Healthy Blue

Medical Policy

Subject:	Liver Transplantation		
Document #:	TRANS.00008	**Publish Date:**	12/16/2020
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Description/Scope

This document addresses liver transplantation for individuals with end-stage liver disease. Donor livers are obtained from deceased donors, in which a whole or partial (split) liver may be transplanted. Living donors are another possible source from adult to child or adult to adult.

Note: Please see the following for additional information:

- CG-TRANS-02 Kidney Transplantation
- TRANS.00013 Small Bowel, Small Bowel/Liver and Multivisceral Transplantation

Position Statement

Note: Members must meet the disease specific criteria as well as the general Individual Selection Criteria below for the transplantation to be considered medically necessary.

Medically Necessary:

A whole or partial liver transplant using a deceased or living donor is considered **medically necessary** for selected individuals with end-stage organ failure due to irreversible liver damage that includes, but is not limited to, the following conditions:

A. Cholestatic liver diseases:
   1. Primary biliary cirrhosis
   2. Primary sclerosing cholangitis
   3. Biliary atresia
   4. Caroli's disease
   5. Familial cholestasis
   6. Arteriohepatic dysplasia (Alagaille's disease)
   7. Cystic Fibrosis

B. Hepatocellular injury:
   1. Viral-induced Hepatitis
   2. Drug induced
      a. Acetaminophen
      b. Associated with halothane, gold, disulfram, others

3. Alcohol induced
4. Toxin exposure: Amanita mushroom poisoning
5. Autoimmune hepatitis

C. Inborn errors of metabolism:
1. Wilson's disease
2. Organic acidurias
3. Hemochromatosis
4. Alpha-1 antitrypsin deficiency
5. Homozygous type II hyperlipoproteinemia
6. Crigler-Najjar Syndrome type I
7. Protoporphyria
8. Some urea cycle deficiencies
9. Glycogen storage diseases types I and IV
10. Tyrosine deficiency
11. Citrullinemia
12. Ornithine transcarboxylase deficiency
13. Familial amyloid polyneuropathy (requires transplantation - polyneuropathy and cardiac amyloidosis development due to the production of a variant transthyretin molecule by the liver)
14. Oxalosis (primary)

D. Acute Diseases:
1. Fulminant hepatic failure

E. Mass Occupying Lesions:
1. Polycystic disease of the liver (requiring transplantation due to the anatomic complications of a hugely enlarged liver)
2. Hepatoblastoma confined to the liver
3. Primary hepatocellular carcinoma confined to the liver
4. Hemangioendothelioma
5. Hilar cholangiocarcinoma (CCA) with a cross-sectional diameter 3 cm or less in conjunction with neoadjuvant chemoradiation therapy and the tumor is unresectable or there is underlying liver disease such that the individual is not a candidate for resection

F. Vascular disease:
1. Budd-Chiari Syndrome

G. Other:
1. Cryptogenic cirrhosis

Liver Retransplantation

Retransplantation in individuals with graft failure of an initial liver transplant, due to either technical reasons or hyperacute rejection is considered **medically necessary.**

Retransplantation in individuals due to either chronic rejection or recurrent disease is considered **medically necessary** when the individual meets general selection criteria as defined below.

Investigational and Not Medically Necessary:

Liver transplants in individuals with extrahepatic malignancy, including, but not limited to, non-hilar extrahepatic cholangiocarcinoma, intrahepatic cholangiocarcinoma or hepatocellular carcinoma when either condition extends beyond the liver, are considered **investigational and not medically necessary.**

Liver transplants for all other conditions that do not lead to end-stage organ failure due to irreversible liver damage are considered **investigational and not medically necessary.**

Xenotransplantation is considered **investigational and not medically necessary.**

Bioartificial liver devices are considered **investigational and not medically necessary.**

Note: For multi-organ transplant requests, criteria must be met for each organ requested. In those situations, a member may present with concurrent medical conditions which would be considered an exclusion or a comorbidity that would preclude a successful outcome, but would be treated with the additional organ transplant. Such cases will be reviewed on an individual basis for coverage determination to assess the member's candidacy for transplantation.

General Individual Selection Criteria

In addition to having end stage liver disease, the member must not have a contraindication as defined by the American Society of Transplantation in Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation (2001) listed below.

Absolute Contraindications- for Transplant *Recipients* include, but are not limited to, the following:

A. Metastatic cancer
B. Ongoing or recurring infections that are not effectively treated
C. Serious cardiac or other ongoing insufficiencies that create an inability to tolerate transplant surgery
D. Serious conditions that are unlikely to be improved by transplantation as life expectancy can be finitely measured
E. Demonstrated patient noncompliance, which places the organ at risk by not adhering to medical recommendations
F. Potential complications from immunosuppressive medications are unacceptable to the patient
G. Acquired immune deficiency syndrome (AIDS) (diagnosis based on Centers for Disease Control and Prevention [CDC] definition of CD4 count, 200 cells/mm^3) unless the following are noted:
    1. CD4 count greater than 200 cells/mm^3 for greater than 6 months

2. HIV-1 RNA undetectable
3. On stable anti-retroviral therapy greater than 3 months
4. No other complications from AIDS (for example, opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi's sarcoma or other neoplasm)
5. Meeting all other criteria for liver transplantation*

*Steinman, Theodore, et al. Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation. Transplantation. Vol. 71, 1189-1204, No. 9, May 15, 2001.

Rationale

Transplantation for progressive liver disease that will ultimately lead to a fatal outcome, or end-stage liver disease, is currently accepted as a practical and established medical therapy. Technical and pharmaceutical advances have made liver transplantation available to individuals who might not have previously qualified, such as those diagnosed with hepatitis or hepatocellular carcinoma (HCC), also known as malignant hepatoma. The question is no longer whether to perform this complex surgery but how to identify the best candidates. The careful selection of candidates utilizing specific selection criteria has steadily improved the survival rates for those that have undergone liver transplantation. Multiple clinical trials have been conducted on various aspects of liver transplantation including, but not limited to surgical technique, immunosuppressive therapy, diagnosis, and the United Network for Organ Sharing (UNOS) status at the time of transplant. Currently to date in 2020 there are 12,371 candidates listed for liver transplantation in the United States, with 5888 (5571 deceased donor and 317 living donor) transplants performed to date this year and a total of 8896 in 2019. The best available evidence, collected from retrospective registry data on liver transplantation in the U.S., is based on UNOS data collected from 2008-2015 which reports 1-year, 3-year and 5-year survival data (89.1%, 80.0%, 71.9%). Liver transplant using a deceased or living donor is considered medically necessary for selected individuals with end-stage organ failure due to irreversible liver damage.

In 2013, the American Association for the Study of Liver Diseases (AASLD) and the American Society of Transplantation (AST) issued joint guidelines on evaluation of adults for liver transplantation. The guidelines recommend liver transplantation for severe acute or advanced chronic liver disease after all effective medical treatments have been attempted. The formal evaluation should confirm the irreversible nature of the liver disease and lack of effective alternative medical therapy (AASLD, 2014).

The guidelines also stated that liver transplant is indicated for the following conditions:

- Acute liver failure complications of cirrhosis
- Liver-based metabolic condition with systemic manifestations
  - α1-Antitrypsin deficiency
  - Familial amyloidosis
  - Glycogen storage disease

  - Hemochromatosis
  - Primary oxaluria
  - Wilson disease
- Systemic complications of chronic liver disease.

The guidelines also included 1A recommendations (strong recommendation with high-quality evidence) for a liver transplant (LT) that:

- Patients with HIV infection are candidates for LT if immune function is adequate and the virus is expected to be undetectable by the time of LT.
- LT candidates with HCV [hepatitis C virus] have the same indications for LT as for other etiologies of cirrhosis.

Contraindications to liver transplant include:

MELD [Model for End-stage Liver Disease] score < 15
Severe cardiac or pulmonary disease
AIDS
Ongoing alcohol or illicit substance abuse
Hepatocellular carcinoma with metastatic spread
Uncontrolled sepsis
Anatomic abnormality that precludes liver transplantation
Intrahepatic cholangiocarcinoma
Extrahepatic malignancy
Fulminant hepatic failure
Hemangiosarcoma
Persistent noncompliance
Lack of adequate social support system

The 2019 American Association for the Study of Liver Diseases guideline on alcohol-associated liver disease provides recommendations on the timing of referral and selection of candidates for liver transplant. The guidance notes that the individual's history of alcohol addiction is a primary driver in selecting appropriate candidates for liver transplantation. Decompensated alcohol-associated cirrhosis (AAC), Child-Pugh-Turcotte class C cirrhosis, or a MELD-Na score ≥ 21 are clinical characteristics that should trigger an evaluation and consideration for liver transplantation. Additionally, the authors suggest that candidate selection "should not be based solely on a fixed interval of abstinence" and instead a formal psychological evaluation can help stratify individuals into higher- or lesser-risk strata for relapse.

The National Comprehensive Cancer Network (NCCN®) Clinical Practice Guidelines (CPG) (V5.2020) in Oncology™ for hepatobiliary cancers provides recommendations for liver transplantation. The NCCN panel

provides a 2A recommendation for individuals meeting the "UNOS criteria ([single lesion ≥ 2 cm and ≤ 5cm, or 2 or 3 lesions ≥ 1 cm and ≤ 3cm] should be considered for transplantation [cadaveric or living donation])." There is retrospective evidence showing selected individuals with hilar CCA receiving preoperative chemoradiation therapy followed by liver transplantation to have significantly improved overall survival compared with individuals undergoing resection.

> Liver transplantation should be considered only for highly selected patients (i.e. Tumor ≤ 3 cm in radial diameter, no intrahepatic or extrahepatic metastases, no nodal disease) with either unresectable disease with otherwise normal biliary and hepatic function or underlying chronic liver disease precluding surgery.

The 2020 UNOS liver allocation policy includes criteria for MELD (Model for End-stage Liver Disease) exception for liver transplantation candidates with hilar CCA. Criteria includes exception for candidates who have received neoadjuvant therapy prior to transplantation and present with cross-sectional imaging study demonstrating a mass measuring 3 cm or less.

In the recent NCCN CPG (V2.2020) in Oncology for neuroendocrine and adrenal tumors the NCCN panel considers liver transplantation investigational for liver metastases of neuroendocrine tumors of the gastrointestinal tract. The panel acknowledges the considerable associated risk with liver transplantation, which is deemed to not be part of routine care at this time. The panel's recommendation is based on several series that reported results of liver transplantation in individuals with carcinoid tumors whose metastases were confined to the liver, as well as "a meta-analysis showed that, while 5-year survival rates are encouraging, the majority of patients undergoing liver transplantation ultimately develop recurrence."

Although the potential benefits are considerable, the use of xenotransplantation raises concerns regarding the potential infection of recipients with both recognized and unrecognized infectious agents and the possible subsequent transmission to their close contacts and into the general human population. A particular public health concern is the potential for cross-species infection by retroviruses, which may be latent and lead to disease years after infection. Moreover, new infectious agents may not be readily identifiable with current techniques. At the present time xenotransplantation is considered investigational and not medically necessary.

A bioartificial liver device is a device that uses living liver cells housed in extracorporeal (outside the body) cartridges to provide temporary liver function. For some medical conditions, the device would be used to keep individuals alive and healthier until a transplantable liver becomes available. At this time there is limited scientific evidence available to support the safety and efficacy of this device and therefore bioartificial liver devices are considered investigational and not medically necessary.

Background/Overview

A liver transplant consists of replacing an end-stage diseased liver with a healthy one. The liver is obtained from either a deceased or a living donor (a living donor gives only a segment of his/her liver to the recipient). In an orthotopic liver transplantation, the donor liver is placed in its correct anatomic location. A heterotopic liver transplantation refers to placement of the donor liver in a different location, typically with the native liver remaining in situ. The overwhelming majority of liver transplantations are orthotopic.

Split liver transplantation refers to dividing a donor liver into two grafts that can be used for two recipients. Generally, a pediatric recipient receives the left lobe and an adult recipient receives the right lobe.

Living-related donor transplantation of the left lateral segment primarily benefits children and is usually performed between parent and child. Adult-to-adult living donor transplantation uses the right lobe of the liver from a related or unrelated donor. Living donation allows the procedure to be scheduled electively, shortens the preservation time for the donor liver and allows time to optimize the recipient's condition pre-transplant.

The limiting factor for liver transplantation is the short supply of donor organs. At the time of this writing, the procurement and distribution of organs for transplantation in the United States is under the direction of the United Network for Organ Sharing (UNOS). In 1990, UNOS established an organ allocation system based on the principles of medical urgency and local priority. In 2002, UNOS replaced the original liver allocation system with a new scoring system based on objective laboratory data, referred to as MELD/PELD (Pediatric End-stage Liver Disease). MELD is a numerical scale, ranging from 6 (less ill) to 40 (gravely ill) that is used for adults, giving each individual a score (number) based on how urgently they need a liver transplantation in the next 3 months. The number is calculated by a formula using bilirubin, prothrombin time, and creatinine. PELD takes into account a child's bilirubin, prothrombin time, albumin, growth failure, and whether the child is less than 1 year old. In 2020 UNOS updated the transplant MELD or PELD exception extension policy; candidates can also receive additional points to increase their MELD/PELD score for conditions such as primary HCC, when tumors meet the modified Tumor-Node-Metastasis (TNM) staging classification. UNOS maintains a national database of transplant candidates, donors, recipients, donor-recipient matching and histocompatibility (UNOS, 2020).

Xenotransplantation is any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal source, or (b) human body fluids, cells, tissues or organs that have had ex-vivo contact with live nonhuman animal cells, tissues or organs. The development of xenotransplantation is, in part, driven by the fact that the demand for human organs for clinical transplantation far exceeds the supply.

Definitions

Cadaver: The physical remains of a deceased person.

End-stage: Being or occurring in the final stages of a terminal disease or condition.

Extrahepatic disease: Cancer that is located outside of the liver.

Fulminant liver failure: The onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease.

Hepatoblastoma: A rare cancerous liver tumor occurring in infants and children that is composed of tissue resembling fetal or mature liver cells.

Heterotopic: Grafted or transplanted into an abnormal position.

In situ: In the natural or original position.

MELD: Model for End-Stage Liver Disease.

Orthotopic: Relating to the grafting of tissue in a natural position.

PELD: Pediatric end-stage liver disease.

Primary hepatocellular cancer: A cancer that originates within liver cells, as opposed to having spread to the liver from other organs.

Xenotransplantation: The surgical removal of an organ or tissue from an animal species and transplanting it into a human.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
00796	Anesthesia for intraperitoneal procedures in upper abdomen including laparoscopy; liver transplant (recipient)
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, IV)
47142	Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII)
47143	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split
47144	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into 2 partial liver grafts (ie, left lateral segment [segments II and III] and right trisegment [segments I and IV through VIII])
47145	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into 2 partial liver grafts (ie, left lobe [segments II, III, and IV] and right lobe [segments I and V through VIII])
47146	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each
47147	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each

ICD-10 Procedure

0FT00ZZ	Resection of liver, open approach
0FT04ZZ	Resection of liver, percutaneous endoscopic approach
0FY00Z0	Transplantation of liver, allogeneic, open approach
0FY00Z1	Transplantation of liver, syngeneic, open approach

ICD-10 Diagnosis

All diagnoses

When services are Investigational and Not Medically Necessary:
For the procedure codes listed above when criteria are not met; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

When services are also Investigational and Not Medically Necessary:

ICD-10 Procedure

0FY00Z2	Transplantation of liver, zooplastic, open approach

5A1C00Z	Performance of biliary filtration, single
5A1C60Z	Performance of biliary filtration, multiple

ICD-10 Diagnosis

All diagnoses

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Sybiol® Synthetic Bio-Liver Device
Transplant, Liver
Xenotransplantation

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, Background, References and Websites sections.
Reviewed	11/07/2019	MPTAC review. Updated Rationale, Background, References and Websites sections.
Reviewed	01/24/2019	MPTAC review. Updated Rationale, References and Websites sections.
Reviewed	03/22/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale, Background, References and Websites sections.
Reviewed	05/04/2017	MPTAC review. Updated formatting in position statement section. Updated References and Websites sections.
Revised	05/05/2016	MPTAC review. Defined abbreviation in absolute contraindication section and corrected grammatically error in position statement. Updated Rationale, References and Websites sections.
	01/01/2016	Updated Coding section with 01/01/2016 CPT changes, removed 47136 deleted 12/31/2015; also removed ICD-9 codes.
Reviewed	05/07/2015	MPTAC review. Updated Description, Rationale, References and Websites.
Reviewed	05/15/2014	MPTAC review. Updated References and Websites.
Revised	05/09/2013	MPTAC review.
Revised	05/08/2013	Hematology/Oncology Subcommittee. Added medically necessary clinical indication for mass occupying lesion: hilar cholangiocarcinoma. Updated investigational and not medically necessary statement for extrahepatic malignancy to include non-hilar extrahepatic cholangiocarcinoma and intrahepatic cholangiocarcinoma. Updated Rationale, References and Websites.
Reviewed	11/08/2012	MPTAC review. Updated Background, References and Websites.
Reviewed	11/17/2011	MPTAC review. Updated References and Websites.
Revised	11/18/2010	MPTAC review. Updated medically necessary covered conditions for liver transplantation. Definitions, References and Websites updated.
Reviewed	11/19/2009	MPTAC review. Clarification of Investigational and Not Medically Necessary statement. Updated definitions and references.

Reviewed	11/20/2008	MPTAC review. Updated references.
Reviewed	11/29/2007	MPTAC review. Updated references. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary."
Reviewed	12/07/2006	MPTAC review. References updated. Coding updated; removed CPT 47134 deleted 12/31/03.
Revised	12/01/2005	MPTAC review. Addition of cryptogenic cirrhosis under the list of liver diseases leading to end organ liver failure. Clarification of investigational/not medically necessary statement.
	11/17/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	MPTAC review.
Revised	04/28/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-merger Organizations	**Last Review Date**	**Document Number**	**Title**
Anthem, Inc.	09/18/2004	TRANS.00008	Liver Transplant
WellPoint Health Networks, Inc.	12/02/2004	7.06.02	Liver Transplantation