Clinical Policy: Pancreas Transplant

Reference Number: WNC.CP.247
Last Review Date: 02/25

Coding Implications
Revision Log

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

Note: 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.

Description[1]

This policy addresses three transplantation services:

- a simultaneous pancreas and kidney transplant;
- a pancreas transplant some time following a kidney transplant; **and**
- a pancreas transplant alone.

Policy/Criteria[1]

I. WellCare of North Carolina® shall cover pancreas transplantation when the Member meets any **ONE** of the following criteria:

- **A.** A *Combined Pancreas-Kidney transplant* when medically necessary in members with Type I diabetes mellitus (DM) with uremia;
- **B.** A *Pancreas transplant after a prior kidney transplant* when medically necessary in members with insulin-dependent diabetes mellitus (Type I DM);
- **C.** A *Pancreas transplant alone* when medically necessary in members with 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; **OR**
- **D.** A *Pancreas retransplant after a failed primary pancreas transplant* when medically necessary for all three types of pancreas transplants (i.e., combined pancreas-kidney transplant, pancreas transplant after a prior kidney transplant, and pancreas transplant alone); **AND**
- **E.** A Member who meets the eligibility criteria for the transplant center performing the procedure; **AND**
- **F.** A Member and caregiver who are willing and capable of following the post-transplant treatment plan.

II. WellCare of North Carolina® shall cover a Member for any type of pancreas transplantation when the Member meets the specific criteria listed in Section I **AND** all of the following criteria:

- **A.** Adequate cardiopulmonary status;
- **B.** Absence of significant infection that could be exacerbated by immunosuppressive therapy (e.g., chronic active viral hepatitis B, hepatitis C and human immunodeficiency virus (HIV)), **AND**
- **C.** No active, potentially life-threatening, malignancy;

D. Documentation of compliance with medical management; **AND**
E. Absence of uncontrolled HIV infection. HIV infection is considered controlled when the following criteria are met:
1. Cluster Differentiation 4 (CD4) count greater than 200 cells mm-3 for more than 6 months;
2. HIV-1 Ribonucleic acid (RNA) undetectable;
3. The Member is stable on anti-retroviral therapy more than 3 months; **AND**
4. The Member has no other complications from acquired human immunodeficiency (AIDS) (e.g., opportunistic infection, including aspergillus. tuberculosis, coccidiosis mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).

III. Candidates for **pancreas transplantation alone** shall additionally meet **ONE** of the following severities of illness criteria:
A. Documentation of severe hypoglycemia unawareness as evidence by chart notes or emergency room visits; **OR**
B. Documentation of potentially life-threatening labile diabetes as evidenced by chart notes or hospitalization for diabetic ketoacidosis.

IV. WellCare of North Carolina® **shall not** cover pancreas transplantation for a Member who does not meet the criteria and guidelines listed in Sections I-III **AND** who has any **ONE** of the following:
A. Poor physiologic age;
B. Significant emotional problems that may impair the Member's ability to adhere to follow up;
C. Current tobacco use (impairs wound and microvascular healing);
D. Other major organ system disease or infection, including major vascular disease;
E. Morbid obesity (defined as BMI greater than or equal to 40);
F. Uncontrolled HIV-positive members
G. Organs sold rather than donated to a Member; **OR**
H. Artificial organs or human organ transplant service for which the cost is covered or funded by governmental, foundation, or charitable grants.

V. WellCare of North Carolina® **shall not** cover pancreas transplantation when the Member's psychosocial history limits the Member's ability to comply with pre- and post-transplant medical care.

VI. WellCare of North Carolina® **shall not** cover pancreas transplantation when there is a current Member or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

VII. WellCare of North Carolina® **shall not** cover pancreas transplantation:
- **A.** When the Member has an active substance use; **OR**
- **B.** For members with a recent history of substance use, where there is no documentation of:
  1. A completed substance abuse or therapy program; **plus**
  2. Six months of negative sequential random drug screens.

Background[1]

Transplantation of a normal pancreas is a treatment method for members with Type 1 diabetes mellitus. Pancreas transplantation can restore glucose control and is intended to prevent, halt, or reverse the secondary complications of Type I diabetes mellitus. Achievement of insulin independence with resultant decreased morbidity and increased quality of life is the primary health outcome. While pancreas transplantation is generally not considered a life-saving treatment, in a small subset of patients who experience life-threatening complications from Type I diabetes, pancreas transplantation could be considered lifesaving.

Pancreas transplantation occurs in several different clinical situations, including:
- a Type I diabetic Member with renal failure who may receive a cadaveric simultaneous pancreas/kidney transplant (SPK);
- a Type I diabetic Member who may receive a cadaveric or living-related pancreas after a kidney transplantation (pancreas after kidney. i.e., PAK); **or**
- a non-uremic Type I diabetic Member with specific severely disabling and potentially life-threatening diabetic problems who may receive a pancreas transplant alone (PTA).

The experience with SPK transplant is more extensive than that of other transplant options.

The approach to re-transplantation varies according to the cause of failure. Surgical technical complications such as venous thrombosis are the leading cause of pancreatic graft loss among diabetic patients. Graft loss from chronic rejection may result in sensitization, increasing both the difficulty of finding a cross-matched donor and the risk of rejection of a subsequent transplant.

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	Description
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48554	Transplantation of pancreatic allograft
48556	Removal of transplanted pancreatic allograft
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50340	Recipient nephrectomy
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	Reviewed Date	Approval Date
Original Approval date.	05/21	05/21
Reviewed CPT and HCPCS codes.	04/21	05/22
Annual Review. NCHC verbiage removed from NC Guidance verbiage.	05/23	05/23
Annual review. ICD-10-CM code table removed.	02/24	02/24
Annual Review. Removed “Medicaid and health choice” verbiage from References.	02/25	02/25

References

1. State of North Carolina Medicaid Clinical Coverage Policy No: 11B-7 Pancreas Transplant. Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov). Published August 15, 2023. Accessed November 5, 2024.

North Carolina Guidance

Eligibility Requirements

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
b. Provider(s) shall verify each Medicaid beneficiary’s eligibility each time a service is rendered.

c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
EPSDT provider page: https://medicaid.ncdhhs.gov/

Provider(s) Eligible to Bill for the Procedure, Product, or Service
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance
Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information
Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

a. Claim Type - as applicable to the service provided:
Professional (CMS-1500/837P transaction)
Institutional (UB-04/837I transaction)
Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report

the procedure, product or service using the appropriate unlisted procedure or service code.
Unlisted Procedure or Service
CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.
HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

d. Modifiers - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
For Medicaid refer to Medicaid State Plan:
https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.