WellCare
Beyond Healthcare. A Better You.

Clinical Policy: Liver Transplantation

Reference Number: WNC.CP.204
Last Review Date: 05/23

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 discusses the medical necessity criteria for liver transplantation.

Policy/Criteria[1]

I. WellCare of North Carolina® 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 members 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. Protoporphyria
   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
      i. members 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.

5. Inborn errors of metabolism
6. Trauma and toxic reactions
7. Miscellaneous
   a. Polycystic disease of the liver
      i. members 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.
   b. Familial amyloid polyneuropathy
      i. members 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 members may not be candidates for liver transplant alone due to coexisting cardiac disease.
8. Asymptomatic human immunodeficiency virus (HIV)-positive members 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, coccidioses 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.

II. Criteria for *transplant recipient selection*:

A. Refractory ascites - unresponsive to medical management, including diuretics, therapeutic paracentesis.
B. Uncontrolled variceal bleeding:
   1. Esophageal: unresponsive to endoscopic treatment, sclerotherapy or rubberband ligation; **or**
   2. Gastric: if no esophageal component, requires either surgical decompression (splenectomy if splenic vein thrombosis) or transplantation.
C. 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.

D. 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.
E. 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.
F. 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.
G. 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.

III. Disease Specific Indications: Liver transplantation may be covered if the recipient has *chronic liver failure* due to **one** of the following:

A. Cholestatic Liver disease: Primary Biliary Cirrhosis, Primary Sclerosing Cholangitis, Congenital Biliary Disease, Polycystic Liver disease;
B. Parenchymal Liver Disease: Autoimmune hepatitis, Chronic Hepatitis C, Cryptogenic Cirrhosis;
C. Metabolic Liver Disease: Wilson's disease, Alpha-1 Antitrypsin deficiency (rule out concurrent hepatocellular carcinoma), galactosemia, protoporphyria;
D. Non-hepatic causes of Portal Hypertension: Trauma, Budd Chiari Syndrome or other vascular causes (inoperable);
E. Other systemic disease: Sarcoidosis, Schistosomiasis;
F. Chronic Hepatitis B with cirrhosis, provided: members 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.
G. 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.
H. 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.
I. Human immunodeficiency virus (HIV) positivity:
   1. Cluster Differentiation 4 (CD4) count greater than 100cells/mm3;
   2. HIV-1 Ribonucleic acid (RNA) undetectable;
   3. On stable anti-retroviral therapy more than 3 months;
   4. No other complications from acquired immunodeficiency syndrome (AIDS) (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioses mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm);
   5. Meets all other criteria for transplantation.

IV. *Other Conditions*:

A. 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, members may meet medical necessity requirements for transplantation for fulminant hepatitis resulting from viral, toxic, anestheticinduced, or medication induced liver injury when they meet **one** of the following sets of criteria:

1. Clichy criteria for acute viral hepatitis:
   a. Stage III or greater coma;
   b. factor V less than 20% (age less than 30 years) or factor V less than 30% (age greater than 30 years); **or**
2. London criteria for non paracetamol-induced acute liver failure:
   a. prothrombin time greater than 100 seconds (s); **or**
   b. any **three** of the following prognostic factors are present:
      i. age less than 10 years or greater than 40 years;
      ii. non-A, non-B hepatitis;
      iii. halothane hepatitis or idiosyncratic drug reaction;
      iv. duration of jaundice before onset of encephalopathy greater than seven days;
      v. prothrombin time greater than 50 seconds;
      vi. serum bilirubin greater than 300 mumol/l.

V. Members with a *history of alcohol (ETOH)/substance use* shall fulfill the following criteria:

A. Actively using ETOH/substance within the past year
   1. These members 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 members shall have a counseling consult and the counselor will decide if the member requires continued recidivism counseling. Medicaid will accept the counselor's recommendations;
   2. These members 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. Member shall have one toxicology/ETOH screen during evaluation; **and**
   3. Member shall have toxicology/ETOH screens PRN

VI. WellCare of North Carolina® **shall not** cover the following:

A. Human organ transplant (HOT) services, for which the cost is covered or funded by governmental. foundation, or charitable grants;

B. Organs that are sold rather than donated to a recipient; **or**
C. An artificial organ.

VII. Liver transplantation is **contraindicated** for the following indications:
A. Extrahepatic malignancy including cholangiocarcinoma;
B. Hepatocellular carcinoma that has extended beyond the liver;
C. Active infection.

VIII. WellCare of North Carolina® **shall not** cover liver transplantation when the members psychosocial history limits the members ability to comply with pre- and post-transplant medical care.

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

X. WellCare of North Carolina **shall not** cover liver transplantation when the recipient has an active substance use or, for members 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.

Background[1]
Liver transplantation is now routinely performed as a treatment of last resort for members with end-stage liver disease. Members 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 members with acute liver failure who have a life expectancy of less than 7 days, and Status 7, which describes members 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 members 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 members 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 members 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, members with higher MELD/PELD scores will always be considered before those with lower scores, even if some members with lower scores have waited longer.

To be considered medically necessary, a liver transplant must provide a demonstrable beneficial effect on health outcome for the individual.

I. 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: members 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**.

WellCare of North Carolina 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 policies and procedures must be followed in addition to the ones listed in this procedure.

Only those members 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.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted

2022, American Medical Association. All rights reserved. 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
47133	Donor hepatectomy (including cold preservation), from cadaver donor
47135	Liver allotransplantation, orthotopic, partial or whole, from cadaver or living donor, any age
47140	Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)
47141	Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III and IV)
47142	Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII)

HCPCS ®* Codes	Description
No applicable codes.	

ICD-10-CM Diagnosis Codes that Support Coverage Criteria
+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description
No applicable codes.	

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date	04/21	06/21
Reviewed CPT codes.	04/22	05/22
Annual Review. NCHC verbiage removed from NC Guidance Verbiage.	05/23	05/23

References

1. State of North Carolina Medicaid. Medicaid and Health Choice Clinical Coverage Policy No: 11B-5 Liver Transplantation. Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov). Published July 1, 2021. Accessed February 1, 2023.

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.

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