life-threatening malignancy."	06/19	6/19
Annual review completed. No changes to policy content.	03/21	03/21
Section I.B, 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."	11/21	11/21
Annual review completed. References reviewed and updated. Updated description and background with no clinical significance. Updated all contraindications in criteria I.B. "Experimental/investigational" verbiage replaced in criteria IV. statement with descriptive language.	4/22	04/22
Annual review. Removed "when meeting all of the following:" from I and revised to note "medically necessary when meeting Criterion A **OR** B along with Criterion C and D." Noted in I.A.1. that member/enrollees with requirements for insulin over one unit/kg should be closely evaluated as they may be less likely to benefit	06/2023	06/2023

from pancreas transplant compared to those with lower insulin doses Added indication in I.A.2 for exocrine pancreatic insufficiency. Added indication I.A.3. for requirement for the procurement or transplantation of a pancreas as part of a multiple organ transplant for technical reasons; Added criterion 1.A.4: There is adequate renal function as defined by the evaluating center that the probability of ESRD after transplant is considered low; Added criterion I.B (including I.B.1 & I.B.2): Diagnosis of Type II DM that persists in spite of optimal medical management and: I.B.1 Uses between 10 – 100 units of insulin per day and BMI is less than 32; I.B.2 There is adequate renal function as defined by the evaluating center that the probability of ESRD after transplant is considered low. Removed 1.C.2 Removed 1.B.2 for limits around Glomerular Filtration rates and added Not enough renal function to reduce high probability of ESRD after pancreas transplant; Changed "chronic" to "active" in infection contraindication in I.C.5. Removed acute renal failure contraindication.; Revised 1.C.7 from "HIV infection with detectable viral load" to "HIV infection with detectable viral load except where optimal management can be demonstrated by a physician with generally recognized expertise in HIV care;" Criteria I.C.10. 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.11. Added contraindication of significant comorbidities in Criteria I.C.12. Added note for I.D medically managed by an endocrinologist for at least 12 months is preferred 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.		
Annual review. Updated description and background with no clinical significance. Coding reviewed. References reviewed and updated.	04/24	04/24

References

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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

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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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, 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, 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.