

Table of Contents

1.0	Description of the Procedure, Product, or Service.....	2
2.0	Eligible Recipients.....	2
2.1	General Provisions.....	2
3.0	When the Procedure, Product, or Service Is Covered.....	2
3.1	General Criteria.....	2
3.2	Specific Criteria.....	3
3.3	Policy Guidelines.....	3
4.0	When the Procedure, Product, or Service Is Not Covered.....	6
4.1	General Criteria.....	6
4.2	Specific Criteria.....	6
4.3	Psychosocial History.....	6
4.4	Medical Compliance.....	6
4.5	Substance Abuse.....	6
4.6	Risk Factors:.....	6
5.0	Requirements for and Limitations on Coverage.....	7
5.1	Prior Approval.....	7
5.2	Prior Approval Requirements.....	7
6.0	Providers Eligible to Bill for the Procedure, Product, or Service.....	7
7.0	Additional Requirements.....	8
7.1	Compliance.....	8
8.0	Policy Implementation/Revision Information.....	8
	Attachment A: Claims-Related Information.....	9
A.	Claim Type.....	9
B.	Diagnosis Codes.....	9
C.	Procedure Code(s).....	9
D.	Modifiers.....	9
E.	Billing Units.....	9
F.	Place of Service.....	9
G.	Co-payments.....	9
H.	Reimbursement.....	9
I.	Billing for Donor Expenses.....	9

1.0 Description of the Procedure, Product, or Service

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

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NC Health Choice (NCHC) recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

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

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

3.2 Specific Criteria

NCHC covers:

- a. A liver transplant using a cadaver or living donor when medically necessary for carefully selected recipients 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 recipients who meet the following criteria:
 - A. Cluster Differentiation 4 (CD4) count greater than 200 cells/mm³ 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 AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm);
 - 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:** recipients shall be assessed for medical necessity in terms of presence of HBeAg and HBV DNA , indicating active viral replication.
 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, recipients 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;
 - 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; 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 s; serum bilirubin greater than 300 mumol/l.
 2. Recipients 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. Recipients 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 recipients may not be candidates for liver transplant alone due to coexisting cardiac disease.
- c. Recipients 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.

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

4.1 General Criteria

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

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

4.2 Specific Criteria

- a. NCHC does 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;

4.3 Psychosocial History

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

4.4 Medical Compliance

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

4.5 Substance Abuse

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

4.6 Risk Factors:

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

- a. **Alcohol abuse** - 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; or
- f. **Chronic Hepatitis B with cirrhosis, provided:** recipients 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.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is required for liver transplantation. A living donor shall require prior approval.

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

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

5.2 Prior Approval Requirements

The provider(s) shall submit to DMA's designee the following:

- a. the prior approval request; and
- b. all health care records and any other records that support the NCHC recipient has met the specific criteria and guidelines in **Subsection 3.2 and 3.3** of this policy

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

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

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**

- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

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

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

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

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

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
7/1/2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
12/1/11	Throughout	NCHC policy developed comparable to DMA Clinical Coverage Policy 11B-5

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

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

C. Procedure Code(s)

CPT Code(s)	Description
47133	Donor hepatectomy(including cold preservation), from cadaver donor
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age
47136	Liver allotransplantation; heterotopic, 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)

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

One unit per day.

F. Place of Service

Acute inpatient hospital

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services

H. Reimbursement

Providers shall bill their usual and customary charges.

I. Billing for Donor Expenses

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

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

Cadaveric/Deceased Organ Donations:

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

Living Organ Donations:

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