

Subject: Liver Transplantation Adult & Pediatric		Original Effective Date: 8/23/12
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MCPC Approval Date: 9/19/17, 9/13/18, 9/18/19		

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL⁴⁵⁷⁸

Liver transplantation is performed to replace a diseased liver in patients with liver disease that progresses to end-stage liver disease eventually causing death. There are a variety of conditions that lead to a disruption of normal anatomy and malfunction of the liver leading to end stage liver disease. The most common indications for liver transplantation in the United States are hepatitis C virus and alcoholic liver disease. Other indications include the following: idiopathic/autoimmune liver disease, primary biliary cirrhosis, primary sclerosing cholangitis, acute liver failure, hepatitis B virus, metabolic liver disease (eg, inborn errors of metabolism), and Cancer (HCC). Biliary atresia is a common indication for liver transplantation in pediatric patients.

Liver transplantation may be all or part of a liver removed from a brain-dead donor (cadaveric) or a portion of a liver from a healthy living donor. Types of transplant are dependent upon the availability of livers and include:

- Standard cadaveric (orthoptic) liver transplantation: The diseased liver is replaced surgically with a healthy whole liver.
- Split Liver Transplantation: In split liver transplantation an adult cadaver liver is split into two grafts; each lobe maintains its vascular and biliary pedicles, which are transplanted along with the graft. Generally, the left lobe is given to a pediatric recipient and the right lobe to an adult patient. The donor organ harvesting procedure is modified accordingly; more preparation time is required since the process of preparing portions of the liver for transplantation is more complex than the process for transplanting the entire organ into a single recipient.

- Living Donor Liver Transplantation: Both left- and right-lobe liver grafts have been used for living donor liver transplantation. The surgical technique is similar to that used for split-liver donations from beating heart donors. Although there is risk to the donor, this procedure allows for optimal preparation of the recipient and an ideally tailored graft.

A major factor in patient survival following transplantation is the degree of hepatic decompensation and associated debility at the time of transplantation. Using the Model for End Stage Liver Disease (MELD) scoring model for an individual who is ≥ 12 years, and the Pediatric End-Stage Liver Disease (PELD) scoring model for a child < 12 years, a donor organ is allocated to a transplant candidate designated as having the greatest risk of death. Exceptions to this policy, which result in the assignment of additional MELD/PELD points and therefore a higher priority for allocation of donor organs, can be requested of a United Network for Organ Sharing (UNOS) regional review board by the transplanting physician and/or facility for individuals with certain diagnoses. Transplant 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. The American Association for the Study of Liver Diseases (AASLD) recommends that patients with a MELD Score of 10 and above be referred for liver transplant evaluation. Patient with MELD Scores less than 15 can be listed but would not be considered for a liver transplant. ⁴

For patients with localized HCC who are not candidates for resection, liver transplantation is an appropriate strategy using the **Milan** criteria: a single lesion ≤ 5 cm, up to three separate lesions, none larger than 3 cm, no evidence of gross vascular invasion, and no regional nodal or extrahepatic distant metastases or **UNOS T2** criteria: a single tumor 1 cm or greater and up to 5 cm or less in diameter or 2 to 3 tumors 1 cm or greater and up to 3 cm or less and without extrahepatic spread or macrovascular invasion.

Much interest has arisen in expansion of usual transplant criteria in highly specialized centers. Most proposals are based strictly upon tumor size and number. A few centers are accepting patients for liver transplantation with **extended criteria** or **UCSF criteria** that accept single tumors of up to 6.5 cm in diameter as long as the cumulative diameters of all tumors does not exceed 8 cm. At this time there is insufficient evidence that supports the extended criteria. ^{5 7 8}

Some centers have adopted the practice of down staging tumors to fit within regional criteria to receive exception points for higher-priority transplant and clinical practice is variable. There is no universal standard regarding the optimal method for down staging with liver-directed therapy (LRT), selection criteria, and whether or how this should impact on prioritization for a graft. Bridging is defined as the use of LRT such as TACE, yttrium-90 (Y90), ablative therapy, or a combination of different types of LRT such as TACE and ablation to induce tumor death and deter tumor progression beyond the Milan criteria. According to OPTN Policy lesions eligible for down staging protocols must meet one of the following criteria: One lesion greater than 5 cm and less than or equal to 8 cm or two or three lesions each greater than 3 cm and less than or equal to 5 cm, and a total diameter of all lesions less than or equal to 8 cm or four to five lesions each less than 3 cm, and a total diameter of all lesions less than or equal to 8 cm. For candidates who meet the down staging criteria and then complete local-regional therapy, their residual lesions must subsequently meet the requirements for T2 lesions. ⁵

All transplants require prior authorization from the Corporate Transplant Department. Solid organ transplant requests will be reviewed by the Medical Director or qualified clinical designee. All other transplants will be by the Medical Director or covering Medical Director. If the criteria are met using appropriate NCD and/or LCD guidelines, state regulations and/or MCP policies the Corporate Medical Director's designee can approve the requested transplant.

Members must meet the Organ Procurement & Transplantation Network (OPTN)/United Network Organ Sharing (UNOS) guidelines for pretransplantation evaluation and listing criteria and the diagnosis of liver disease must be made by a Hepatologist and/or Transplant Surgeon.

Pre-Transplant Evaluation:

Criteria for transplant evaluation include all of the following:

- History and physical examination: includes a complete evaluation that meets the transplant center's protocol eligibility criteria
- Psychosocial evaluation and clearance:
 - No behavioral health disorder by history or psychosocial issues:
 - if history of behavioral health disorder, no severe psychosis or personality disorder
 - mood/anxiety disorder must be excluded or treated
 - member has understanding of surgical risk and post procedure compliance and follow-up required
 - Adequate family and social support
- EKG
- Chest x-ray
- Cardiac clearance in the presence of any of the following:
 - chronic smokers
 - > 50 years age
 - those with a clinical or family history of heart disease or diabetes
- Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease
- Lab studies:
 - *Complete blood count, Kidney profile (blood urea nitrogen, creatinine), electrolytes, calcium, phosphorous, albumin, liver function tests, Coagulation profile (prothrombin time, and partial thromboplastin time)
 - *Serologic screening for HIV, Epstein Barr virus (EBV), Hepatitis virus B (HBV), and Hepatitis C(HCV), cytomegalovirus (CMV), RPR and/or FTA:
 - If HIV positive all of the following are met:
 - CD4 count >200 cells/mm-3 for >6 months
 - HIV-1 RNA undetectable
 - On stable anti-retroviral therapy >3 months
 - No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm)

If abnormal serology need physician plan to address and/or treatment as indicated

- Antinuclear antibody, smooth muscle antibody, antimitochondrial antibody
- Ceruloplasmin, α_1 -antitrypsin phenotype
- Alpha-fetoprotein
- UDS (urine drug screen) if patient is current or gives a history of past drug abuse
- *Colonoscopy (if indicated or if patient is $50 \geq$ older should have had an initial screening colonoscopy, after initial negative screening requires follow up colonoscopy every ten years) with complete workup and treatment of abnormal results as indicated
- *GYN examination with Pap smear for women ≥ 21 to ≤ 65 years of age or indicated (not indicated in women who have had a TAH or TVH) with in the last three year with complete workup and treatment of abnormal results as indicated

Within the last 12 months:

- Dental examination or oral exam showing good dentition and oral care or no abnormality on panorex or plan for treatment of problems pre or post-transplant
- *Mammogram (if indicated or $>$ age 40) with complete workup and treatment of abnormal results as indicated
- *PSA if history of prostate cancer or previously elevated PSA with complete workup and treatment of abnormal results as indicated

***Participating Centers of Excellence may waive these criteria**

Criteria for Transplantation:

Molina Healthcare considers liver transplantation (with cadaveric organ, reduced-size organ, living related organ, and split liver) transplantation medically necessary in adults and children when all pre-transplant criteria are met above, meets UNOS criteria for MELD/PELD scores for transplant where applicable and ALL of the following criteria are met:

Must have any of the following Conditions: [ONE]

- Acute Diseases:
 - Fulminant hepatic failure
- Cholestatic liver diseases:
 - Biliary atresia
 - Cystic Fibrosis
 - Primary biliary cirrhosis
 - Primary sclerosing cholangitis
- Hepatocellular injury:
 - Alcohol induced cirrhosis
 - Autoimmune hepatitis
 - Cryptogenic cirrhosis
 - Toxic reactions (fulminant hepatic failure due to mushroom poisoning, acetaminophen (Tylenol) overdose, etc.)
 - Viral-induced Hepatitis
- Metabolic disorders and metabolic liver diseases with cirrhosis (not an all-inclusive list): [ONE]
 - Alpha 1-antitrypsin deficiency
 - Hemochromatosis
 - Inborn errors of metabolism

- Protoporphyrin
- Wilson's disease.
- ☐ Tumors:
 - Hepatoblastoma confined to the liver
 - Primary hepatocellular carcinoma (HCC) and all of the following: [ALL]
 - not a candidate for subtotal liver resection; and
 - no identifiable extra-hepatic spread of tumor to surrounding lymph nodes, abdominal organs, bone or other sites; and
 - no macrovascular involvement; and
 - meets the following criteria for tumor size and number:
 - ❖ Milan criteria: a single tumor 5 cm or less in diameter or 2 to 3 tumors 3 cm or less; OR
 - ❖ UNOS T2 criteria: a single tumor 1 cm or greater and up to 5 cm or less in diameter or 2 to 3 tumors each ≥ 1 cm and ≤ 3 cm; or
 - Hemangioma
 - Intrahepatic cholangiocarcinoma confined to the liver;
 - Neuroendocrine tumor and ALL of the following: [ALL]
 - Confined to the liver; and
 - Not otherwise resectable; and
 - Not responding to treatment; and
 - Causing life-threatening hormonal symptoms; or
- ☐ Vascular disease:
 - Budd-Chiari Syndrome
 - Veno-occlusive disease
- ☐ Other:
 - Hepatopulmonary syndrome with all of the following: [ALL]
 - 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); or
 - Portopulmonary hypertension with a mean pulmonary artery pressure by catheterization of less than 35 mm Hg
 - Polycystic disease of the liver (requiring transplantation due to the anatomic complications of a hugely enlarged liver)

The requesting transplant recipient should not have any of the following **absolute contraindications**:

- ☐ Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery
- ☐ Malignant neoplasm with a high risk for recurrence, non-curable malignancy (excluding localized skin cancer)
- ☐ Systemic and/or uncontrolled infection
- ☐ AIDS (CD4 count < 200cells/mm³)
- ☐ Unwilling or unable to follow post-transplant regimen

- Documented history of non-compliance with inability to follow through with medication adherence or office follow-up
- Chronic illness not reversible with liver transplant with one year or less life expectancy
- Limited, irreversible rehabilitation potential
- Active untreated substance abuse issues, requires documentation supporting free from addiction for minimally 6 months if previous addiction was present except in the following circumstance:
 - patients with alcohol-induced liver failure who are too ill to complete 6 months of abstinence (ie; have a high level of end stage liver disease documented by MELD scores) ^{4 27 31}
- No adequate social/family support
- Living Donor with any of the following conditions:
 - ongoing alcohol abuse; or
 - active malignancy, with the exception of non-melanoma skin cancer; or
 - persistent, recurrent or unsuccessfully treated infections, including hepatitis A, B or C or HIV; or
 - active systemic illness or serious comorbidities that would be expected to substantially negatively impact the successful completion and/or outcome of transplant surgery; or
 - active systemic illness that is likely to negatively affect survival

The requesting transplant recipient should be evaluated carefully and potentially treated if the following **relative contraindications** are present:

- Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation, this includes the following:
- Smoking, documentation supporting free from smoking for 6 months OR meets transplant center criteria
- Active peptic ulcer disease
- Active gastroesophageal reflux disease
- CVA with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months
- Obesity with body mass index of $>30 \text{ kg/m}^2$ may increase surgical risk
- Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation

Re-transplantation for Adult and Pediatric:

- Must meet all of the other requirements for transplantation outlined above AND have one of the following: [ONE]
 - Primary graft nonfunction; or
 - Hepatic artery thrombosis; or
 - Chronic rejection; or
 - Ischemic type biliary lesions after donation after cardiac death; or
 - Recurrent non-neoplastic disease causing late graft failure; and
- Requests for a third or subsequent liver transplant are considered not medically necessary

Multi-Organ Transplantation

- For multi-Organ transplantation requests, criteria must be met for each organ requested.

CONTINUATION OF THERAPY

When extension of a previously approved transplant authorization is requested, review using updated clinical information is appropriate.

- If Molina Healthcare has authorized prior requests for transplantation, the following information is required for medical review: [ALL]
 - Presence of no absolute contraindications as listed above;
 - History and physical within the last 12 months;
 - Liver chemistries within the last 12 months;
 - Stress test within the last 2 years (≥ 50 years of age);
 - Psychosocial evaluation or update within the last 12 months;
 - Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.

- If authorized prior requests for transplantation were obtained from another insurer, the following information is required for medical review: [ALL]
 - Authorization letter/documentation from previous insurer;
 - Presence of no absolute contraindications as listed above;
 - History and physical within the last 12 months;
 - Liver chemistries within the last 12 months;
 - Stress test within the last 2 years (≥ 50 years of age);
 - Psychosocial evaluation or update within the last 12 months;
 - Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.

EXCLUSIONS ^{4-5 27-31}

The following procedures and devices are excluded because these are considered investigational and not medically necessary:

- Bioartificial liver devices
- Xenotransplantation

SUMMARY OF MEDICAL EVIDENCE ²⁻⁷⁻²⁶

The published medical evidence and outcomes for liver transplantation in children and adults in the United States consists of registry data obtained from transplant centers that perform adult and pediatric transplantation and is available from the United Network for Organ Sharing (UNOS) database. Registry data demonstrates graft survival rates and outcomes comparable to other organ transplants.

Professional Society Guidelines ³⁻⁶

The Organ Procurement and Transplantation Network (OPTN) Policies 2019:

- The Organ data source, Reasons for Liver Transplants. Indications for transplantation.
- The Organ Distribution: Policy 9: Allocation of Livers and Liver-Intestines. Allocation of Livers and criteria for transplantation. ⁵

American Association for the Study of Liver Disease (AASLD)/ American Society of Transplantation (AST):

Practice Guidelines:

- Evaluation for Liver Transplantation in Adults (2014) specify that liver transplantation (LT) is appropriate for severe acute or advanced chronic liver disease when the limits of medical therapy have been reached. Recognition of cirrhosis per se does not imply a need for LT. Many patients with cirrhosis in the absence of an index complication such as ascites or variceal hemorrhage will not develop hepatic decompensation, although patients with cirrhosis have diminished survival compared to the population as a whole. Acute liver failure complications of cirrhosis include ascites, chronic gastrointestinal blood loss due to portal hypertensive gastropathy, encephalopathy, liver cancer, refractory variceal hemorrhage and synthetic dysfunction. ⁴
- Evaluation of the Pediatric Patient for Liver Transplantation (2014) specify that LT is appropriate for the following conditions: biliary atresia, metabolic/genetic conditions, acute liver failure, cirrhosis, liver tumor, immune-mediated liver and biliary injury, and other miscellaneous conditions. ⁴
- Treatment of Hepatocellular Carcinoma (2018) suggest that bridging to transplant with liver-directed therapy (LRT) in patients listed for liver transplantation within OPTN T2 (Milan) criteria to decrease progression of disease and subsequent dropout from the waiting list. The AASLD does not recommend one form of LRT over another for the purposes of bridging to liver transplantation for patients within OPTN T2 (Milan) criteria. ⁴

National Comprehensive Cancer Network Guidelines (NCCN Guidelines): Version (2.2018) for Hepatobiliary Cancers under Principles of Surgery Hepatocellular carcinoma indicates that a single lesion ≤ 5 cm, or 2 or 3 lesions ≤ 3 cm should be considered for transplantation (cadaveric or living donation). More controversial are those patients whose tumor characteristic are marginally outside of the UNOS guidelines and may be considered at some institutions for transplantation. Patients with tumor characteristics beyond Milan criteria that are down staged to within criteria can also be considered for transplantation. Patients with Child-Pugh Class A function, who fit UNOS criteria and are resectable, could be considered for resection or transplant. There is controversy over which initial strategy is preferable to treat such patients. ⁶

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
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 and 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 two 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 two partial liver grafts (ie, left lobe (segments II, III, and IV) and right lobe (segments I and V-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

HCPCS	Description
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor (s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and Rehabilitative services, and the number of days of pre- and post-transplant care in the global definition

ICD-10	Description: [For dates of service on or after 10/01/2015]
	All Diagnoses

RESOURCE REFERENCES

Government Agency

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 - National Coverage Determination (NCD) for Adult Liver Transplantation. 260.1. Effective June, 2012.
 - National Coverage Determination (NCD) for Pediatric Liver Transplantation. 260.2. Effective April, 1991.
- Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN / SRTR National Data Report Liver Transplant. Rockville, MD: Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation. Accessed at: <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>

Professional Society Guidelines

3. National Cancer Institute (NCI):
 - Childhood Liver Cancer Treatment (PDQ®)—Health Professional Version. 2019. Accessed at: <https://www.cancer.gov/types/liver/hp/child-liver-treatment-pdq>
 - Adult Primary Liver Cancer Treatment (PDQ®)—Health Professional Version. 2019: Accessed at: <https://www.cancer.gov/types/liver/hp/adult-liver-treatment-pdq>
4. American Association for the Study of Liver Disease (AASLD) Clinical Practice Guidelines. Accessed at: <http://www.aasld.org/publications/practice-guidelines-0>
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 - Treatment of Hepatocellular Carcinoma. Heimbach et al. Hepatology. 2018. 67(1):358-380
5. Organ Procurement Transplant Network OPTN and United Network for Organ Sharing (UNOS) Policies: Accessed at: <https://optn.transplant.hrsa.gov/resources/by-organ/liver-intestine/>
 - Allocation calculators. MELD & PELD.
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Peer Reviewed Publications and Institutional Transplant Outcomes

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8. UCSF Liver transplant Criteria. Liver transplantation criteria for hepatocellular carcinoma should be expanded: a 22-year experience with 467 patients at UCLA. Ann Surg. 2007 Sep;246(3):502-9; discussion 509-11. <http://www.ncbi.nlm.nih.gov/pubmed/17717454>
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 31. Advanced Medical Review (AMR):
 - Policy reviewed by practicing MD board certified in Surgery, Transplant. June 18, 2012
 - Policy reviewed by practicing MD board certified in Surgery General, Surgery Transplant. June 29, 2018.

Review/Revision History:

8/23/12: New Policy

1/9/13: Policy reviewed, no changes.

12/24/14: This policy was reviewed and revised and both the pretransplant criteria and transplant criteria were updated.

12/16/15, 9/15/16: Policy reviewed, no changes.

8/3/17: The policy was reviewed and the clinical criteria has changed. Hepatoblastoma was added as a medically necessary indication for liver transplant in children. The following sections were also updated: Summary of medical evidence, professional guidelines and references.

6/14/18: Policy reviewed and the criteria were completely revised according to UNOS, OPTN, and professional society guidelines.

9/18/19: Policy reviewed, no changes.