MASSACHUSETTS

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Medical Policy

Liver Transplant and Combined Liver-Kidney Transplant

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Policy Number: 198

BCBSA Reference Number: 7.03.06
NCD/LCD: National Coverage Determination (NCD) for Adult Liver Transplantation (260.1)

Related Policies

None

Policy

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

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

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

A. 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
- Protoporhyria
- Wilson's disease

B. Cholestatic liver diseases
- Primary biliary cirrhosis
- Primary sclerosing cholangitis with development of secondary biliary cirrhosis
- Biliary atresia

C. Vascular disease
- Budd-Chiari Syndrome

D. Primary hepatocellular carcinoma

E. Inborn errors of metabolism

F. Trauma and toxic reactions

G. Miscellaneous

- Familial amyloid polyneuropathy
- Amyloidosis[1]
- Cryptogenic cirrhosis[1]
- End-stage liver disease in children[1]
- Familial cholestasis[1]
- Intrahepatic bile duct paucity (Alagill's syndrome).[1]

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

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

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

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

Combined liver-kidney transplantation may be considered **MEDICALLY NECESSARY** in patients who qualify for liver transplantation and have advanced irreversible kidney disease.

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

- Patients with intrahepatic cholangiocarcinoma
- Patients with neuroendocrine tumors metastatic to the liver.

Liver transplantation is considered **NOT MEDICALLY NECESSARY** in the following patients:

- Patients with hepatocellular carcinoma that has extended beyond the liver
- Patients with ongoing alcohol and/or drug abuse. (Evidence for abstinence may vary among liver transplant programs, but generally a minimum of 3 months is required.)

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

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

- Known current malignancy, including metastatic cancer
- 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 (e.g. weekly meetings such as Alcoholics Anonymous, partial or full day programs or inpatient programs).

Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Medical necessity criteria and coding guidance can be found through the link below.

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

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.
N/A indicates that this service is primarily performed in an inpatient setting.

	Outpatient
Commercial Managed Care (HMO and POS)	N/A
Commercial PPO and Indemnity	N/A
Medicare HMO Blue[SM]	N/A
Medicare PPO Blue[SM]	N/A

CPT Codes / HCPCS Codes / ICD Codes

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.

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

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	**Code Description**
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age

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

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 Organ Procurement and Transplantation Network and United Network of Organ Sharing. 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 2002, status 2A, 2B, and 3 were replaced with 2 disease severity scales: Model for End-stage Liver Disease (MELD) and Pediatric End-stage Liver Disease (PELD) for patients younger than age 12 years. In 2013, the Organ Procurement and Transplantation Network and United Network of Organ Sharing published its most recent allocation system, which previously expanded status 1 to status 1A and 1B in September 2012. 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 disease. Status 1A patients must be recertified every 7 days. Status 1B patients are pediatric patients (age range, 0-17 years) with chronic liver disease, which may include the following: fulminant liver failure, primary nonfunction, hepatic artery thrombosis, acute decompensated Wilson disease, chronic liver disease; and nonmetastatic hepatoblastoma. Pediatric patients move to status 1A at 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), 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 and PELD scores will always be considered before those with lower scores, even if some patients with lower scores have waited longer.[1] 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 X.

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.

Management
Management of acute rejection of liver transplant using either intravenous immunoglobulin or plasmapheresis is discussed separately policy #466 and policy #310. Also, the role of chemoembolization or radiofrequency ablation as a bridge to transplant in patients with hepatocellular cancer is addressed separately in policy #634 and policy #292.

Summary

For individuals who have hepatocellular disease who receive liver transplant, the evidence includes case series, registry studies, and systematic reviews. Relevant outcomes include overall survival (OS), morbid events, and treatment-related morbidity and mortality. Studies on liver transplantation for viral hepatitis have found that survival is lower than for other liver diseases. Although these statistics raise questions about the most appropriate use of a scarce resource (donor livers), the long-term survival rates are significant in a group of patients who have no other treatment options. Also, survival can be improved by eradication of hepatitis virus before transplantation. For patients with nonalcoholic steatohepatitis, OS rates have been shown to be similar to other indications for liver transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary hepatocellular carcinoma who receive liver transplant, the evidence includes systematic reviews of observational studies. Relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. In the past, long-term outcomes in patients with primary hepatocellular malignancies had been poor (19%) compared with the OS of liver transplant recipients. However, recent use of standardized patient selection criteria (eg, the Milan criteria diameter) has dramatically improved OS rates. In appropriately selected patients, liver transplant has been shown to result in higher survival rates than resection. In patients who present with unresectable organ-confined disease, transplant represents the only curative approach. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have extrahepatic cholangiocarcinoma who receive liver transplant, the evidence includes a systematic review of observational studies. Relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. For patients with extrahepatic (hilar or perihilar) cholangiocarcinoma who are treated with adjuvant chemotherapy, survival rates have been reported as high as 76%. Society guidelines also recommend liver transplant in select patients with unresectable extrahepatic cholangiocarcinoma. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have intrahepatic cholangiocarcinoma who receive liver transplant, the evidence includes registry studies. Relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. Five-year survival rates after liver transplantation in patients with cholangiocarcinoma are less than 30%. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have metastatic neuroendocrine tumors who receive liver transplant, the evidence includes systematic reviews of case series. Relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. In select patients with nonresectable, hormonally active liver metastases refractory to medical therapy, liver transplantation has been considered as an option to extend survival and minimize endocrine symptoms. While there may be centers that perform liver transplants on select patients with neuroendocrine tumors, the available studies are limited by their heterogeneous populations. Further studies are needed to determine appropriate selection criteria. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pediatric hepatoblastoma who receive liver transplant, the evidence includes case series. Relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. 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 United Network for Organ Sharing criteria for patients eligible for liver transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a failed liver transplant who receive liver retransplant, the evidence includes observational studies. Relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. 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 has suggested outcomes after retransplantation may be less favorable than for initial transplantation in some patients, long-term survival benefits have been demonstrated. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with indications for liver and kidney transplant who receive combined liver-kidney transplant, the evidence includes registry studies. Relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. Most of the evidence involves adults with cirrhosis and kidney failure. Indications for combined liver-kidney transplant in children are rare and often congenital, and include liver-based metabolic abnormalities affecting the kidney, along with structural diseases affecting both the liver and kidney. In both adults and children, comparisons with either liver or kidney transplantation alone would suggest that combined liver-kidney transplant is no worse, and possibly better, for graft and patient survival. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Liver transplant is an accepted treatment of end-stage liver disease that provides a survival benefit in appropriately selected patients and may be considered medically necessary for the indications listed in the Policy Statement and in patients otherwise meeting United Network of Organ Sharing 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 worsen comorbid conditions significantly. 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 neuroendocrine tumors metastatic to the liver is considered investigational. Clinical vetting supported retransplantation following primary graft nonfunction, hepatic artery thrombosis, ischemic biliary injury after donation after cardiac death, chronic rejection, or certain recurrent non-neoplastic 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
10/2018	BCBSA National medical policy review. No changes to policy statements. New references added. Summary clarified.
2/2018	BCBSA National medical policy review. Combined liver-kidney transplantation considered medically necessary. Clarified coding information. Policy title changed to Liver Transplant and Combined Liver-Kidney Transplant. Effective 2/1/2018.
4/2016	Policy statement on psychosocial conditions or chemical dependency affecting ability to adhere to therapy clarified. 4/1/2016
1/2016	Medical policy criteria clarified. Clarified coding information. 1/1/2016
11/2015	Added coding language.
3/2015	New references added from BCBSA National medical policy.
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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Endnotes

[1] Based on expert opinion, NEMCI