Molina Clinical Policy
Liver Transplantation: Policy No. 114

Last Approval: 12/11/2024
Next Review Due By: December 2025

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Liver transplantation is the surgical replacement of a diseased liver in patients with acute or chronic liver disease that progresses to end-stage liver failure. There are a variety of conditions that lead to the malfunction of the liver including, but not limited to, viral hepatitis B and C, alcoholic liver disease, biliary atresia, idiopathic/autoimmune liver disease, primary biliary cirrhosis, primary sclerosing cholangitis, acute liver failure, metabolic liver disease (e.g., inborn errors of metabolism), and hepatocellular carcinoma (Dove and Brown 2023). In the United States, the most common underlying conditions leading to liver failure in adults are alcohol-associated liver disease, non-alcoholic steatohepatitis, and hepatocellular carcinoma; contrasted with the pediatric population, in which biliary atresia is the most common indication for liver transplantation (Kirchner et al. 2020).

Types of transplants are dependent upon the availability of livers and include:

- **Standard Cadaveric (Orthoptic) Liver:** Recipient's diseased liver is surgically replaced with a healthy whole liver from a deceased donor.
- **Split Liver:** 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 since more preparation time is required as 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:** Both left- and right-lobe liver grafts have been used for living donor liver transplantation. The technique is similar to that used for split-liver donations from beating heart donors. While there is donor risk, the procedure allows for optimal preparation of the recipient and an ideally tailored graft.

Liver Allocation Process

The American Association for the Study of Liver Disease (AASLD) notes that 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. MELD/PELD scores range from 6 to 40, the higher the number indicates more severe liver dysfunction, and is based on medical presentation and lab results. Score update frequency is based on the severity of disease, with higher scores being updated more frequently than lower. (OPTN 2023, OPTN n.d.). The AASLD recommends that patients with a MELD/PELD Score of 10 and above be referred for liver transplant evaluation; however, patients with MELD/PELD Score less than 15 would not be allocated a donor liver due to such a low score.

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, or if they meet certain standard score exceptions as stipulated in the OPTN's *Policy 9 Allocation of Livers and Liver-intestines* (OPTN 2024). Transplant candidates can also receive additional points to increase their MELD/PELD score for conditions such as primary hepatocellular carcinoma when the tumors meet the modified Tumor-Node-Metastasis staging classification.

According to the Organ Procurement Transplant Network (2024) some centers have adopted the practice of down staging tumors to fit within regional criteria to receive exception points for higher-priority transplant. There is no universal standard regarding the optimal method for down staging with liver-directed therapy, selection criteria, and how this should impact graft prioritization. For candidates who meet the down staging criteria and then complete bridging therapies, residual lesions must subsequently meet the requirements for T2 lesions. Bridging is defined as the use of locoregional therapies such as trans-arterial chemoembolization, yttrium-90, ablative therapy, or a combination of different types of locoregional therapies to induce tumor death and deter tumor progression beyond the T2/Milan criteria.

RELATED POLICIES

MCP-459 Pre-Transplant and Transplant Evaluation

COVERAGE POLICY

All transplants require prior authorization from the Corporate Transplant Department. Solid organ transplant requests will be reviewed by the Corporate Senior Medical Director or qualified clinical designee. All other transplants will be reviewed by the Corporate Senior 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 Senior Medical Director's designee can approve the requested transplant.

Office visits with participating Providers do NOT require prior authorization. Providers should see the Member in office visits as soon as possible and without delay. Failure to see the Member in office visits may be considered a serious quality of care concern.

Please see *MCP-459 Pre-Transplant and Transplant Evaluation* for pre-transplant criteria and transplant evaluation criteria that must be met prior to solid organ transplant.

Criteria for Liver Transplants in Adults and Pediatrics

Liver transplantation (with cadaveric organ, reduced-size organ, living related organ, and split liver) transplantation may be **considered medically necessary** in adults and children when **ALL** the following criteria are met:

1. All pre-transplant and transplant evaluation criteria are met

2. Member meets United Network for Organ Sharing (UNOS) criteria for Model for End Stage Liver Disease (MELD)/ Pediatric End Stage Liver Disease (PELD) scores for transplant, when applicable

3. Member has **ONE** of the following conditions:
   a. Acute disease (fulminant hepatic failure)
   b. **ONE** of the following cholestatic liver diseases:
      i. Biliary atresia
      ii. Cystic Fibrosis
      iii. Primary biliary cirrhosis
      iv. Familial cholestatic syndromes
      v. Primary sclerosing cholangitis
   c. **ONE** of the following hepatocellular injuries:
      i. Alcohol induced cirrhosis
      ii. Nonalcoholic steatohepatitis
      iii. Autoimmune hepatitis
      iv. Cryptogenic cirrhosis
      v. Viral – induce Hepatitis

vi. Toxic reactions (fulminant hepatic failure due to mushroom poisoning, acetaminophen overdose, etc.)

d. **ONE or more** of the following metabolic disorders and metabolic liver diseases with cirrhosis:
   i. Alpha 1-antitrypsin deficiency
   ii. Hemochromatosis
   iii. Inborn errors of metabolism
   iv. Protoporphyria
   v. Familial amyloid polyneuropathy
   vi. Primary hyperoxaluria
   vii. Wilson's disease
e. **ONE** of the following tumors:
   i. Hepatoblastoma confined to the liver
   ii. Hemangioendothelioma
   iii. Intrahepatic cholangiocarcinoma confined to the liver
   iv. Primary hepatocellular carcinoma (HCC) and **ALL** the following:
      1. Not a candidate for subtotal liver resection
      2. No identifiable extra-hepatic spread of tumor to surrounding lymph nodes, abdominal organs, bone, or other sites
      3. No macrovascular involvement
      4. Meets the following criteria for tumor size and number:
         i. Milan Criteria: a single tumor 5 cm or less in diameter or 2 to 3 tumors 3 cm or less
         ii. 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
   v. Neuroendocrine tumor and **ALL** the following:
      1. Confined to the liver
      2. Not otherwise resectable
      3. Not responding to treatment
      4. Causing life-threatening hormonal symptoms
f. Vascular disease (including Budd-Chiari Syndrome or Veno-occlusive disease)
g. Portopulmonary hypertension with a mean pulmonary artery pressure by catheterization of less than 35mmHg
h. Polycystic disease of the liver (requiring transplantation due to the anatomic complications of a hugely enlarged liver) and/or Caroli disease
i. Congenital hepatic fibrosis
j. Hepatopulmonary syndrome with **ALL** the following:
   i. Arterial hypoxemia (PaO2 less than 60 mm Hg or AaO2 gradient greater than 20 mm Hg in supine or standing position)
   ii. Chronic liver disease with non-cirrhotic portal hypertension
   iii. Intrapulmonary vascular dilatation (as indicated by contrast-enhanced echocardiography, technetium-99 macroaggregated albumin perfusion scan, or pulmonary angiography)

Adults with Alcoholic Liver Disease

For Members with alcoholic liver disease, documentation of a reasonable expectation that the member can maintain sobriety is required and should include:

1. At least 6 months of continued sobriety
2. Clearance for transplant from a mental health provider with experience and expertise in substance abuse or addiction medicine
3. Completion of a formal, intensive relapse prevention program
4. Engagement with community resources such as Alcoholics Anonymous

For Members who are too ill to likely survive long enough to achieve six (6) months of sobriety, **ALL** the following criteria must be met to document a reasonable expectation that the member can maintain sobriety after transplant:

1. Documentation of abstinence from alcohol and drug use from the time of the first diagnosis of alcoholic liver disease

2. Documentation of Member acceptance of alcoholic liver disease with insight
3. Documentation that the Member has not had > 1 unsuccessful attempt at addiction rehabilitation
4. Documentation of the lack of other current substance use/dependency
5. A comprehensive assessment of the risk of relapse by a multidisciplinary psychosocial team including a social worker and an addiction medicine specialist/mental health professional with addiction and transplantation expertise. (Member must be awake, alert, and able to be directly interviewed. Comatose, intubated, or Members with significant encephalopathy cannot be adequately assessed. Assessment of the Member's family is not adequate and is not a substitute for assessing the member)
6. Documentation of an acceptable risk for relapse resulting from the comprehensive assessment above
7. Documentation of clear and unambiguous clearance for transplant from the addiction medicine provider who conducted the assessment of the risk of relapse
8. Documentation of a robust, formal program of relapse monitoring and prevention including frequent (at least monthly) testing and a requirement of negative test results for continued active transplant listing
9. Documentation of a robust, mandatory program of relapse prevention

Re-Transplantation Criteria

A second transplant may be **considered medically necessary** in adult and pediatric patients when **ALL** the above requirements for transplantation have been met, **AND** when **ONE** of the following conditions are present:

1. Primary graft nonfunction
2. Hepatic artery thrombosis
3. Chronic rejection
4. Ischemic type biliary lesions after donation after cardiac death
5. Recurrent non-neoplastic disease-causing late graft failure

Multi-Organ Transplantation Criteria

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

Limitations and Exclusions

1. Requests for a third or subsequent intestinal transplant are **NOT considered medically necessary**
2. Bioartificial liver devices are considered **experimental, investigational, and unproven** for any indication
3. Xenotransplantation is considered **experimental, investigational, and unproven** for any indication

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

National and Specialty Organizations

The **American Association for the Study of Liver Disease (AASLD)** published the following practice guidelines:

- *Evaluation for Liver Transplantation in Adults* ([1] AASLD, 2014) specifies that transplantation is appropriate for severe acute or advanced chronic liver disease when the limits of medical therapy are attained. Recognition of cirrhosis per se does not imply a need for liver transplant. 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 total population. 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.

- *Evaluation of the Pediatric Patient for Liver Transplantation* ([2] AASLD 2014) specifies that liver transplantation 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.

- *Long-Term Management of the Adult Liver Transplant* ([1] AASLD 2013) notes that approximately 100,000 persons in the United States underwent liver transplant between 1985 and 2011. Five-year survival found that 30,000 recipients were alive; over 16,000 recipients had a survival of 10 years or more. The guideline assists providers in the management of adult recipients who have received a liver transplant. In addition, barriers to maintaining health are identified along with recommendations on the prevention of such barriers. A special section is included on management beyond the first 90 days after transplantation.

- *Long-Term Management of the Pediatric Liver Transplant* ([2] AASLD 2013) notes an increase in pediatric liver transplantation which has changed the prognosis and survival for infants and children. Long-term maintenance resources exceed perioperative care requirements. The most common indication of liver transplant among this population in the United States population is biliary atresia (50%); among infants and children in Europe this condition accounts for 74% of liver transplants. Most deaths are likely to occur within 3 months following transplantation. Causes of graft loss during one-week post-transplant include primary nonfunction, hepatic artery thrombosis or portal vein thrombosis, systemic sepsis, and multiorgan failure. Other complications include acute rejection, chronic rejection, biliary leaks and strictures, viral infections (specifically cytomegalovirus and Epstein-Barr virus), acute kidney injury, and fluid imbalance. Survival rate at one-year post-transplant is 90%; the survival rate at 15-20 years is 75% with good quality of life. Five-year survival rate is over 90% for chronic liver disease and 89% for metabolic liver disease. Higher survival rates correlate to improved selection using prioritization and management of candidates with the Pediatric End-Stage Liver Disease score. In addition, survival increases with good preoperative management of hepatic complications and nutritional support, innovative surgical techniques for expanding the donor pool, and improved postoperative immunosuppression and management.

- The 2019 AASLD practice guidance on alcohol-associated liver disease offers recommendations regarding the timing of referral and selection of candidates for liver transplantation. It highlights that the individual's history of alcohol addiction plays a crucial role in selecting suitable candidates. Liver transplantation should be considered for individuals with decompensated alcohol-associated cirrhosis (AAC), Child-Pugh-Turcotte class C cirrhosis, or a MELD-Na score of 21 or higher. The guideline emphasizes that candidate selection should not rely solely on a fixed period of abstinence. Instead, a formal psychological evaluation is recommended to categorize individuals into higher or lower risk levels for relapse (Crabb et al. 2019).

- *Treatment of Guideline on Management of Hepatocellular Carcinoma* (Heimbach et al. 2018) suggests that bridging to transplant with liver-directed therapy in patients listed for liver transplantation within Milan criteria to decrease progression of disease and subsequent dropout from the waiting list. The AASLD does not recommend one form of locoregional therapies over another for the purposes of bridging to liver transplantation for patients within Milan criteria.

The **National Comprehensive Cancer Network (NCCN) published the following guidelines:**

- *Hepatocellular Carcinoma* (NCCN 2024) indicates that a single lesion 2-5 cm, or 2 or 3 lesions 1-3 cm should be considered for transplantation, cadaveric or living donation according to UNOS criteria. The guidelines also indication a patient with Child-Pugh Class A or B, with no portal hypertension, suitable tumor location, adequate liver reserve and suitable liver remnant should be considered for resection or transplant. Patients whose tumor characteristics are marginally outside of the UNOS guidelines should be assessed and considered 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, though controversy surrounds which initial strategy is preferable.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	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 (e.g., 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 (e.g., 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
0894T	Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion
0895T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment)
0896T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (e.g., perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure)

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
S2053	Transplantation of small intestine and liver allografts
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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/11/2024 Policy reviewed**.** No change to coverage criteria. Updated Summary of Medical Evidence and References.
06/12/2024 Coverage criteria revised with removal of transplant evaluation, continuation of therapy, and general contraindication coverage

	criteria as it is now stipulated in MCP 459 Pre-Transplant and General Transplant Evaluation. Annual Review Scheduled for Dec 2024.
12/13/2023	Policy reviewed, changes to criteria include age for colonoscopy reduced to 45 years, addition of non-life limiting neurological impairment criteria and disease processes to criteria, removal of abnormal serology criteria and daily cannabis use section, and addition of active pregnancy and substance abuse statement under absolute contraindications. Updated Overview, Summary of Medical Evidence, and References. IRO Peer Review by a practicing physician board certified in transplant hepatology October 2023.
12/14/2022	Policy reviewed, no changes to coverage criteria, included section on marijuana use.
12/08/2021	Policy reviewed, included items regarding sobriety for Members with alcoholic liver disease; included items from professional organizations, updated references.
09/16/2020	Policy reviewed, no changes to coverage criteria, updated references.
09/18/2019	Policy reviewed, no changes to coverage criteria, updated references.
06/14/2018	Policy reviewed, updated coverage criteria according to UNOS, OPTN, and professional society guidelines.
08/03/2017	Policy reviewed, updated clinical criteria. Hepatoblastoma added as a medically necessary indication for liver transplant in children, updated Summary of Medical Evidence section and references.
09/15/2016	Policy reviewed, no changes to coverage criteria, updated references.
12/16/2015	Policy reviewed, no changes to coverage criteria, updated references.
12/24/2014	Policy reviewed, revised the pretransplant criteria and transplant criteria.
01/09/2013	Policy reviewed, no changes to coverage criteria, updated references.
08/23/2012	New policy.

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