BENEFIT COVERAGE POLICY

Title: BCP-75 Liver Transplantation

Effective Date: 10/01/2020

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following coverage policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Coverage determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

Health Plan covers liver transplantation for members with end-stage liver failure due to an irreversibly damaged liver and have a MELD score greater than 15 or member has received approval for transplant from UNOS Regional Review Board.

All transplant related services require prior approval for coverage of Covered Health Services provided at a Health plan designated transplant facility. Contact the Transplant Case Manager to verify if a provider is contracted as a designated transplant facility.

There is no benefit coverage for non-network transplant services (see section 5.0 for exceptions).

Refer to member's benefit coverage document for specific benefit description, guidelines, coverage, and exclusions.

Liver transplants can only be done in an inpatient setting.

2.0 Background:

A. Recipients:

1. Liver transplantation is now routinely performed as a treatment of last resort for patients with end-stage liver disease. Patients are prioritized for transplant by mortality risk and severity of illness criteria developed by OPTN and UNOS. The liver allocation system includes the Model for End-stage Liver Disease (MELD) and Pediatric End-stage Liver Disease (PELD) scales. OPTN and UNOS updated the allocation system:

    a. Status 1A patients:

        i. Have acute liver failure with a life expectancy of less than 7 days without a liver transplant.

        ii. Also includes primary graft non-function, hepatic artery thrombosis and acute Wilson's disease.

iii. Must be recertified as Status 1A every 7 days.

b. Status 1B patients are:

i. Pediatric patients (age range, 0-17 years) with chronic liver disease listed as: fulminant liver failure, primary non-function, hepatic artery thrombosis, acute decompensated Wilson disease, chronic liver disease; and non-metastatic hepatoblastoma. Pediatric patients move to status 1A at age18 but still qualify for pediatric indications.

2. Following Status 1, recipients are prioritized by MELD or PELD scores. The numerical score ranges from 6 (less ill) to 40 (gravely ill). MELD is calculated using three routine lab test results: bilirubin, INR (prothrombin time), and creatinine. PELD uses albumin, bilirubin, INR growth failure, and age at listing. A patient's score may go up or down over time depending on the status of his or her liver disease. Most candidates have their MELD score assessed a number of times while they are on the waiting list.

3. Waiting time is only used to break ties among patients with the same MELD or PELD score and blood type compatibility. Status 7 describes patients who are temporarily inactive on the transplant waiting list due to a temporary condition making them unsuitable for transplant. Pediatric patients who turn 18 are status X.

B. Donors:

1. 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 two segments that can be used for two recipients. Living donor liver transplantation (LDLT) of 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, living donation 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.

3.0 Clinical Determination Guidelines:

A. Liver transplantation is considered medically necessary and appropriate when all of the following are met:

1. One evaluation per transplant approval; AND

   Note: A second opinion consult only would be approved to determine candidacy at a PHP designated transplant facility if a second transplant evaluation is requested and the member has been previously turned down for transplant.

2. Documentation of compliance with medical management; AND

3. Member should have received prior authorization for pre-transplant services (evaluation, outpatient diagnostics and labs) at a PHP designated transplant facility linked to one of the transplant networks: *Interlink, LifeTrac* or *Cigna LifeSource*. If a member is not receiving services at a PHP designated facility, the member will be redirected to a designated facility; AND

4. Member has completed an evaluation and has been accepted by the transplant committee at a designated transplant facility. Documentation must include a summary letter from the transplant center indicating acceptance and outlining the preoperative tests and their results; AND

5. Social work evaluation indicating member does not have any unresolvable psychosocial problems which may interfere with compliance with transplant management; AND
6. Member meets transplant institution's protocol eligibility criteria regarding age; AND
7. Attending physician has determined there are no prohibitive risk factors or absolute contraindications for transplant recipients. All the following criteria must be met and none of the contraindications should be present:
    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 that places the organ at risk by not adhering to medical recommendations.
    f. Potential complications from immunosuppressive medications that are unacceptable to the patient.
    g. Acquired immune deficiency syndrome (AIDS), unless the following are noted:
        i. CD4 count greater than 200 cells/mm^3 for greater than six months; AND
        ii. HIV-1 RNA (viral load) undetectable; AND
        iii. On stable antiviral therapy, greater than three months; AND
        iv. No other complications from AIDS< such as opportunistic infection (e.g., aspergillus, tuberculosis, coccidiodomycosis, resistant fungal infections) or neoplasms (e.g., Kaposi's sarcoma, non-Hodgkin's lymphoma).
8. No uncontrolled and/or untreated psychiatric disorders that interfere with compliance to a strict treatment regimen; AND
9. Members with a history of using alcohol, tobacco and other substances of abuse must be abstinent for a minimum of three consecutive months before being considered an eligible transplant candidate. This is determined by random urine drugs screens with a negative result. Use of marijuana for medical purposes requires written approval from the referring specialist (gastroenterologist, cardiologist, nephrologist, etc.) and transplant eligibility is subject to the transplanting institution's criteria.

B. A liver transplant, using a cadaver or living donor, may be medically necessary for patients with irreversible, end-stage liver failure due to conditions that include, but are not limited to, the following:

1. Cholestatic liver diseases.
    a. Biliary atresia.
    b. Familial cholestasis.
    c. Primary biliary cirrhosis
    d. Primary sclerosing cholangitis with development of secondary biliary cirrhosis.
    e. Cystic fibrosis.
2. Hepatocellular injury.
    a. Alcoholic induced.
    b. Drug induced: acetaminophen, halothane, gold, disulfram.

c. Toxin exposure: Amanita mushroom poisoning.

d. Viral hepatitis (either A, B, C, or non-A, non-B)

e. Idiopathic autoimmune hepatitis.

f. Cryptogenic cirrhosis (non-alcoholic steatohepatitis/NASH).

3. Malignancies such as the following:

a. Hepatocellular carcinoma

b. Cholangiocarcinoma (CCA)

c. Liver metastases due to a neuroendocrine tumor (NET)

d. Hemangioendothelioma (HAE); see specific criteria at OPTN website, https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

4. Metabolic disorders and metabolic liver diseases with cirrhosis (not an all-inclusive list):

a. Alpha 1-antitrypsin deficiency.

b. Hemochromatosis.

c. Hyperoxaluria.

d. Inborn errors of metabolism.

e. Protoporphyria.

f. Tyrosine deficiency.

g. Wilson's disease.

5. Vascular disease.

a. Budd-Chiari syndrome (congenital hepatic vein thrombosis).

b. Veno-occlusive disease.

6. Miscellaneous

a. Polycystic disease of the liver.

b. Amyloidosis, familial amyloid polyneuropathy (FAP).

c. Disorders of branch chain amino acids (e.g., Maple syrup urine disease (MSUD), branched chain a-ketoacid dehydrogenase (BCKD).

d. Glycogen storage disease type IV.

e. Trauma.

7. Indications for liver re-transplantation due to failed previous liver transplantation, including non-function of the grafted organ caused by:

a. Hepatic artery thrombosis.

b. Portal vein thrombosis.

c. Chronic rejection.

d. Primary graft non-function.

e. Recurrent non-neoplastic disease (hepatitis C, primary biliary cirrhosis, primary sclerosing cholangitis, non-alcoholic steatohepatitis) causing late graft failure.

C. Per OPTN Policy 9, the following diagnoses qualify for a MELD/PELD exception. See https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf for specific scoring information and criteria.

1. Cholangiocarcinoma.
2. Cystic Fibrosis.
3. Familial Amyloid Polyneuropathy (FAP).
4. Hepatic Artery Thrombosis (HAT).
5. Hepatocellular Carcinoma (HCC).
6. Hepatopulmonary Syndrome (HPS).
7. Metabolic Disease (pediatric).
8. Portopulmonary Hypertension.
9. Primary Hyperoxaluria.

D. Procedures that are considered experimental, investigational, or unproven and are not covered:

1. Xenotransplantation of any organ (CPT 47399).
2. Molecular Adsorbent Recirculating System (MARS), normothermic machine perfusion of donor liver – no specific code assigned.

4.0 Coding:

Prior Approval Legend: Y = All lines of business; N = None required; 1 = HMO/POS; 2 = PPO; 3 = ASO group L0000264; 4 = ASO group L0001269 Non-Union & Union; 5 = ASO group L0001631; 6 = ASO group L0002011; 7 = ASO group L0001269 Union Only.

COVERED CODES			
Code	**Description**	**Prior Approval**	**Benefit Plan Reference**
47133	Donor hepatectomy (including cold preservation), from cadaver donor	Y	Benefits and Coverage; Transplantation Services
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age	Y	Benefits and Coverage; Transplantation Services
47140	Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)	Y	Benefits and Coverage; Transplantation Services
47141	Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III and IV)	Y	Benefits and Coverage; Transplantation Services
47142	Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII)	Y	Benefits and Coverage; Transplantation Services
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	Y	Benefits and Coverage; Transplantation Services

COVERED CODES			
Code	**Description**	**Prior Approval**	**Benefit Plan Reference**
	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 (i.e., left lateral segment (segments II and III) and right trisegment (segments I and IV through VIII))	Y	Benefits and Coverage; Transplantation Services
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 (i.e., left lobe (segments II, III, and IV) and right lobe (segments I and V-VIII))	Y	Benefits and Coverage; Transplantation Services
47146	Donor hepatectomy (including cold preservation), from cadaver donor	Y	Benefits and Coverage; Transplantation Services
47147	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each	Y	Benefits and Coverage; Transplantation Services
47399	Unlisted procedure, liver (when used to report a liver xenotransplantation)	Y	Experimental/ Investigational/Unproven

5.0 Unique Configuration/Prior Approval/Coverage Details:

Fully-insured SPD plans and self-funded group L0001631 plans have a Travel and Lodging Benefit included in the transplant benefit (see COCs/SPDs for details).

6.0 Terms & Definitions:

Allograft – Transplant of an organ or tissue from one individual to another. Also called allogeneic or homograft.

Amyloidosis – A rare but potentially fatal group of diseases that result from the abnormal deposition of a particular protein called amyloid in the body's organs. This condition most frequently affects the heart, liver, kidneys, spleen, nervous system and gastrointestinal tract.

Backbench work – Preparation of a cadaver donor organ prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare the organ and vasculature for implantation.

Biliary atresia – Biliary atresia is the congenital absence or closure of the ducts that drain bile from the liver. It is a progressive process that begins very soon after birth. Bile is trapped inside the liver and

rapidly causes damage and scarring to the liver cells. Further scarring of the liver tissue may result in cirrhosis.

Budd-Chiari Syndrome – A rare disorder caused by blood clots that completely or partially block the large veins that carry blood from the liver (hepatic veins).

Cirrhosis – A condition which causes irreversible scarring of the liver. As scar tissue replaces normal tissue, blood flow through the liver is affected. Excessive use of alcohol and chronic infection with the hepatitis C virus are the leading causes of cirrhosis.

Fulminant liver failure – Acute liver failure with the rapid development of acute liver injury with severe impairment of the synthetic function and hepatic encephalopathy in a patient without obvious, previous liver disease. Most commonly happens during acute viral hepatitis, but is also the result of mushroom poisoning and toxic reactions to some medicines, like an overdose of acetaminophen. This is a special category of candidates for liver transplant because of the speed of their disease and the immediate need of treatment.

Hepatitis – An inflammation of the liver than can be caused by viruses (A, B, C, D, E), chemicals, drugs, alcohol, inherited diseases or a patient's own immune system.

Heterotopic liver transplant – The recipient's liver is left in place, and the donor's liver is transplanted to an ectopic site. Although rare, this approach is used with acute liver failure or increased liver volumes, when it is expected that function of the native liver will recover.

Model for End-stage Liver Disease (MELD) – A numerical score, ranging from 6 (less ill) to 40 (gravely ill), that is used for transplant candidates age 12 and older. Each person is given a score based on how urgently he or she needs a liver transplant within the next 3 months. The number is calculated using three routine lab test results: bilirubin, INR (prothrombin time), and creatinine.

A liver transplantation is rarely necessary for persons with a MELD score of less than 10.

Organ Procurement and Transplantation Network (OPTN) – The Organ Procurement and Transplantation Network (OPTN) is a unique public-private partnership that links all professionals involved in the U.S. donation and transplantation system. The goals of the OPTN are to increase the number of and access to transplants, improve survival rates after transplantation, and to promote patient safety and efficient management of the system. Available at URL address http://optn.transplant.hrsa.gov/

Orthotopic liver transplant – Replacing the recipient's liver with the donor's liver. This is the most common type of liver transplant procedure.

Pediatric End-stage Liver Disease (PELD) **–** Similar to MELD but uses some different criteria to recognize the specific growth and development needs of children. PELD scores may also range from negative values to very high numbers. The PELD scoring system takes into account the patient's bilirubin, INR, albumin, growth failure, and whether the child is less than one year old. PELD is used for pediatric patients under the age of 12.

Reduced-size liver transplant – The replacement of a whole diseased liver with a portion of a healthy donor liver. Reduced-size liver transplants are most often performed on children.

Steatohepatitis – "Fatty liver", inflammation of the liver caused by alcohol abuse or non-alcoholic steatohepatitis (NASH) most commonly associated with obesity, diabetes, and/ or hyperlipidemia. This condition can progress to cirrhosis or liver failure.

Transvenous intra-hepatic portosystemic shunt (TIPS) – A procedure performed in the radiology department to insert a catheter into the liver via the jugular vein to treat complications of portal hypertension including variceal bleeding, gastropathy and ascites.

United Network of Organ Sharing (UNOS) – A nationwide organization that controls the allocation and registry of organs. Their policies are developed by peer review and compliance is voluntary. However, in order to be reimbursed by Medicare, a transplant facility must belong to UNOS. Therefore, all transplant centers belong to UNOS. Policy and wait time information are available at this site.

Available at URL address: www.unos.org

7.0 References, Citations & Resources:

1. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Adult Liver Transplantation (260.1) https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCAId=259&NcaName=Liver+Transplantation+for+Malignancies&ExpandComments=n&CommentPeriod=0&NCDId=70&id=186.
2. Organ Procurement Transplant Network (OPTN), Policy 9 Allocation of Livers and Liver-Intestines 05/23/2019. Available at URL address: https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.
3. UNOS Liver Allocation. Available at URL address https://www.unos.org/wp-content/uploads/unos/Liver_patient.pdf.

8.0 Associated Documents [For internal use only]:

Policies - MM-03 Benefit determinations; MM-25 Transition/Continuity of care; MM-55 Peer-to-Peer Conversations .

Standard Operating Procedure (SOP) –; SOP 001 Completing a HCN; MMS-03 Algorithm for Use of Criteria for Benefit Determinations; SOP 027 Case Management Referrals, SOP 028 Transplant Evaluation, SOP 029 Transplant Event, SOP 030 Post Transplant Process.

Sample Letter – TCS Approval Letter; Clinically Reviewed Exclusion Letter; Specific Exclusion Denial Letter.

Form – Request Form: Out of Network/ Prior Authorization; High Cost Notification Form; Transplant Travel and Lodging Reimbursement Form.

9.0 Revision History

Original Effective Date: 10/11/2006

Next Revision Date: 10/01/2021

Revision History	
Revision Date	Reason for Revision
December 2015	Annual review and revision; ICD-10 codes added, References and Resources updated.
December 2016	Annual review and revision: removed references to Medicaid/DHHS, removed Hepatitis A from B. 2. B., added Sec. D. 1-9.
November 2017	Annual review and revision: Converted from Medical Policy 013 to Benefit Coverage Policy format. Added criteria regarding use of marijuana and non-covered CPT code. Updated References and Resources.
12/13/17	Annual renewal approved by QI/MRM.
May 2018	Initial review by BCC. QI/MRM review 12/13/17. References updated.
8/8/18	Annual renewal approved by QI/MRM.
July 2019	Annual review; Added language regarding: evaluation criteria, Status 1A and 1B for recipients, living donors, updated Exception MELD/PELD scoring criteria and references.
8/14/19	Annual renewal approved by QI/MRM.
4/20	Annual review, approved by BCC 7/6/20.