Molina Clinical Policy
Liver Transplantation (Adult and Pediatric): Policy No. 114

Last Approval: 12/8/2021
Next Review Due By: December 2022

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.[1] References included were accurate at the time of policy approval and publication.

OVERVIEW

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 (e.g., inborn errors of metabolism), and hepatocellular carcinoma 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 (Brennan et al., 2021; Dove & Brown, 2021; DynaMed, 2018; Flam et al., 2020; Friedman, 2020; Lok, 2020; Squires, 2020; Tsoulfas et al., 2021). Types of transplant are dependent upon the availability of livers and include:

- **Standard Cadaveric (orthoptic) Liver:** Diseased liver is replaced surgically with a healthy whole liver.
- **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; 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:** 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.

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. 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.

For patients with localized HCC who are not candidates for resection, liver transplantation is an appropriate strategy using the Milan* or UNOS T2^ criteria. (UCSF, 2007; Mazzaferro et al., 2011).

* Milan Criteria is defined as 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.

^ UNOS T2 Criteria is defined as 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. There is insufficient evidence that supports the extended criteria. (UCSF, 2007; Mazzaferro et al., 2011; OPTN).

According to the Organ Procurement Transplant Network (OPTN) 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, residual lesions must subsequently meet the requirements for T2 lesions.

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.

Members must meet United Network for Organ Sharing (UNOS) / Organ Procurement and Transplantation Network (OPTN) policies and guidelines for pre-transplantation evaluation and listing criteria and the diagnosis must be made by a specialist in the disease (Hepatologist) and/or a Transplant Surgeon.

Pre-Transplant Evaluation

Please see *MCP-323 Pre-Transplant Evaluation* for additional criteria and information.

Criteria for transplant evaluation include:

1. History and physical examination; **AND**
2. 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.

   AND
   - Adequate family and social support.

AND

3. EKG; **AND**
4. Chest x-ray; **AND**
5. Cardiac clearance in the presence of any of the following:
   a. Chronic smokers; **OR**
   b. Members > 50 years age; **OR**

c. Those with a clinical or family history of heart disease or diabetes.

AND

6. Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease; **AND**

7. Pulmonary Function Tests; **AND**

8. Lab studies that include:
   a. Complete blood count; kidney profile (blood urea nitrogen, creatinine); electrolytes; calcium; phosphorous; albumin; liver function tests; and coagulation profile (prothrombin time, and partial thromboplastin time);*
   b. Serologic screening for: HIV; Epstein Barr virus (EBV); Hepatitis virus B (HBV); Hepatitis C (HCV); cytomegalovirus (CMV); RPR and/or FTA:*
      - If HIV positive **ALL** of the following must be met:
        i. CD4 count >200 cells/mm-3 for >6 months; **AND**
        ii. HIV-1 RNA undetectable; **AND**
        iii. On stable anti-retroviral therapy >3 months; **AND**
        iv. 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.
        i. Antinuclear antibody, smooth muscle antibody, antimitochondrial antibody
        ii. Ceruloplasmin, α1-antitrypsin phenotype
        iii. Alpha-fetoprotein
   c. Urine drug screen (UDS) if Member is current or gives a history of past drug abuse.

AND

9. Colonoscopy (if indicated or if Member is age ≥ 50) with complete workup and treatment of abnormal results as indicated; an initial screening colonoscopy after initial negative screening requires a follow-up colonoscopy every 10 years).*

AND

10. Gynecological examination with Pap smear for women ages ≥ 21 to ≤ 65 years of age or if indicated (not indicated in women who have had a total abdominal hysterectomy [TAH] or a total vaginal hysterectomy [TVH]) within the last three years with complete workup and treatment of abnormal results as indicated.

Within the last 12 months:

1. 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; **AND**
2. Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated;* **AND**
3. 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.

Adult and Pediatric Criteria

Liver transplantation (with cadaveric organ, reduced-size organ, living related organ, and split liver) transplantation **is considered 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:

1. Must have **ONE** of the following conditions:

   a. Acute Disease (fulminant hepatic failure); **OR**

b. Cholestatic liver diseases including **ONE** of the following:
   - Biliary atresia; **OR**
   - Cystic Fibrosis; **OR**
   - Primary biliary cirrhosis; **OR**
   - Primary sclerosing cholangitis

OR

c. Hepatocellular injury including **ONE** of the following:
   - Alcohol induced cirrhosis; **OR**
   - Autoimmune hepatitis; **OR**
   - Cryptogenic cirrhosis; **OR**
   - Toxic reactions (fulminant hepatic failure due to mushroom poisoning, acetaminophen [Tylenol] overdose, etc.); **OR**
   - Viral-induced Hepatitis.

OR

d. Metabolic disorders and metabolic liver diseases with cirrhosis including, but not limited to **ONE** of the following:
   - Alpha 1-antitrypsin deficiency; **OR**
   - Hemochromatosis; **OR**
   - Inborn errors of metabolism; **OR**
   - Protoporphyria; **OR**
   - Wilson's disease

OR

e. Tumors including **ONE** of the following:
   - Hepatoblastoma confined to the liver; **OR**
   - Primary hepatocellular carcinoma (HCC) and **ALL** of the following:
     i. Not a candidate for subtotal liver resection; **AND**
     ii. No identifiable extra-hepatic spread of tumor to surrounding lymph nodes, abdominal organs, bone or other sites; **AND**
     iii. No macrovascular involvement; **AND**
     iv. 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
   - Hemangioendothelioma; **OR**
   - Intrahepatic cholangiocarcinoma confined to the liver; **OR**
   - Neuroendocrine tumor and **ALL** of the following:
     i. Confined to the liver; **AND**
     ii. Not otherwise resectable; **AND**
     iii. Not responding to treatment; **AND**
     iv. Causing life-threatening hormonal symptoms

OR

f. Vascular disease (including Budd-Chiari Syndrome or Veno-occlusive disease); **OR**

g. Other indications including **ONE** of the following:
   - Hepatopulmonary syndrome with **ALL** of the following:
     i. Arterial hypoxemia (PaO2 less than 60 mm Hg or AaO2 gradient greater than 20 mm Hg in supine or standing position); **AND**
     ii. Chronic liver disease with non-cirrhotic portal hypertension; **AND**

iii. 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; **OR**
- Polycystic disease of the liver (requiring transplantation due to the anatomic complications of a hugely enlarged liver).

2. The requesting transplant recipient should not have any of the following absolute contraindications:
   a. Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery; **OR**
   b. Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer); **OR**
   c. Systemic and/or uncontrolled infection; **OR**
   d. AIDS (CD4 count < 200cells/mm3); **OR**
   e. Unwilling or unable to follow post-transplant regimen:
      - Documented history of non-compliance
      - Inability to follow through with medication adherence or office follow-up

   OR

   f. Chronic illness with one year or less life expectancy; **OR**
   g. Limited, irreversible rehabilitation potential; **OR**
   h. Active untreated substance abuse issues, requires documentation supporting free from addiction for minimally 6 months if previous addiction was present; **OR**
   i. No adequate social/family support.

AND

3. The requesting transplant recipient should be evaluated carefully and potentially treated if any of the relative contraindications below are present. (Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation).
   a. Smoking, documentation supporting free from smoking for 6 months; **OR**
   b. Active peptic ulcer disease; **OR**
   c. Active gastroesophageal reflux disease; **OR**
   d. CVA with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months; **OR**
   e. Obesity with body mass index of >30 kg/m^2 may increase surgical risk; **OR**
   f. Chronic liver disease such as Hepatitis B/C/D, or cirrhosis which increases the risk of death from sepsis and hepatic failure requires consultation by a gastroenterologist or hepatologist; **OR**
   g. Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation.

Adult and Pediatric Re-Transplantation Criteria

1. Member must meet **ALL** the requirements for transplantation outlined above AND have **ONE** of the following:
   a. Primary graft nonfunction; **OR**
   b. Hepatic artery thrombosis; **OR**
   c. Chronic rejection; **OR**
   d. Ischemic type biliary lesions after donation after cardiac death; **OR**
   e. Recurrent non-neoplastic disease-causing late graft failure.

AND

2. Requests for a third or subsequent liver transplant **are considered not medically necessary.**

Adult and Pediatric Multi-Organ Transplantation Criteria

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

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 (Asrani et al., 2020):

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

For Members who are too ill to likely survive long enough to achieve six (6) months of sobriety, **ALL** of the following criteria must be met to document a reasonable expectation that the member can maintain sobriety after transplant (Asrani et al., 2020):

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.

Continuation of Therapy

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

1. If Molina Healthcare has authorized prior requests for transplantation **ALL** of the following information is required for medical review:
   a. Presence of no absolute contraindication as listed above; **AND**
   b. History and physical within the last 12 months; **AND**
   c. Kidney profile within the last 12 months; **AND**
   d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **AND**
   e. Psychosocial evaluation or update within the last 12 months; **AND**
   f. 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.

2. If authorized prior requests for transplantation were obtained from another insurer, **ALL** of the following information is required for medical review:
   a. Authorization letter/documentation from previous insurer; **AND**
   b. Presence of no absolute contraindication as listed above; **AND**
   c. History and physical within the last 12 months; **AND**
   d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **AND**

e. Psychosocial evaluation or update within the last 12 months; **AND**
f. 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.

Limitations and Exclusions

The following procedures and devices **are considered experimental and investigational:**
1. Bioartificial liver devices
2. Xenotransplantation

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

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.

National and Specialty Organizations

The **Organ Procurement Transplant Network (OPTN)** has a number of resources available, including those listed below, at https://optn.transplant.hrsa.gov/resources.

- *Allocation Calculators: MELD and PELD*
- *Policy 9: Allocation of Liver-Intestine*
- *Organ Data Source: Liver – Reasons for Liver Transplants*
- *Reasons for Liver Transplants – Indications for Transplantation*

The **American Association for the Study of Liver Disease (AASLD) / American Society of Transplantation (AST)** *Practice Guidelines* are summarized below:

- *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.
- *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.
- *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.

The **National Comprehensive Cancer Network (NCCN) Guidelines** (2020) for *Hepatobiliary Cancers* (under Principles of Surgery Hepatocellular Carcinoma) indicates that a single lesion ≤5cm, or 2 or 3 lesions ≤3cm 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. Controversy surrounds which initial strategy is preferable.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

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 (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

HCPCS Code

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

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

12/8/2021	Policy reviewed, included items regarding sobriety for Members with alcoholic liver disease; included items from professional organizations, updated references.
9/18/2019, 9/16/2020	Policy reviewed, no changes, updated references.
6/14/2018	Policy reviewed, updated criteria according to UNOS, OPTN, and professional society guidelines.
8/3/2017	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.
12/16/2015, 9/15/2016	Policy reviewed, no changes.
12/24/2014	Policy reviewed, revised the pretransplant criteria and transplant criteria.
1/9/2013	Policy reviewed, no changes.
8/23/2012	New policy.

REFERENCES

Government Agency

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: "adult liver transplantation 260.1"). Effective June 2012. Available from CMS. Effective June 21, 2012. Accessed November 28, 2021.
2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: "pediatric liver transplantation 260.2"). Available from CMS. Effective April 12, 1991. Accessed November 28, 2021.

Evidence Based Reviews and Publications

1. AMR Peer Review. Policy reviewed on June 29, 2018 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the areas of Surgery General, Surgery Transplant.
2. Asrani SK, Trotter J, Lake J, Ahmed A, Bonagura A, Cameron A, et al. Meeting report: The Dallas Consensus Conference on Liver Transplantation for Alcohol Associated Hepatitis. Liver Transpl. 2020 Jan;26(1):127-140. doi: 10.1002/lt.25681. Accessed Nov. 28, 2021.
3. Brennan DC, Rodeheffer RJ, Ambinder RF. Development of malignancy following solid organ transplantation. Available from UpToDate. Updated August 5, 2021. Accessed November 28, 2021. Registration and login required.
4. Dove LM, Brown RS. Liver transplantation in adults: Patient selection and pre-transplantation evaluation. Available from UpToDate. Updated March 26, 2021. Accessed November 28, 2021. Registration and login required.
5. DynaMed. Hepatocellular carcinoma in adults. Available from DynaMed. Updated November 18, 2018. Accessed November 28, 2021.
6. DynaMed. Pulmonary artery hypertension. Available from DynaMed. Updated November 18, 2018. Accessed November 28, 2021.
7. Flam S, Gordon F, Poupon R. Liver transplantation in primary biliary cholangitis. Available from UpToDate. Updated October 7, 2020. Accessed November 28, 2021. Registration and login required.
8. Friedman SL. Liver transplantation for alcoholic liver disease. Available from UpToDate. Updated October 19, 2020. Accessed November 28, 2021. Registration and login required.
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13. Tsoulfas G, Curley SA, Abdalla EK, Barnett CC, Hertl M. Liver transplantation for hepatocellular carcinoma. Available from UpToDate. Updated February 22, 2021. Accessed November 28, 2021. Registration and login required.

National and Specialty Organizations

1. Martin P, DiMartini A, Feng S, Brown R, Fallon M. Evaluation for liver transplantation in adults: 2013 practice guideline by the American Association for the Study of Liver Diseases and the American Society of Transplantation. Hepatology. 2014 Mar;59(3):1144-65. doi: 10.1002/hep.26972. Accessed November 28, 2021.
2. American Association for the Study of Liver Diseases (AASLD). Clinical Practice Guidelines. Available from AASLD.
3. Squires RH, Ng V, Romero R, Ekong U, Hardikar W, Emre S, Mazariegos GV. Evaluation of the pediatric patient for liver transplantation: 2014 practice guideline by the American Association for the Study of Liver Diseases, American Society of Transplantation and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. Hepatology. 2014 Jul;60(1):362-98. doi: 10.1002/hep.27191. Accessed November 28, 2021.
4. Heimbach JK, Kulik LM, Finn RS, Sirlin CB, Abecassis MM, Roberts LR, et al. AASLD guidelines for the treatment of hepatocellular carcinoma Hepatology. 2018 Jan;67(1):358-380. doi: 10.1002/hep.29086. Accessed November 28, 2021.
5. Mazzaferro V, Bhoori S, Sposito C, Bongini M, Langer M, Miceli R, Mariani L. Milan criteria in liver transplantation for hepatocellular carcinoma: An evidence-based analysis of 15 years of experience. Liver Transplantation. 2011;17(S2): S44-S57. Available here. Accessed November 28, 2021.
6. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: Hepatobiliary cancers. Available from NCCN. Published 2020. Accessed November 28, 2021.
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8. Organ Procurement Transplant Network (OPTN). Questions and answers about HCC automatic approval criteria changes. Available from OPTN. Published December 12, 2017. Accessed November 28, 2021.
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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*