



MASSACHUSETTS

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Medical Policy Liver Transplantation

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Policy Number: 198

BCBSA Reference Number: 7.03.06

Related Policies

- Small bowel/Liver and Multivisceral transplant, #[632](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Liver transplantation may be **MEDICALLY NECESSARY** using a cadaver or living donor for carefully selected patients with end-stage liver failure due to irreversibly damaged livers.

Liver transplantation may be **MEDICALLY NECESSARY** in patients with unresectable hilar cholangiocarcinoma.

Liver transplantation may be **MEDICALLY NECESSARY** in patients with polycystic disease of the liver who have massive hepatomegaly causing obstruction or functional impairment. One of the following complications should be present:

- Enlargement of liver impinging on respiratory function
- Extremely painful enlargement of liver
- Enlargement of liver significantly compressing and interfering with function of other abdominal organs.

Liver transplantation may be **MEDICALLY NECESSARY** in pediatric patients with nonmetastatic hepatoblastoma.

Liver *retransplantation* may be **MEDICALLY NECESSARY** in patients with:

- Primary graft non-function
- Hepatic artery thrombosis
- Chronic rejection
- Ischemic type biliary lesions after donation after cardiac death
- Recurrent non-neoplastic disease causing late graft failure.

Liver transplantation is **INVESTIGATIONAL** in the following patients:

- Patients with intrahepatic cholangiocarcinoma.

- Patients with neuroendocrine tumors metastatic to the liver.

Liver transplantation is **INVESTIGATIONAL** in all other situations not described above.

Etiologies of end-stage liver disease include, but are not limited to, the following:

- **Hepatocellular Diseases**
 - Alcoholic liver disease
 - Viral hepatitis (either A, B, C, or non-A, non-B)
 - Autoimmune hepatitis
 - Alpha-1 antitrypsin deficiency
 - Hemochromatosis
 - Nonalcoholic steatohepatitis
 - Protoporphyria
 - Wilson's disease
- **Cholestatic Diseases**
 - Primary or secondary biliary cirrhosis
 - Primary sclerosing cholangitis with development of secondary biliary cirrhosis
 - Biliary atresia
- **Vascular Disease**
 - Budd-Chiari Syndrome
- **Other**
 - Primary hepatocellular carcinoma
 - Inborn errors of metabolism
 - Trauma and toxic reactions
 - Familial amyloid polyneuropathy
 - Amyloidosis
 - Cryptogenic cirrhosis
 - End-stage liver disease in children
 - Familial cholestasis, and
 - Intrahepatic bile duct paucity (Alagille's syndrome).

In addition to the above information, we do not cover liver transplantation when any of the following conditions are present:

- Known current non-hepatic malignancy, including metastatic cancer
- Patients with hepatocellular carcinoma that has extended beyond the liver
- Recent malignancy with high risk of recurrence
 - Note: the assessment of risk of recurrence for a previously treated malignancy is made by the transplant team; providers must submit a statement with an explanation of why the patient with a recently treated malignancy is an appropriate candidate for a transplant.
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage disease not attributed to liver disease
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy
 - Patients with liver disease related to alcohol or drug abuse must be actively involved in a substance abuse treatment program

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Indications and Limitations of Coverage

CIM 35-53

General

Effective July 15, 1996, adult liver transplantation when performed on beneficiaries with end stage liver disease other than hepatitis B or malignancies is covered under Medicare when performed in a facility which is approved by CMS as meeting institutional coverage criteria.

Effective December 10, 1999, adult liver transplantation when performed on beneficiaries with end stage liver disease other than malignancies is covered under Medicare when performed in a facility which is approved by CMS as meeting institutional coverage criteria.

Effective September 1, 2001, Medicare covers adult liver transplantation for hepatocellular carcinoma when the following conditions are met:

- The patient is not a candidate for subtotal liver resection;
- The patient's tumor(s) is less than or equal to 5 cm in diameter;
- There is no macrovascular involvement;
- There is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone; and
- The transplant is furnished in a facility that is approved by CMS as meeting institutional coverage criteria for liver transplants (See 65 FR 15006).

Adult liver transplantation for other malignancies remains excluded from coverage. Coverage of adult liver transplantation is effective as of the date of the facility's approval, but for applications received before July 13, 1991, can be effective as early as March 8, 1990. (See "Federal Register" 56 FR 15006 dated April 12, 1991.)

Follow-up Care

Follow-up care or retransplantation required as a result of a covered liver transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hospital after receiving noncovered liver transplant. Coverage for follow-up care is for items and services that are reasonable and necessary as determined by Medicare guidelines.

National Coverage Determination (NCD) for Adult Liver Transplantation (260.1)

<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=70&ncdver=2&bc=AgAAgAAAAAA&>

Prior Authorization Information

Pre-service approval is required for all inpatient services for all products.

See below for situations where prior authorization may be required or may not be required for outpatient services.

Yes indicates that prior authorization is required.

No indicates that prior authorization is not required.

Outpatient

Commercial Managed Care (HMO and POS)	NA
Commercial PPO and Indemnity	NA
Medicare HMO BlueSM	NA
Medicare PPO BlueSM	NA

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

CPT codes:	Code Description
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

ICD-9 Procedure Codes

ICD-9-CM procedure codes:	Code Description
00.91	Transplant from live related donor (used with code for transplant procedure)
00.92	Transplant from live non-related donor (used with code for transplant procedure)
00.93	Transplant from cadaver (used with code for transplant procedure)
50.22	Partial hepatectomy
50.4	Total hepatectomy
50.51	Auxiliary liver transplant
50.59	Other transplant of liver

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
0FB03ZZ	Excision of Liver, Percutaneous Approach
0FB00ZZ	Excision of Liver, Open Approach
0FB04ZZ	Excision of Liver, Percutaneous Endoscopic Approach
0FB10ZZ	Excision of Right Lobe Liver, Open Approach
0FB13ZZ	Excision of Right Lobe Liver, Percutaneous Approach
0FB14ZZ	Excision of Right Lobe Liver, Percutaneous Endoscopic Approach
0FB20ZZ	Excision of Left Lobe Liver, Open Approach
0FB23ZZ	Excision of Left Lobe Liver, Percutaneous Approach
0FB24ZZ	Excision of Left Lobe Liver, Percutaneous Endoscopic Approach
0FT00ZZ	Resection of Liver, Open Approach
0FY00Z0	Transplantation of Liver, Allogeneic, Open Approach
0FY00Z1	Transplantation of Liver, Syngeneic, Open Approach

Description

Liver transplantation is currently performed routinely as a treatment of last resort for patients with end-stage liver disease. Liver transplantation may be performed with liver donation after brain or cardiac death or with a liver segment donation from a living donor. Patients are prioritized for transplant by mortality risk and severity of illness criteria developed by the Organ Procurement and Transplantation Network (OPTN) and the United Network of Organ Sharing (UNOS). The severity of illness is determined by the model for end-stage liver disease (MELD) and pediatric end-stage liver disease (PELD) scores.

Background

Recipients

Liver transplantation is now routinely performed as a treatment of last resort for patients with end-stage liver disease. Liver transplantation may be performed with liver donation after brain or cardiac death or with a liver segment donation from a living donor. Patients are prioritized for transplant by mortality risk

and severity of illness criteria developed by the Organ Procurement and Transplantation Network (OPTN) and the United Network of Organ Sharing (UNOS). The original liver allocation system was based on assignment to Status 1, 2A, 2B, or 3. Status 2A, 2B, and 3 were based on the Child-Turcotte-Pugh score, which included a subjective assessment of symptoms as part of the scoring system. In February 2002, Status 2A, 2B, and 3 were replaced with 2 disease severity scales: the model for end-stage liver disease (MELD) and pediatric end-stage liver disease (PELD) for patients younger than age 12 years scoring systems. In June 2013, OPTN/UNOS published its most recent allocation system, which previously expanded Status 1 to Status 1A and 1B in September 2012.(1) Status 1A patients have acute liver failure with a life expectancy of less than 7 days without a liver transplant. Status 1A patients also include primary graft nonfunction, hepatic artery thrombosis and acute Wilson's disease. Status 1A patients must be recertified as Status 1A every 7 days. Status 1B patients are pediatric patients (age range, 0-17 years) with chronic liver disease listed as: fulminant liver failure, primary nonfunction, hepatic artery thrombosis, acute decompensated Wilson's disease, chronic liver disease; and nonmetastatic hepatoblastoma. Pediatric patients move to Status 1A upon age 18 but still qualify for pediatric indications.

Following Status 1, donor livers will be prioritized to those with the highest scores on MELD or PELD. With this allocation system, the highest priority for liver transplantation is given to patients receiving the highest number of points. The scoring system for MELD and PELD is 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 patients waiting on the transplant list. The MELD score incorporates bilirubin, prothrombin time (ie, international normalized ratio [INR]), and creatinine into an equation, producing a number that ranges from 6 to 40. The PELD score incorporates albumin, bilirubin, INR, growth failure, and age at listing. Waiting time will only be used to break ties among patients 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 because some patients were listed early in the course of their disease, while others were listed only when they became sicker. In the revised allocation systems, patients with a higher mortality risk and higher MELD/PELD scores will always be considered before those with lower scores, even if some patients with lower scores have waited longer.(2) Status 7 describes patients who are temporarily inactive on the transplant waiting list due to being temporarily unsuitable for transplantation. Pediatric patients who turn 18 are Status

Donors

Due to the scarcity of donor livers, a variety of strategies have been developed to expand the donor pool. For example, split graft refers to dividing a donor liver into 2 segments that can be used for 2 recipients. Living donor liver transplantation (LDLT) is now commonly performed for adults and children from a related or unrelated donor. Depending on the graft size needed for the recipient, either the right lobe, left lobe or the left lateral segment can be used for LDLT. In addition to addressing the problem of donor organ scarcity, LDLT allows the procedure to be scheduled electively before the recipient's condition deteriorates or serious complications develop. LDLT also shortens the preservation time for the donor liver and decreases disease transmission from donor to recipient.

Summary

Liver transplant is an accepted treatment of end-stage liver disease that provides a survival benefit in appropriately selected patients and thus, may be considered medically necessary for the above indications listed in the Policy Statement and in those otherwise meeting United Network of Organ Sharing (UNOS) criteria. Liver transplantation is investigational in patients in whom the procedure is expected to be futile due to comorbid disease or in whom posttransplantation care is expected to significantly worsen comorbid conditions. Case series and case-control data indicate that human immunodeficiency virus (HIV)-infection is not an absolute contraindication to liver transplant; for patients who meet selection criteria, these studies have demonstrated patient and graft survival rates are similar to those in the general population of kidney transplant recipients.

Recent literature continues to address expanded criteria for transplantation for HCC, predictors of recurrence, the role of neoadjuvant therapy in patients with hepatocellular carcinoma (HCC), expanded

donor criteria, transplantation and retransplantation for hepatitis C, and living donor transplantation. Further study is needed before liver transplant selection criteria can be expanded for HCC. Additionally, further study is needed to address salvage liver transplantation for HCC recurrence after primary liver resection.

Liver transplantation for hilar cholangiocarcinoma is performed at some transplant centers, and long-term survival has been reported in select patients with unresectable disease. For metastatic NET, cure of disease is not achieved, and 5-year survival is generally not high. However, there have been reports of survival benefit in patients receiving liver transplantation for unresectable neuroendocrine tumor metastasis confined to the liver. Based on survival data and clinical vetting input, transplantation in patients with hilar cholangiocarcinoma who meet strict eligibility criteria may be considered medically necessary; transplantation for NET metastatic to the liver is considered investigational.

The literature on liver transplantation for pediatric hepatoblastoma is limited, but case series have demonstrated good outcomes and high rates of long-term survival. Additionally, nonmetastatic pediatric hepatoblastoma is included in UNOS criteria for patients eligible for liver transplantation. Therefore, liver transplantation for nonmetastatic pediatric hepatoblastoma may be considered medically necessary.

Case series have demonstrated favorable outcomes with liver retransplantation in certain populations, such as when criteria for an original liver transplantation are met for retransplantation. While some evidence suggests outcomes after retransplantation may be less favorable than for initial transplantation in some patients, long-term survival benefits have been demonstrated. There was support from clinical vetting for retransplantation following primary graft nonfunction, hepatic artery thrombosis, ischemic biliary injury after donation after cardiac death, chronic rejection or certain recurrent nonneoplastic diseases resulting in end-stage liver failure in a primary transplant. As a result, retransplantation after initial failed liver transplant may be considered medically necessary in these situations.

Policy History

Date	Action
10/2014	Medical policy remediation: New indications for non-coverage. Coding information clarified. Effective 10/1/2014.
6/2014	BCBSA National medical policy review. New medically necessary and investigational indications described. Effective 6/1/2014.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, Effective 10/2015.
12/2013	Removed ICD-9 diagnosis codes as the policy requires prior authorization
7/2013	BCBSA National medical policy review. New medically and investigational indications described. Effective 7/1/2013.
11/2012	CMS NCD medical policy review. Changes to policy statements. Effective 6/21/2012.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
11/2010	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
11/2009	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
2/2009	BCBSA National medical policy review. No changes to policy statements.
11/2008	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
11/2007	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
8/2007	BCBSA National medical policy review. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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