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Introduction

Transplantation is the procedure involving the removal of a bodily organ or tissue from one person, and the insertion of that organ or tissue into another person to replace a damaged organ or tissue.

Definition of Terms:
Allograft—transplant from one individual to another (synonymous with homograft)
Heterotopic graft—transplant placed in a site different than the organ's normal location
Orthotopic graft—transplant placed in its normal anatomical site
Syngeneic graft (isograft)—transplant between identical twins
Xenograft—transplant between different species

Organ transplantation is now well established as an effective treatment for selected patients with end-stage organ failure. Transplantation of the kidney, liver, pancreas, heart, and lungs are all routine procedures, and transplantation of the small intestine is becoming more widely practiced. Currently, transplant activity is limited only by the shortage of cadaveric organs.

The following policy contains the minimal criteria for solid organ transplants. Additional justification may be required at the discretion of the Division of Medical Assistance Hospital Consultant staff.

1.0 Definition of the Procedure

Pancreas transplant (PTA), simultaneous pancreas kidney (SPK), and simultaneous cadaver-donor pancreas and living donor kidney (SPLK) procedures involve the removal of diseased organs (pancreas or pancreas/kidney) from the recipient and replacing them with healthy organs from a deceased or living donor.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

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

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

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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/medbillcaguide.htm

EPSDT provider page: http://www.ncdhhs.gov/dma/EPSDTprovider.htm

3.0 When the Procedure 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, see **Section 2.0** of this policy.

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage. The N.C. Medicaid program covers pancreas transplantation related to PTA, SPK, and SPLK for patients who meet *all* of the following criteria.

3.1 PTA

a. History of labile (brittle) insulin-dependent diabetes mellitus (IDDM)

b. Recurrent and acute life-threatening metabolic complications:

1. Hypoglycemia
2. Hyperglycemia
3. Ketoacidosis
4. Hypoglycemic unawareness with high risk of injury

c. Consistent failure of exogenous insulin management:

HbA1C of 8.0 or greater documented, with aggressive conventional management (insulin pump, adjusting of amounts and frequencies of insulin injected, multiple daily blood glucose levels, and strict diet and exercise)

d. Satisfactory kidney function (creatinine clearance > 40 ml/min)

e. Adequate cardiac status

3.2 SPK and SPLK

a. Type 1 insulin-dependent (juvenile onset) diabetes

b. ESRD requiring dialysis or expected to require dialysis in the next 12 months

c. One type of progressive secondary diabetic complication, which is more serious than the risk of major surgery and immunosuppression

d. Glucose levels 300mg/dl or more with a C-peptide level of 0.2ng/ml or less

e. Creatinine clearance calculated by Cockcroft-Gault < 30ml/min

4.0 When the Procedure 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, see **Section 2.0** of this policy.

Pancreas transplant is not covered when the medical necessity criteria listed in Section 3.0 are not met. Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

The N.C. Medicaid program does not cover pancreas transplant when one of the following conditions exists (not all inclusive).

4.1 Allogeneic and Xeno Islet Cell Transplants

Allogeneic and xeno islet cell transplants are not covered for any diagnosis.

4.2 PTA

a. Active infection
b. HIV positive
c. History of malignancy within five years
d. History of or active substance abuse—must have documentation of substance abuse program completion plus six months of negative sequential random drug screens

   Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.
e. Psychosocial history that would limit ability to comply with medical care pre and post transplant
f. Morbid obesity
g. Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable
h. Ejection fraction < 40%
i. Myocardial infarction within last six months
j. Uncontrolled hypertension
k. Severe peripheral vascular disease

4.3 SPK and SPLK (Absolute)

a. Un-reconstructable coronary artery disease, or refractory CHF
b. Cancer within last five years
c. Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable
d. Morbid obesity
e. Psychosocial history that would limit ability to comply with medical care pre and post transplant
f. History of or active substance abuse—must have documentation of substance abuse program completion plus six months of negative sequential random drug screens

   Note: To satisfy the requirement for sequential testing as designated in this policy, DMA must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.
g. HIV positive

4.4 SPK and SPLK (Relative)

a. Cardiac disease: EF < 40%, MI within last six months
b. Chronic liver disease
c. Severe peripheral vascular disease
d. Severe cerebrovascular disease
e. Uncontrolled hypertension
f. Age 65 years or older

4.5 Donors

Living donor expenses **are not covered** for a pancreas transplant.

5.0 Requirements for and Limitations on Coverage

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

All procedures must be prior approved by DMA.

6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

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

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 form.

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

Physicians bill professional services on the CMS-1500 claim form.

Hospitals bill for services on the UB-92 or UB-04 claim form.

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity for pancreas transplant (PTA).

C. Procedure Codes

Codes that are covered include

48554	48556	50300	50320
50340	50360	50365	S2065

D. Reimbursement

Providers must bill their usual and customary charges.