BENEFIT COVERAGE POLICY

Title: BCP-75 Liver Transplantation

Effective Date: 07/01/2021



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:

The 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:

- 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:

See InterQual policy, Liver Transplantation for criteria.

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; 8 = ASO group L0002184.

COVERED CODES				
Code	Description	Prior Approval	Benefit Plan Cost Share Reference	
47133	Donor hepatectomy (including cold preservation), from cadaver donor	Y	Transplantation Services	
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age	Y	Transplantation Services	
47143	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including	N	Transplantation Services	

	COVERED CODES				
Code	Description	Prior Approval	Benefit Plan Cost Share Reference		
	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				
47146	Donor hepatectomy (including cold preservation), from cadaver donor	Y	Transplantation Services		

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:

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

<u>Amyloidosis</u> – 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.

<u>Backbench work</u> – 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.

<u>Biliary atresia</u> – 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.

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

<u>Cirrhosis</u> – 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.

<u>Fulminant liver failure</u> – 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.

<u>Hepatitis</u> – 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.

<u>Heterotopic liver transplant</u> – 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.

<u>Model for End-stage Liver Disease (MELD)</u> – 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/

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

<u>Pediatric End-stage Liver Disease (PELD)</u> – 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.

<u>Reduced-size liver transplant</u> – 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.

<u>Steatohepatitis</u> – "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.

<u>Transvenous intra-hepatic portosystemic shunt (TIPS)</u> – 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.

<u>United Network of Organ Sharing (UNOS)</u> – 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. InterQual- Liver Transplantation 4-16-21.
- 2. 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.
- 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.
- 4. 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]:

Benefit Coverage Policies - BCP-17 Retransplantation and Pediatric Transplantation; BCP-33 Pre-Transplant Services.

Policies and Procedures (P&Ps) - MMP-02 Transition/Continuity of care; MMP-06 Peer-to-Peer Conversations; MMP-09 Benefit determinations.

Standard Operating Procedures (SOPs) –MMS-03 Algorithm for Use of Criteria for Benefit Determinations; MMS-05 Completing a High Cost Notification Form; MMS-09 Case Management Referrals, MMS-10 Pre-Transplant Process, MMS-11 Transplant Event and Listing, MMS-12 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: 07/01/2022

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 noncovered 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.	
4/21	Annual Review, removed medical criteria, added reference to InterQual criteria, removed backbench and unlisted procedure codes. Updated associated documents. Aligned codes with InterQual criteria.	