

TITLE:	LIVER TRANSPLANT POLICY
POLICY #:	MM-PNP-030
VERSION #:	01
DEPARTMENT:	UTILIZATION REVIEW
ORIGINAL EFFECTIVE DATE:	12/01/2023
CURRENT REVISION DATE:	N/A

1. PURPOSE

To establish medical necessity criteria and requirements for Liver Transplantation..

2. SCOPE

For use by the Medical UM Department.

3. DEFINITIONS

N/A

4. RESPONSIBILITIES

N/A

5. POLICY

Provides guidelines regarding the medical necessity review of liver transplant requests.

Curative makes every attempt to ensure that people chosen for transplant evaluation are the most suitable for the surgery.

There are many requirements for liver transplant surgery. Before you can begin the liver transplant evaluation process, you must be free of:

- Cancer outside the liver
- Alcohol for at least 6 months
- Substance abuse
- Active infections
- Disabling psychiatric conditions
- Documented medical non-compliance
- Lack of adequate social support
- Lack of adequate insurance
- Other diseases or conditions
- You must also be willing and able to make lifestyle changes to support the gift of life that a liver transplant provides.

Medical Necessity

Curative considers liver transplantation medically necessary for the indications listed below in Section I.B. for *the following*:

- o Adolescents 12 years of age or older and adults with *either*:
 - o a Model of End-stage Liver Disease (MELD) score (see Appendix) greater than 10; *or*
 - o who are approved for transplant by the United Network for Organ Sharing (UNOS) Regional Review Board; *or*
 - o who meet the transplant institution's selection criteria; **and**
- o Children less than 12 years of age who meet the transplanting institution's selection criteria.

NOTE: In the absence of an institution's selection criteria, requests for liver transplantation are subject to medical necessity review for children, and for adolescents and adults with a MELD score of 10 or less who have not been approved by the UNOS Regional Review Board.

Medically Necessary Indications (not an all-inclusive list)

Curative considers orthotopic (normal anatomical position) liver transplantation (with cadaveric organ, reduced-size organ, living related organ, and split liver) medically necessary for members with end-stage liver disease (ESLD) due to *any* of the following conditions who meet medical necessity criteria.

- o **Cholestatic diseases**

- o Biliary atresia;
- o Familial cholestatic syndromes;
- o Primary biliary cirrhosis;
- o Primary sclerosing cholangitis with development of secondary biliary cirrhosis;

- o **Hepatocellular diseases**

- o Alcoholic cirrhosis;
- o Chronic active hepatitis with cirrhosis (hepatitis B or C);
- o Cryptogenic cirrhosis;
- o Idiopathic autoimmune hepatitis;
- o Post-necrotic cirrhosis due to hepatitis B surface antigen negative state;

- o **Malignancies**

- o Primary hepatocellular carcinoma confined to the liver when *all* of the following criteria are met:
 - Any lung metastases that have been shown to be responsive to chemotherapy; *and*
 - Member is not a candidate for subtotal liver resection; *and*
 - Member meets UNOS criteria for tumor size and number; *and*
 - There is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, abdominal organs, bone or other sites; *and*
 - There is no macrovascular involvement;

Note: These criteria are intended to be consistent with UNOS guidelines for selection of liver transplant candidates for hepato-cellular carcinoma (HCC).

o Hepatoblastomas in members less than 12 years of age when *all* of the following criteria are met:

- Member is not a candidate for subtotal liver resection; and
- Member meets UNOS criteria for tumor size and number; and
- There is no identifiable extrahepatic spread of tumor to surrounding lungs, abdominal organs, bone or other sites; Note: Spread of hepatoblastoma to veins and lymph nodes does not disqualify a member for coverage of a liver transplant;

o Epithelioid hemangioendotheliomas;

- Intrahepatic cholangiocarcinomas (i.e., cholangiocarcinomas confined to the liver);
- Large, unresectable fibrolamellar HCCs;
- Metastatic neuroendocrine tumors (carcinoid tumors, apudomas, gastrinomas, glucagonomas) in persons with severe symptoms and with metastases restricted to the liver, who are unresponsive to adjuvant therapy after aggressive surgical resection including excision of the primary lesion and reduction of hepatic metastases;

o Vascular diseases

- Budd-Chiari syndrome;
- Veno-occlusive disease;

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

- Alpha 1-antitrypsin deficiency;
- Hemochromatosis;
- Inborn errors of metabolism;
- Protoporphyrria;
- Wilson's disease;

o Miscellaneous

- Familial amyloid polyneuropathy;
- Polycystic disease of the liver;
- Porto-pulmonary hypertension (pulmonary hypertension associated with liver disease or portal hypertension) in persons with a mean pulmonary artery pressure by catheterization of less than 35 mm Hg;
- Toxic reactions (fulminant hepatic failure due to mushroom poisoning, acetaminophen (Tylenol) overdose, etc.);
- Trauma;

- Hepato-pulmonary syndrome when the following selection criteria are met:
- Arterial hypoxemia (PaO₂ less than 60 mm Hg or AaO₂ gradient greater than 20 mm Hg in supine or standing position); and
- Chronic liver disease with non-cirrhotic portal hypertension; and
- Intrapulmonary vascular dilatation (as indicated by contrast-enhanced echocardiography, technetium-99 macroaggregated albumin perfusion scan, or pulmonary angiography).

Retransplantation

Curative considers retransplantation following a failed liver transplant medically necessary if the initial transplant was performed for a covered indication.

Contraindications

Curative considers liver transplantation not medically necessary for members with *any* of the following absolute contraindications to liver transplantation:

- Active sepsis outside the biliary tract;
- Other effective medical treatments or surgical options are available;
- Presence of significant organ system failure other than kidney, liver or small bowel.

Experimental and Investigational

The following interventions are considered experimental and investigational because their safety and effectiveness has not been established:

- Basiliximab for induction immunosuppression in individuals undergoing liver transplantation (LT);
- Bioartificial liver transplantation;
- Biomarkers (acid labile nitroso-compounds (NO_x), serum amyloid A protein, procalcitonin, peripheral blood T-cell activation, interleukin 2 (IL-2) receptor, guanylate-binding protein-2 mRNA, graft-derived cell-free DNA, pi-glutathione S-transferase, alpha-glutathione S-transferase and serum HLA class I soluble antigens) for diagnosis of acute allograft rejection following liver transplantation;
- Ectopic or auxiliary liver transplantation;
- Everolimus to prevent organ rejection after liver transplantation;
- Factor V Leiden and F2 testing for member scheduled to receive partial liver transplant for primary sclerosing cholangitis;
- Hepatocellular (hepatocyte) transplantation;
- Hypothermic machine perfusion for reduction of the incidences of early allograft dysfunction and biliary complications after LT;
- Liver transplantation for malignancies other than those listed as covered above;
- Liver transplantation for the treatment of extra-hepatic hilar cholangiocarcinoma;
- Measurements of plasma and urinary neutrophil gelatinase-associated lipocalin (NGAL) for predicting acute kidney injury following orthotopic liver transplantation;
- Molecular Adsorbent Recirculating System (MARS) for the treatment of progressive familial intrahepatic cholestasis;
- Normothermic machine perfusion of donor liver;

- OrganOx metra System for transportation and preservation of the liver prior to transplantation;
- Perioperative use of vasopressin in liver transplantation;
- Perioperative use of sorafenib in liver transplantation;
- Scaffold-based transplantation (combination of xeno-organ and cell transplantations) as an alternative for orthotopic LT;
- Transient elastography for diagnosis of acute cellular rejection following liver transplantation;
- Ursodeoxycholic acid (UDCA), adjuvant use to prevent acute cellular rejection after liver transplantation;
- Xenotransplantation.

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

- All Medical UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

N/A

11. COLLABORATING DEPARTMENTS

- Medical and Pharmacy UM Departments

12. DOCUMENT CONTROL

APPROVED BY:		
(Printed Name)	(Date)	(Signature)

REVISION HISTORY			
Date	Author	Version	Comments
			Initial Version

APPENDICES

Any applicable attachments, resources or other materials should be included as appendices in this section. Label each appendix as follows:

Appendix A: