

To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP.

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**NC Medicaid
Liver Transplantation**

**Medicaid and Health Choice
Clinical Coverage Policy No: 11B-5
Amended Date: March 15, 2019**

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1.0 Description of the Procedure, Product, or Service

Liver transplantation is now routinely performed as a treatment of last resort for beneficiaries with end-stage liver disease. Beneficiaries are prioritized for transplant according to length of time on the waiting list and severity of illness criteria developed by the United Network of Organ Sharing (UNOS).

UNOS eliminated the original liver allocation system, which was based on assignment to Status 1, 2A, 2B, or 3. The new system retains Status 1, which is intended to describe beneficiaries with acute liver failure who have a life expectancy of less than 7 days, and Status 7, which describes beneficiaries who are temporarily inactive due to intercurrent medical problems. Status 2A, 2B, and 3 are now replaced with a new scoring system: model for end-stage liver disease (MELD) and pediatric end-stage liver disease (PELD) for beneficiaries-under age 18 years. MELD and PELD are a continuous disease severity scale based entirely on objective laboratory values. These scales have been found to be highly predictive of the risk of dying from liver disease for beneficiaries waiting on the transplant list. The MELD score incorporates bilirubin, prothrombin time (i.e., international normalized ratio [INR]), and creatinine into an equation, producing a number that ranges from 1 to 40. The PELD score incorporates albumin, bilirubin, INR growth failure, and age at listing. Aside from Status 1, donor livers will be prioritized to those with the highest MELD or PELD number; waiting time will only be used to break ties among beneficiaries with the same MELD or PELD score and blood type compatibility.

In the previous system, waiting time was often a key determinant of liver allocation, and yet waiting time was found to be a poor predictor of the urgency of liver transplant. In the new MELD/PELD allocation system, beneficiaries with higher MELD/PELD scores will always be considered before those with lower scores, even if some beneficiaries with lower scores have waited longer.

1.1 Definitions

None Apply.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term “General” found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC 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.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

- a. Medicaid
None Apply.
- b. NCHC
None Apply.

2.2 Special Provisions

2.2.1 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.

b. 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/>

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when 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 beneficiary'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 beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

Medicaid and NCHC shall cover liver transplantation when the recipient meets the following criteria:

- a. A liver transplant using a cadaver or living donor when medically necessary for carefully selected beneficiaries with end-stage liver failure due to irreversibly damaged livers from conditions that include the following:
 1. Hepatocellular diseases
 - A. Alcoholic cirrhosis
 - B. Viral hepatitis (A, B, C, or non-A, non-B)
 - C. Autoimmune hepatitis
 - D. Alpha-I Antitrypsin deficiency
 - E. Hemochromatosis
 - F. Protoporphyrria
 - G. Wilson's disease
 2. Hepatoblastoma which is confined to the liver
 3. Cholestatic liver diseases
 - A. Primary biliary cirrhosis
 - B. Primary sclerosing cholangitis with development of secondary biliary cirrhosis
 - C. Biliary atresia
 4. Vascular diseases
 - A. Budd-Chiari syndrome
 - B. Primary hepatocellular carcinoma
 5. Inborn errors of metabolism
 6. Trauma and toxic reactions
 7. Miscellaneous
 - A. Polycystic disease of the liver
 - B. Familial amyloid polyneuropathy
 8. Asymptomatic human immunodeficiency virus (HIV)-positive beneficiaries who meet the following criteria:
 - A. Cluster Differentiation 4 (CD4) count greater than 200 cells/mm-3 for more than 6 months;
 - B. HIV-1 Ribonucleic acid (RNA) undetectable;
 - C. On stable anti-retroviral therapy more than 3 months;
 - D. No other complications from acquired immune deficiency syndrome (AIDS) (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm); and
 - E. Meets all the other criteria for transplantation;
- AND**
- b. The recipient and caregiver are willing and capable of complying with the post transplant treatment plan.

3.3 Policy Guidelines

To be eligible for liver transplantation, it must be likely that the procedure will provide a demonstrable beneficial effect to the recipient receiving the liver. Criteria for making this determination includes the following:

- a. **Criteria for transplant recipient Selection:**
 1. **Refractory ascites** - unresponsive to medical management, including diuretics, therapeutic paracentesis.
 2. **Uncontrolled variceal bleeding:**

- A. Esophageal: unresponsive to endoscopic treatment, sclerotherapy or rubberband ligation; or
 - B. Gastric: if no esophageal component, requires either surgical decompression (splenectomy if splenic vein thrombosis) or transplantation.
3. **Encephalopathy** - To be distinguished from organic disease or chronic neuropsychiatric disorder. Hypokalemia or azotemia must be corrected and the recipient placed on a strict protein restricted diet, lactulose, or neomycin.
4. **Wasting** - Not useful as a sole criterion. Occurs early in parenchymal disease, preterminal in cholestatic disease. When extreme, transplantation is no longer feasible due to increased operative-postoperative complications.
5. **Fatigue interfering with normal daily activities** - Usually other criteria for transplant are present. In the absence of other criteria, a detailed psychiatric evaluation must be performed to rule out other factors causing fatigue.
6. **Hypoxemia secondary to liver disease** - Arterial desaturation due to severe portal hypertension. The hepatopulmonary syndrome is caused by arteriovenous (A-V) shunting or ventilation/perfusion (V/Q) mismatch. If corrected by breathing 100% oxygen, then it is due to A-V shunting and transplant will likely correct it.
7. **Hepatorenal syndrome** - Functional renal failure secondary to liver disease must be distinguished from primary renal disease to predict potential for reversibility, and the need for combined liver and kidney transplant.
- b. To be considered medically necessary, a liver transplant must provide a demonstrable beneficial effect on health outcome for the individual. Refer to **Subsection 4.3** for Risk Factors.
- c. **Disease Specific Indications:**
Liver transplantation may be covered if the recipient has chronic liver failure due to one of the following:
 1. **Cholestatic Liver disease:** Primary Biliary Cirrhosis, Primary Sclerosing Cholangitis, Congenital Biliary Disease, Polycystic Liver disease;
 2. **Parenchymal Liver Disease:** Autoimmune hepatitis, Chronic Hepatitis C, Cryptogenic Cirrhosis;
 3. **Metabolic Liver Disease:** Wilson's disease, Alpha-1 Antitrypsin deficiency (rule out concurrent hepatocellular carcinoma), galactosemia, protoporphyria;
 4. **Non-hepatic causes of Portal Hypertension:** Trauma, Budd Chiari Syndrome or other vascular causes (inoperable);
 5. **Other systemic disease:** Sarcoidosis, Schistosomiasis;
 6. **Chronic Hepatitis B with cirrhosis, provided:** beneficiaries shall be assessed for medical necessity in terms of presence of HBeAg and HBV DNA, indicating active viral replication. HBeAg neg, HBV DNA neg, meets medical necessity criteria.
 7. **Chronic Alcoholic Liver Disease, provided:** Abstinence must be documented for six months. Enrollment is required in an active support group, such as Alcoholics Anonymous, in addition to strong support by the family or a close friend.
 8. **Neoplastic disease, provided:** Hepatocellular carcinoma found in conjunction with cirrhosis, (i.e., single lesion less than or equal to 5 cm, up to three separate lesions, none larger than 3 cm), and where extensive evaluation yields no evidence of metastasis or systemic symptoms (e.g. weight loss) meets medical necessity requirements for liver transplant. Exploratory laparotomy at the time of the transplant must confirm absence of metastatic disease.

9. **Human immunodeficiency virus (HIV) positivity:**
 - A. Cluster Differentiation 4 (CD4) count greater than 100cells/mm³;
 - B. HIV-1 Ribonucleic acid (RNA) undetectable;
 - C. On stable anti-retroviral therapy more than 3 months;
 - D. No other complications from acquired immunodeficiency syndrome (AIDS) (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm);
 - E. Meets all other criteria for transplantation.
- d. Other Conditions:
 1. **Fulminant hepatic failure:** Fulminant hepatic failure is defined by the appearance of severe liver injury with hepatic encephalopathy in a previously healthy recipient, generally within two weeks of onset of liver disease. Subfulminant hepatic failure appears within 2-12 weeks of onset of liver disease. In general, beneficiaries may meet medical necessity requirements for transplantation for fulminant hepatitis resulting from viral, toxic, anesthetic-induced, or medication induced liver injury when they meet **one** of the following sets of criteria:
 - A. Clichy criteria for **acute viral hepatitis**: 1) Stage III or greater coma; 2) factor V less than 20% (age less than 30 years) or factor V less than 30% (age greater than 30 years); or
 - B. London criteria for **non paracetamol-induced acute liver failure**: 1) prothrombin time greater than 100 seconds (s); or 2) any three of the following prognostic factors are present: age less than 10 years or greater than 40 years; non-A, non-B hepatitis; Halothane hepatitis or idiosyncratic drug reaction; duration of jaundice before onset of encephalopathy greater than seven days; prothrombin time greater than 50 seconds; serum bilirubin greater than 300 mumol/l.
 2. Beneficiaries with **polycystic disease of the liver** do not develop liver failure but may require transplantation due to the anatomic complications of a massively enlarged liver. One of the following complications must be present, which are not amenable to non transplant surgery:
 - A. Enlargement of liver impinging on respiratory function;
 - B. Extremely painful enlargement of liver; or
 - C. Enlargement of liver significantly compressing and interfering with function of other abdominal organs.
 3. Beneficiaries with **familial amyloid polyneuropathy** do not experience liver disease, per se, but develop polyneuropathy and cardiac amyloidosis due to the production of a variant transthyretin molecule by the liver. Candidacy for liver transplant is an individual consideration based on the morbidity of the polyneuropathy. Many beneficiaries may not be candidates for liver transplant alone due to coexisting cardiac disease.
- c. Beneficiaries with **hepatocellular carcinoma** are appropriate candidates for liver transplant only if the disease remains confined to the liver. Therefore, the recipient must be periodically monitored while on the waiting list, and if metastatic disease develops, the recipient must be removed from the transplant waiting list. In addition, at the time of transplant a backup candidate must be scheduled. If locally extensive or metastatic cancer is discovered at the time of exploration prior to hepatectomy, the transplant must be aborted, and the backup candidate scheduled for transplant.

Beneficiaries with a history of alcohol (ETOH)/substance use shall fulfill the following criteria:

- a. Actively using ETOH/substance within the past year
 1. These beneficiaries shall have six months of counseling (at least twice per month);-provided by a substance abuse provider.
 2. Shall have monthly toxicology/ETOH screens, continuing these screens monthly until listed; and
 3. Shall have toxicology/ETOH screens as needed (PRN).
- b. Clean/sober up to 2 years
 1. These beneficiaries shall have a counseling consult and the counselor will decide if the beneficiary requires continued recidivism counseling. Medicaid will accept the counselor's recommendations;
 2. These beneficiaries shall have ONE toxicology/ETOH screen during their evaluation; and
 3. Shall have toxicology/ETOH screens PRN.
- c. Clean/sober for greater than 2 years
 1. No counseling is necessary;
 2. Beneficiary shall have one toxicology/ETOH screen during evaluation; and
 3. Beneficiary shall have toxicology/ETOH screens PRN

3.3.1 Medicaid Additional Criteria Covered

None Apply.

3.3.2 NCHC Additional Criteria Covered

None Apply.

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

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service 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 Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

- a. Medicaid and NCHC shall not cover the following:
 1. human organ transplant (HOT) services, for which the cost is covered or funded by governmental. foundation, or charitable grants;
 2. organs that are sold rather than donated to a recipient; or
 3. an artificial organ.

- b. Liver transplantation is contraindicated for the following indications:
 - 1. extrahepatic malignancy including cholangiocarcinoma;
 - 2. hepatocellular carcinoma that has extended beyond the liver;
 - 3. active infection.

4.2.2 Psychosocial History

Medicaid and NCHC shall not cover liver transplantation when the beneficiary's psychosocial history limits the beneficiary's ability to comply with pre- and post-transplant medical care.

4.2.3 Medical Compliance

Medicaid and NCHC shall not cover liver transplantation when there is current recipient or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

4.2.4 Substance Use

Medicaid and NCHC shall not cover liver transplantation when the recipient has an active substance use or, for beneficiaries with a recent history of substance use, there is no documentation of the completion of a substance use or therapy program plus six months of negative sequential random drug screens.

4.2.5 Risk Factors:

Examples of risk factors which would reduce or remove beneficial outcome include:

- a. **Alcohol use** - abstinence for at least six months (documented in the progress notes of a formal program) is an absolute requirement;
- b. **Cardiac** - severe valvular disease complicated by severe pulmonary hypertension; alcoholic cardiomyopathy; aortic stenosis with left ventricular (LV) dysfunction; coronary artery disease uncorrected or with residual LV dysfunction are all contraindications. Cardiac evaluation must exclude significant cardiomyopathy. A history of bacterial endocarditis with valvular damage significantly worsens prognosis and precludes eligibility;
- c. **Pulmonary** - severe progressive primary lung disease whose pulmonary functions are irreversibly compromised is a contraindication. Active pulmonary tuberculosis must be treated for at least 3 months prior to transplant. Functional lung disease (e.g., asthma), lung disease secondary to liver disease, and unilateral pneumonectomy are not absolute contraindications to transplant;
- d. **Chronic infectious disease** - chronic suppurative infections (e.g., osteomyelitis, sinusitis); HIV; chronic fungal disease;
- e. **Rheumatic disease** - Scleroderma with gastrointestinal or pulmonary involvement;
- f. **Advanced physiological age**; or **Chronic Hepatitis B with cirrhosis, provided:** beneficiaries must be assessed for medical necessity in terms of presence of HBeAg and HBV DNA, indicating active viral replication.
- g. **Neoplastic disease, provided:** Treatment of hepatocellular carcinoma with transplant in the absence of the above criteria is considered investigational. Refer to **Subsection 3.3.c.8** for criteria.

4.2.6 Medicaid Additional Criteria Not Covered

None Apply.

4.2.7 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) “Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 1. No services for long-term care.
 2. No nonemergency medical transportation.
 3. No EPSDT.
 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection.”

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

5.1 Prior Approval

Medicaid and NCHC shall require prior approval for liver transplantation. The provider shall obtain prior approval before rendering liver transplantation.

A living donor shall require prior approval.

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

Only those beneficiaries 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 applicable.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

- a. the prior approval request; and
- b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.3 Specific Transplant Prior Approval Requirements

The provider(s) shall submit the following to the NC Medicaid transplant nurse consultant:

- a. Letter of medical necessity **signed by the attending transplant physician**, requesting transplant, summarizing the clinical history, social history and the transplant evaluation;

- b. All health care records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy including:
 - 1. Lab results (less than three months old) to include Complete Blood Count (CBC), complete electrolytes, liver enzymes, Prothrombin Time (PT), International Normalized Ratio (INR), glucose and A1C (Glycated Hemoglobin if Type I or Type II diabetic), and blood type;
 - 2. Baseline drug, alcohol, and nicotine/cotinine screenings on all adult transplant candidates;
 - 3. Serologies to include Human Immunodeficiency Virus (HIV), Hepatitis, Rapid Plasma Reagin (RPR), Epstein-Barr Virus (EBV), Cytomegalovirus (CMV), Varicella, Rubella, Herpes Simplex Virus (HSV) I/II, and toxoplasmosis. (*Positive* serology results may be reported that are greater than three months old);
 - 4. Diagnostic studies (less than six months old) required in a complete packet include:
 - A. Cardiac: Echocardiogram, Electrocardiogram (ECG), and/or cardiac catheterization as appropriate for beneficiary's clinical status;
 - B. Pulmonary: Pulmonary Function Test if beneficiary has cardiac or pulmonary issues, or a history of smoking; and
 - C. Chest x-ray for all transplant candidates;
 - 5. Other diagnostic tests may be requested as appropriate;
 - 6. Beneficiary's height and weight
 - 7. Results of all diagnostic and procedure results (not more than six months old)
- c. Complete psychological and social evaluation to include:
 - 1. beneficiary's medical compliance;
 - 2. beneficiary's support network;
 - 3. post-transplant care plan, with identification of primary and secondary care providers; and
 - 4. history of mental health issues/substance use/legal issues
- d. Beneficiaries with a psychiatric history are required to have an evaluation by a psychiatrist with expertise in evaluating the specific psychiatric issues that relate to transplant candidates.

Beneficiaries with a history of alcohol (ETOH)/substance use shall fulfill the following criteria:

- d. Actively using ETOH/substance within the past year
 - 4. These beneficiaries shall have six months of counseling (at least twice per month) provided by a substance abuse provider.
 - 5. Shall have monthly toxicology/ETOH screens, continuing these screens monthly until listed; and
 - 6. Shall have toxicology/ETOH screens as needed (PRN).
- e. Clean/sober up to 2 years
 - 4. These beneficiaries shall have a counseling consult and the counselor will decide if the beneficiary requires continued recidivism counseling. Medicaid will accept the counselor's recommendations;
 - 5. These beneficiaries shall have ONE toxicology/ETOH screen during their evaluation; and
 - 6. Shall have toxicology/ETOH screens PRN.

- f. Clean/sober for greater than 2 years
- 4. No counseling is necessary;
- 5. Beneficiary shall have one toxicology/ETOH screen during evaluation; and
- 6. Beneficiary shall have toxicology/ETOH screens PRN

6.0 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 or NCHC 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.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 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).

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

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the beneficiary'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
07/01/2005	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
09/01/2005	Section 2.2	The special provision related to EPSDT was revised.
12/01/2005	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/01/2006	Section 2.2	The special provision related to EPSDT was revised.
12/01/2006	Section 3.0	A note regarding EPSDT was added to this section.
12/01/2006	Section 3.4	Hepatoblastoma was added as a covered condition; item #5 was added as one of the criteria that must be met.
12/01/2006	Section 3.5	This section was added as a covered criterion.
12/01/2006	Section 3.8	The stipulation that living donor expenses are only covered when the donor is a Medicaid recipient was deleted.
12/01/2006	Section 3.8.1	This section was reformatted to address cadaveric/deceased organ donations
12/01/2006	Section 3.8.2	This section was added to address living organ donations.
12/01/2006	Section 4.0	A note regarding EPSDT was added to this section.
12/01/2006	Section 4.2	Item #2 was revised to indicate that non-coverage of extra hepatic malignancy does not apply to hepatic metastasis from treatable primary neuroendocrine tumors.
12/01/2006	Section 4.3	Item # 10 was added to the list of non-covered conditions for adults.
12/01/2006	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.
12/01/2006	Section 4.5	Items #8 and #9 were added to the list of non-covered conditions for pediatric beneficiaries.
12/01/2006	Section 4.6	This section was added to address contraindications for living organ donations.
12/01/2006	Attachment A	Billing instructions for living organ donations and cadaveric/deceased organ donations were added.
05/01/2007	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for beneficiaries under 21 years of age.
07/01/2010	Throughout	Session Law 2009-451, Section 10.31(a) Transition of NC Health Choice Program administrative oversight from the State Health Plan to the Division of Medical Assistance (DMA) in the NC Department of Health and Human Services.

Date	Section Revised	Change
12/01/2011	Throughout	Policy was updated to include coverage criteria and requirements to meet current community standards of practice.
12/01/2011	Throughout	To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 11B-5 under Session Law 2011-145, § 10.41.(b)
03/12/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
08/01/2012	Subsection 5.3	Prior authorization requirements for recipients with ETOH/substance abuse issues was added.
08/01/2012	Throughout	Replaced "recipient" with "beneficiary."
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and Attachments	Updated policy template language.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, NCTracks 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 and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

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.

ICD-10-CM Code(s)
0FY00Z0
0FY00Z1

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.

CPT Code(s)
47133
47135
47136
47140
47141
47142

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

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

F. Place of Service

Acute inpatient hospital.

G. Co-payments

For Medicaid refer to Medicaid State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

For NCHC refer to NCHC State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>

I. Billing for Donor Expenses

1. Billing for Donor Expenses for Medicaid Beneficiaries

Donor transplant-related medical expenses are billed on the Medicaid beneficiary's transplant claim using the beneficiary's Medicaid identification number.

Medicaid reimburses only for the actual donor's transplant-related medical expenses.

Medicaid does not reimburse for unsuccessful donor searches.

2. Billing for Donor Expenses for NCHC Beneficiaries

Donor transplant-related medical expenses donors are billed on the NCHC beneficiary's transplant claim.

NCHC reimburses only for the actual donor's transplant-related medical expenses. NCHC does not reimburse for unsuccessful donor searches.

3. Cadaveric/Deceased Organ Donations

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

4. Living Organ Donations for a NCHC Beneficiary

Donor medical 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 beneficiary has received prior approval for a living organ transplant procedure. NCHC only covers reimbursement for the approved donor.

5. Living Organ Donations for a Medicaid Beneficiary

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