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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 Description of the Procedure

Liver transplant is surgery to replace a diseased liver with a healthy liver from a recently deceased donor or a piece of a healthy liver from a live 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 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 liver transplants for patients who meet indications for transplantation related to the following disease processes (not all inclusive).

3.1 Hepatocellular Diseases

- a. Alcoholic cirrhosis
- b. Alpha-1 antitrypsin deficiency
- c. Viral hepatitis (all blood types)
- d. Autoimmune hepatitis
- e. Wilson's disease
- f. Protoporphyrria
- g. Hemochromatosis
- h. Inborn errors of metabolism

3.2 Cholestatic Diseases

- a. Biliary atresia
- b. Primary biliary cirrhosis
- c. Primary sclerosing cholangitis with secondary biliary cirrhosis
- d. Familial cholestatic syndromes

3.3 Vascular Diseases

- a. Budd Chiari syndrome

3.4 Primary Hepatocellular Carcinoma

Primary hepatocellular carcinoma and hepatoblastoma confined to the liver when *all* of the following criteria are met.

- a. Carcinoma has not infiltrated the hepatic vein
- b. Patient is not a candidate for a subtotal liver resection
- c. There is no macrovascular involvement
- d. There is no extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone
- e. Tumor is 5 cm or less in diameter; or has no more than three tumors, each less than 3 cm in diameter

3.5 Epithelial Hemangioendotheliomas (EHE) without Metastatic Disease

3.6 Trauma and Toxic Reactions

3.7 Miscellaneous

- a. Polycystic disease of the liver
- b. Familial amyloid polyneuropathy
- c. Cryptogenic cirrhosis

3.8 Donors

Refer to **Attachment A** for billing guidance on donor-related costs.

3.8.1 Cadaveric/Deceased Organ Donations

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

3.8.2 Living Organ Donations

Donor expenses (**procuring, harvesting, and associated surgical and laboratory costs**) for living organ donations are covered for an adult-to-child split liver transplant if the transplant recipient has received prior approval for a living organ transplant procedure.

Medicaid only covers reimbursement for the approved donor. Medicaid does not cover expenses for donors who are tested and not approved as the donor.

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.

Liver transplants are 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 liver transplants when one of the following conditions exists (not all inclusive).

4.1 Adult Living Donor Transplants

N.C. Medicaid does not cover adult-to-adult living donor transplants.

4.2 Adult (Absolute)

- a. Advanced cardiac or pulmonary disease
- b. Extra-hepatic malignancy, with the exception of hepatic metastasis from treatable primary neuroendocrine tumors
- c. HIV positive
- d. Active sepsis outside the liver
- e. Thrombosis of mesenteric venous system
- f. Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable

- g. Psychosocial history that would limit ability to comply with medical care pre and post transplant
- h. Previous liver transplants
- i. Pulmonary hypertension unresponsive to medical therapy
- j. 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 less 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.

4.3 Adult (Relative)

- a. Portal vein thrombosis
- b. Age > 65 years
- c. HBS AG (+) hepatitis B surface antigen
- d. Hepatocellular carcinoma
- e. Renal failure
- f. Pulmonary hypertension
- g. Extensive prior surgery on portal vein, biliary system, or stomach
- h. Severe multisystem failure
- i. Cholangiocarcinoma
- j. Primary neuroendocrine tumors (metastases restricted to the liver)

4.4 Pediatric (Absolute)

- a. Advanced cardiac or pulmonary disease
- b. Extra hepatic malignancy or cholangiocarcinoma with the exception of hepatic metastasis from treatable primary neuroendocrine tumors
- c. Active sepsis outside the liver
- d. Thrombosis of mesenteric venous system
- e. 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 less 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.

- f. HIV positive

- g. Psychosocial history that would limit ability to comply with medical care pre and post transplant
- h. Pulmonary hypertension unresponsive to medical therapy

4.5 Pediatric (Relative)

- a. Congenital heart disease
- b. Renal failure
- c. Pulmonary hypertension
- d. Hbs ag (+) hepatitis b surface antigen
- e. Extensive pre-existing surgery on portal vein, biliary system, or stomach excluding kasai procedure
- f. Previous liver transplants
- g. Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable
- h. Primary neuroendocrine tumors (metastases restricted to the liver)
- i. Cholangiocarcinoma

4.6 Living Donors

Absolute contraindications to organ donation include a donor who has

- a. A transmissible infectious disease that will adversely affect the recipient such as HIV, active hepatitis B virus (HBV) infection, West Nile virus, encephalitis of unknown cause, Jakob-Creutzfeldt's disease, malaria, or disseminated tuberculosis
- b. Active visceral or hematologic neoplasm
- c. Clinical signs that indicate the organ is unlikely to function

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 liver transplants 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 for liver transplants.

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	Section 2.2	The special provision related to EPSDT was revised.
12/1/06	Section 3.0	A note regarding EPSDT was added to this section.
12/1/06	Section 3.4	Hepatoblastoma was added as a covered condition; item #5 was added as one of the criteria that must be met.
12/1/06	Section 3.5	This section was added as a covered criterion.
12/1/06	Section 3.8	The stipulation that living donor expenses are only covered when the donor is a Medicaid recipient was deleted.
12/1/06	Section 3.8.1	This section was reformatted to address cadaveric/deceased organ donations
12/1/06	Section 3.8.2	This section was added to address living organ donations.
12/1/06	Section 4.0	A note regarding EPSDT was added to this section.
12/1/06	Section 4.2	Item #2 was revised to indicate that noncoverage of extra hepatic malignancy does not apply to hepatic metastasis from treatable primary neuroendocrine tumors.
12/1/06	Section 4.3	Item # 10 was added to the list of noncovered conditions for adults.
12/1/06	Section 4.4	Item #2 was revised to indicate that noncoverage of extra hepatic malignancy or cholangiocarcinoma does not apply to metastasis from treatable primary neuroendocrine tumors.
12/1/06	Section 4.5	Items #8 and #9 were added to the list of noncovered conditions for pediatric recipients.
12/1/06	Section 4.6	This section was added to address contraindications for living organ donations.
12/1/06	Attachment A	Billing instructions for living organ donations and cadaveric/deceased organ donations were added.
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 that Support Medical Necessity

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

1. CPT Procedure Codes

47133	47135	47136	47140	47141	47142
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2. RC Codes

Code	Description
811	Living organ donation
812	Cadaveric/deceased organ donation

D. Reimbursement

Providers must bill their usual and customary charges.

E. 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.

In all cases, physician professional fees are billed on the CMS-1500 or 837 professional claim transaction and the facility charges are billed on the UB-92, UB-04, or 837 institutional claim transaction using the appropriate Revenue Code.