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## **1.0 Description of the Procedure, Product, or Service**

This policy addresses three transplantation services: 1) a simultaneous pancreas and kidney transplant; 2) a pancreas transplant some time following a kidney transplant; and 3) a pancreas transplant alone.

Transplantation of a normal pancreas is a treatment method for recipients 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 life saving.

Pancreas transplantation occurs in several different clinical situations, including:

1. a Type I diabetic recipient with renal failure who may receive a cadaveric simultaneous pancreas/kidney transplant (SPK);
2. a Type I diabetic recipient who may receive a cadaveric or living-related pancreas after a kidney transplantation (pancreas after kidney. i.e., PAK); or
3. a non-uremic Type I diabetic recipient 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 retransplantation 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.

## **2.0 Eligible Recipients**

### **2.1 General Provisions**

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

### **2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age**

#### **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 recipients 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 clinician).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/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 recipient'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 recipient's right to a free choice of providers.

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

- a. that is unsafe, ineffective, or experimental/investigational.
- b. 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/or 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 will correct or improve or maintain the recipient'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**

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

*Basic Medicaid Billing Guide:* <http://www.ncdhhs.gov/dma/basicmed/>

**EPSDT provider page:** <http://www.ncdhhs.gov/dma/epsdt/>

### 3.0 When the Procedure, Product, or Service Is Covered

**IMPORTANT NOTE:** EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient'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 DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED.** For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

### 3.1 General Criteria

Medicaid covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

### 3.2 Specific Criteria

Medicaid covers pancreas transplantation for any one of the following:

- a. a **Combined Pancreas-Kidney transplant** when medically necessary in recipients with **Type I diabetes mellitus (DM)** with uremia;
- b. a **Pancreas transplant after a prior kidney transplant** when medically necessary in recipients with insulin-dependent diabetes mellitus (Type I DM);
- c. a **Pancreas transplant alone** when medically necessary in recipients 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 recipient who meets the eligibility criteria for the transplant center performing the procedure; and
- f. a recipient and caregiver who are willing and capable of following the post transplant treatment plan.

### 3.3 Policy Guidelines

Medicaid covers a recipient for any type of pancreas transplantation when the recipient meets the specific criteria listed in **Subsection 3.2** 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<sup>-3</sup> for more than 6 months;
  2. HIV-1 Ribonucleic acid (RNA) undetectable;
  3. the recipient is stable on anti-retroviral therapy more than 3 months; and
  4. the recipient has no other complications from acquired human immunodeficiency (AIDS) (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).

Candidates for **pancreas transplantation alone** shall additionally meet one of the following severity 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.

#### 4.0 When the Procedure, Product or Service Is Not Covered

**IMPORTANT NOTE:** EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient'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 DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED.** For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

##### 4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

##### 4.2 Specific Criteria

Medicaid does not cover pancreas transplantation for a recipient who does not meet the criteria and guidelines listed in **Section 3.0** and who has any one of the following:

- a. poor physiologic age;
- b. significant emotional problems that may impair the recipient'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 recipients
- g. organs sold rather than donated to a recipient; or
- h. artificial organs or human organ transplant service for which the cost is covered or funded by governmental, foundation, or charitable grants.

#### 4.3 Psychosocial History

Pancreas transplantation is not covered when the recipient's psychosocial history limits the recipient's ability to comply with pre- and post-transplant medical care.

#### 4.4 Medical Compliance

Current recipient or caretaker non-compliance that would make compliance with a disciplined medical regime improbable

#### 4.5 Substance Abuse

Pancreas transplantation is not covered when the recipient has an active substance abuse or, for recipients with a recent history of substance abuse, there is no documentation of the completion of a substance abuse or therapy program plus six months of negative sequential random drug screens.

### 5.0 Requirements for and Limitations on Coverage

**IMPORTANT NOTE:** EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient'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 DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED.** For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

#### 5.1 Prior Approval

Prior approval is required for pancreas transplantation.

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

Only those recipients accepted for transplantation by a transplantation center and eligible for transplant listing shall be considered for prior approval. Guidelines must be followed for transplant network or consortiums, if available.

#### 5.2 Prior approval requirements

Refer to *Basic Medicaid Billing Guide, section 6:*  
<http://www.ncdhhs.gov/dma/basicmed/>

## 6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet Medicaid's qualifications for participation;
- b. be currently enrolled with N.C. Medicaid; 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.

## 7.0 Additional Requirements

**IMPORTANT NOTE:** EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient'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 DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED.** For additional information about EPSDT and prior approval requirements, refer to **Subsection 2.2** of this policy.

### 7.1 Compliance

Providers shall comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

FDA approved procedures, products, and devices for implantation must be utilized for pancreas transplantation.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

## 8.0 Policy Implementation/Revision Information

**Original Effective Date:** January 1, 1994

**Revision Information:**

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/1/06	Sections 2.2	The special provision related to EPSDT was revised.
12/1/06	Sections 3.0 and 4.0	A note regarding EPSDT was added to these sections.
5/1/07	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.
5/1/07	Attachment A	Added the UB-04 as an accepted claims
12/1/11	Entire Policy	Policy was updated to include coverage criteria and requirements to meet current community standards of practice.

### Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

#### A. Claim Type

Professional (CMS-1500/837P transaction)

#### B. Diagnosis Codes

Providers shall bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

#### C. Procedure Code(s)

CPT Code(s)	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(separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy

HCPCS Code	Description
S2065	Simultaneous pancreas kidney transplantation

ICD-9 Procedure Codes	Description
52.80	Pancreatic transplant, not otherwise specified
52.81	Reimplantation of pancreatic tissue
52.82	Homotransplant of pancreas
52.83	Heterotransplant of pancreas

#### **D. Modifiers**

Providers are required to follow applicable modifier guidelines.

#### **E. Billing Units**

One unit per day

#### **F. Place of Service**

Acute Inpatient hospital

#### **G. Co-payments**

Co-payments are not required for pancreas transplantation

#### **H. Reimbursement**

Providers shall bill their usual and customary charges.

#### **I. Billing for Donor Expenses**

Donor expenses for non-Medicaid donors are billed on the Medicaid recipient's transplant claim using the recipient's Medicaid identification number. Donor expenses for Medicaid donors are billed on the Medicaid donor's claim using the donor's Medicaid identification number.

Medicaid reimburses only for the actual donor's expenses. Medicaid does not reimburse for unsuccessful donor searches.

**Cadaveric/Deceased Organ Donations:**

Donor expenses (procuring, harvesting, and associated surgical and laboratory costs) for cadaveric/deceased organ donations are covered for a pancreas transplant if the transplant recipient has received prior approval for a cadaveric/deceased organ transplant procedure.

**Living Organ Donations:**

Donor expenses (procuring, harvesting, and associated surgical and laboratory costs) for living organ donations are covered for a pancreas transplant if the transplant recipient has received prior approval for a living organ transplant procedure. Medicaid only covers reimbursement for the approved donor.