Clinical Policy: Liver Transplant
Reference Number: MI.CP.MP.516
Last Review Date: 03/22

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

If this request is for a Medicare or MMP member please see NCD 260.1 (Adult Liver Transplantation) or NCD 260.2 (Pediatric Liver Transplantation)

Description:

To ensure that the selection criteria are consistently followed and documented**.** Meridian Health Plan (MHP) considers liver transplantation medically necessary for the indications listed below. Indications for liver transplant include irreversible liver dysfunction or the general effects of liver dysfunction after alternative medical or surgical treatments have been utilized and where the benefits of transplantation outweigh the risk of alternative modalities. Because liver transplantation has a 10% to 15% mortality rate during the first year post transplantation, only patients who are projected to survive less than 2 years because of their chronic liver disease should be considered for transplantation.

Organ allocation in the United States is managed by the United Network for Organ Sharing (UNOS) and is based largely on disease severity scores for adults (Model for End-Stage Liver Disease {MELD}) and children (Pediatric End-Stage Liver Disease {PELD}) to support organ allocation for patients with chronic liver disease. MELD is used for patients 12 years and older. PELD and MELD are used to allocate organs for patients with chronic liver disease, they were not designed for use in Acute Liver Failure (ALF). Per UNOS, PELD is not required for listing but may be usedfor organ allocation.

Policy/Criteria:

All requests MUST be reviewed by a Medical Director

The Chief Medical Officer and/or Senior Medical Director must receive notification for all possible approved requests by the reviewing Medical Director.

Indications for First-Time Transplantation: MHP considers orthotopic (normal anatomical position) liver transplantation (with cadaver 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.

1. Cholestatic diseases:
    a. Biliary atresia *
    b. Primary biliary cirrhosis
    c. Primary sclerosing cholangitis with development of secondary biliary cirrhosis
    d. Familial intrahepatic cholestasis (Pediatric members)
    e. Alagille Syndrome (Pediatric members)

f. Nonalcoholic Steatohepatitis (NASH)

2. Hepatocellular diseases:
   a. Alcoholic cirrhosis
   b. Chronic active hepatitis with cirrhosis (hepatitis B or C) *
   c. Idiopathic autoimmune hepatitis *
   d. Pediatric recurrent cholangitis, pediatric unmanageable bile duct strictures or pediatric concerns for the risk of cholangiocarcinoma.
   e. Cryptogenic cirrhosis
   f. Pediatric parenteral nutrition-associated liver disease with enteral autonomy and complications of cirrhosis.
3. Malignancies:
   a. Primary hepatocellular carcinoma confined to the liver when all of the following criteria are met (Milan Selection Criteria):
      i. Member is not a candidate for subtotal liver resection; *and*
      ii. Member meets criteria for Stage T2 lesion with a single tumor that is greater than or equal to 2cm and less than or equal to 5 cm or two/three tumors that are less than or equal to 3 cm each. [1] Tumors can be downstage with hepatic artery chemoembolization (HACE or TACE) with or without radiofrequency ablation. If successfully downstage to be within Milan criteria, the tumor(s) must meet the Milan criteria after the downstaging procedure, as assessed by imaging requirements, and there will be a minimum time-out or observation period of 3 months from the date on which imaging is documented to meet the Milan Criteria before eligibility for transplant is approved *and*
      iii. There is no macrovascular involvement, *and*
      iv. There is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, abdominal organs, bone or other sites.
   b. Special consideration may be given to Hepatocellular carcinoma, T2 lesion, eligible for MELD exception points.
   c. Hepatocellular carcinoma that has been "downstage". (Pomfret et al, Yao et al and Ravaioli et al)
      i. The inclusion criteria for downstaging should be a single tumor < 8 cm or 2 to 3 tumors, each < 5 cm, with a total tumor diameter < 8 cm and no vascular invasion by imaging criteria.
      ii. The criteria for successful downstaging should be as follows:
         a. The tumor must meet the Milan Criteria after the downstaging procedure(s), as assessed by imaging requirements for priority listing and maintaining listing for liver transplant every 3 months.
         b. Successful downstaging also requires a significant decrease in the AFP level to <500 ng/ml for those patients with an initial AFP level > 1000 ng/ml.
      iii. There will be a minimum time-out or observation period of 3 months from the date on which the imaging is documented to meet the Milan Criteria before eligibility for active priority listing.

[1] *Ravaioli M, Grazi GL, et al. Liver Transplantation for hepatocellular carcinoma: results of down-staging in patients initially outside the Milan selection criteria. Am J Transplant 2008 Dec; 8 (12):2547-57*

Pomfret EA, Washburn K, Yao F, Report of a national conference on liver allocation in patients with hepatocellular carcinoma in the United States. Liver Transplant. 2010 Mar; 16(3):262-78

iv. Those with acute hepatic decompensation after downstaging procedures are not eligible for transplant unless they meet the above criteria.

d. Hepatoblastoma in children (less than 18 years old) when all of the following criteria are met: * The patient will not have received more than 2 rounds of chemotherapy as part of the initial management of the tumor prior to consideration for transplant.
   i. Member is not a candidate for subtotal liver resection; *and*
   ii. There is no identifiable extrahepatic spread of tumor to surrounding lungs, abdominal organs, bone or other sites or extrahepatic disease is in complete remission after chemotherapy.
   iii. Children with Hepatoblastoma will be given PELD score exception.
   iv. Liver transplantation should be considered for patients with nonmetastatic disease recurrence in the liver that is not amenable to resection.

4. Vascular diseases:
   a. Budd-Chiari syndrome
5. Metabolic disorders and metabolic liver diseases with cirrhosis
   a. Alpha 1-antitrypsin deficiency (with ESLD or HCC) *
   b. Hemochromatosis (with ESLD or HCC) OR Gestational alloimmune liver disease (previously known as neonatal hemochromatosis)
   c. Inborn errors of metabolism: *

      1. Pediatric Hereditary tyrosinemia Type I unresponsive to medical therapy or who have hepatic malignancy.
      Pediatric organic academia with metabolic decompensation despite conventional therapy OR uncontrollable hyper-ammonia OR restricted growth OR severe impairment of health-related quality of life despite conventional therapy.
      3.Pedaitric Fatty acid oxidation defects with failed medical therapy OR recurrent episodes of complication
      s
      4.Pediatric Glycogen storage disease Type I with either poor metabolic control, multiple hepatic adenomas or concern for HCC
         i. Type III or IV with either poor metabolic control, complications of cirrhosis, progressive hepatic failure or suspected HCC.

      5.Severe urea cycle defects in the first year of life
   d. Wilson's disease (with ESLD or HCC)*
   e. Acute intermittent porphyria
   f. Primary Oxaluria –Type I at the time of diagnosis.
   g. Familial Amyloidosis
   h. Familial Amyloid Polyneuropathy
   i. Cystic fibrosis (with ESLD or HCC) or unmanageable complications of portal hypertension in pediatric members)
   j. Crigler-Naijar Type I at the time of diagnosis
   k. Multidrug resistance protein 3 disease that fails to respond to ursodeoxycholdic acid
   l. Inborm errors of bile acid synthesis or those refractory to medical therapy.
6. Miscellaneous
   a. Acute liver failure
      i. Severe acute liver injury with encephalopathy and impaired synthetic function with international normalized ratio [INR] of ≥ 1.5 or ≥ INR > 2.0 regardless of the presence of clinical encephalopathy.

ii. In a patient without cirrhosis or preexisting liver disease. (Viral and drug-induced hepatitis are the most common causes of acute liver failure in adults)

b. Hepato-pulmonary syndrome --when the following selection criteria are met:
   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).

c. Neuroendocrine tumors (NET). There may be a role for neuroendocrine tumors that have metastasized to the liver, but experience in this setting is limited. Refer to Medical Director to evaluate on a case-by-case basis. (Martin et al.)

d. Hemangioendothelioma (HAE). CMS and AASLD have concluded that generally patients with HAE have a better prognosis than do patients with HCC and may not have evidence of significant underlying liver disease. Consequently, transplantation is not common, but not necessarily contraindicated. For patients with large tumors liver transplantation should be considered for patients with unresectable HAE. Refer to Medical Director. (Martin et al.).
   1. In pediatric members with hemangioendothelioma, member must have failed medical therapy AND condition is associated with life-threatening complications

e. Pediatric non-cirrhotic portal hypertension with cardiopulmonary complications

f. Pediatric Factor VIII deficiency that has failed medical therapy

g. Pediatric Protein c deficiency that has failed medical therapy.

* Denotes diagnoses most commonly associated with indications for pediatric transplant.

All requests MUST be reviewed by a Medical Director.

Indications for Living Donor Liver Transplant:

Living donor liver transplant may provide a viable alternative to cadaveric liver transplantation in adult and pediatric patients with an urgent need for transplantation or for those with a deteriorating quality of life and no available cadaveric organ.

Live donor transplant should only be contemplated when liver transplant with a deceased donor is unlikely to occur within a reasonable time frame given the severity of the potential candidate's liver disease.

Living donor transplants may be considered with MELD <15 when patients have complicating medical conditions that do not qualify for MELD exception points, yet their MELD score is not reflective of their severity of disease noted below.

Potential recipients must still undergo required documentation as noted below and have no absolute contraindications.

Meridian considers a living donor liver transplant medically necessary when recipients considered for LDLT fulfill the same minimal listing criteria established for deceased donor liver transplantation as noted in this policy.

The optimal Model for End-stage Liver Disease (MELD) score at which patients should undergo LDLT has yet to be determined. The optimal MELD score is one that identifies the recipient when

the chance of liver disease-related mortality is greater than the chance of mortality from surgical complications. Thus, living donor liver transplant is a valid treatment option for patients with low MELD scores, especially in cases where a decreased donor offer is not likely to occur.

Indications for Simultaneous Liver-Kidney Transplantation:
For multi organ transplant, patient must meet criteria for each organ.
Meridian considers a simultaneous liver and kidney transplant medically necessary when any of the following criteria are met as per UNOS criteria, and is determined/documented by a nephrologist

1. Chronic kidney disease (CKD) with cirrhosis and symptomatic portal hypertension or hepatic vein wedge pressure gradient ≥10 mmHg.
    a. CKD defined as a measured or calculated GRF < or = 60ml/min for > 90 consecutive days
    b. And AT LEAST ONE OF THE FOLLOWING:
        i. Candidate has begun regularly administered dialysis as an ESRD patient in a hospital based, independent non-hospital based or home setting.
        ii. The candidate's most recent measured or calculated CrCl or GFR is < or = 35 ml/min at the time of registration on the kidney waiting list.
2. Acute kidney injury (AKI) or hepatorenal syndrome with AT LEAST ONE OF THE FOLLOWING:
    a. Candidate has been on dialysis for at least 6 consecutive weeks
    b. The candidate has a measured of calculated CrCL or GFR < or = 25 ml/min for at least 6 consecutive weeks and this is documented in the candidate's medical records every 7 days beginning with the date of the first test with this value.
    c. The candidate has any combination of #1 or #2 above for six consecutive weeks.
3. Metabolic Disease
    a. An additional diagnosis of at least one of the following:
        i. Hyperoxaluria
        ii. Atypical HUS from mutations in factor H and possible factor `1
        iii. Familial non-neuropathic systemi amyloid
        iv. Methylmalonic aciduria

Required Documentation:
Documentation Required Post-Evaluation
Following evaluation, all candidates for transplant must submit the following documentation:
- a. Transplant team evaluation recommending listing for transplant, documenting indications and contraindications, if any.
- b. Psychosocial evaluation completed by qualified mental health professional.
- c. Documentation of blood or urine screening for alcohol, tobacco, and illicit drug use.
- d. Cardiac evaluation with assessment of cardiac risk factors in all patients over 40 years of age and for those younger than 40 with multiple risk factors for coronary artery disease. This must include EKG, stress test, and echocardiogram as an initial screening test and cardiac catheterization where clinically indicated.

e. Pulmonary evaluation with pulse ox to screen for hepatopulmonary syncrone. Chest X-Ray if > 50 years of age. If pulse ox is < 96% patients should have additional testing to rule out hepatorenal syndrome and other causes of abnormal lung function. Pulmonary function testing should be performed in those able to do so.
f. Documentation of us with doppler to document portal vein patency unless patency documented in other imaging studies.
g. Documentation of triple-phase CT or MRI for tumor diagnosis and staging for Hepatocellular Carcinoma when appropriate.
h. Documentation of age-appropriate screening for extrahepatic malignancies (e.g., colonoscopy, mammogram, pap smear) and abdominal CT or MRI to screen for hepatocellular carcinoma).
i. Upper endoscopy in those with cirrhosis of portal hypertension.
j. Dental clearance
k. Documentation of completion of dietary counseling in patients with BMI > 30.

Requests for transplant will generally be approved where this documentation establishes an indication for transplant as described below and does not establish any contraindications.

Repeat Transplant:
Indications for Re-Transplantation
MHP considers re-transplantation following a failed liver transplant medically necessary if the initial transplant was performed for a covered indication or medical diagnosis and patient has one of the above qualifying diagnoses with required documentation and without absolute contraindications.

MHP considers re-transplantation medically necessary regardless of MELD score for the following indications only:

- Primary graft non-function
- Hepatic artery thrombosis
- Portal vein thrombosis
- Chronic rejection
- Chronic cholestasis without chronic rejection
- Ischemic type biliary lesions after donation after cardiac death
- Recurrent non-neoplastic disease-causing late graft failure

These patients should still have the required documentation and be without absolute contraindications except as noted above

Absolute Contraindications:
Presence of any of the following conditions are absolute contraindications to liver transplant:
Patients exhibiting one or more of these traits will generally not be approved for transplant unless otherwise provided for in this policy:

1. Uncontrolled sepsis
2. Presence of significant organ system failure other than kidney, liver or small bowel.
3. Malignancy outside the liver not meeting oncologic criteria for cure with the exception of non-melanotic skin cancer
4. Intrahepatic cholangiocarcinoma

5. Hemangiosarcoma
6. Hepatocellular carcinoma with metastatic disease
7. Persistent noncompliance
8. BMI > 40 is a relative contraindication
9. Psychosocial evaluation documents evidence of intractable noncompliance with medical directives, inadequate support from able caregivers, or an absence of active psychiatric disorders with the potential to impact compliance or include behaviors harmful to health (including alcohol, tobacco, illicit drug use, current suicidal ideation or evidence of multiple past suicide attempts).Members with severe mental illness (SMI) or minor members with severe emotional disturbance (SED) with core symptoms including lack of insight into illness causing non-adherence to psychotropic medications or medical regimen must be assessed for adequacy of and engagement with psychosocial resource supports in Care Coordination prior to non-compliance determinations. Where developmental or acquired cognitive impairment or dementia is present, psychosocial and guardianship support as well as reversibility of impairment must be assessed and documented prior to non-compliance determinations.
10. MELD score < 15 unless Hepatocellular carcinoma that meets the Milan selection criteria is present or documentation of conditions that qualify for meld exception points as per transplant society guidelines. These include:
    a. Hepatopulmonary syndrome.
    b. Portopulmonary hypertension (provided the mean arterial pressure can be maintained at <35 mmHg with treatment).
    c. Familial amyloid polyneuropathy/Familial amylosidosis.
    d. Primary hyperoxaluria.
    e. Cystic fibrosis (with signs of reduced pulmonary function with forced expiratory volume at one second (FEV1) that falls below 40%).
    f. Hilar cholangiocarcinoma (provided the liver transplantation center has a UNOS-approved protocol detailing the work-up and management of patients with cholangiocarcinoma undergoing transplantation).
    g. Hepatic artery thrombosis (occurring within 14 days of liver transplantation but not meeting criteria for status 1A).
    h. Hepatobalstoma (pediatric) – see page 2.
    i. Urea cycle disorders and organic academia (pediatric).
11. For those that may have complicating medical conditions that do not qualify for meld exception points yet their MELD score is not reflective of their severity of disease, an appeal for MELD exception points should be made to the regional review board. These include, but are not limited to:
    1. Recurrent cholangitis in patients with primary sclerosing cholangitis who are on antibiotic suppressive therapy or require repeated biliary interventions
    2. Refractory ascites
    3. Refractory hepatic encephalopathy
    4. Refractory variceal hemorrhage
    5. Portal hypertensive gastropathy leading to chronic blood loss
    6. Intractable pruritus in a patient with primary biliary cirrhosis
    7. Refractory hepatic hydrothorax
    8. Moderate to severe malnutrition
    9. Intractable hepatic encephalopathy
    10. Severe thrombocytopenia with complications
    11. Intractable hyponatremia

12. Polycystic liver disease
13. Recurrent spontaneous bacterial peritonitis (SBP)
14. Muscle wasting due to liver disease with other systemic illnesses excluded
15. Debilitating fatigue due to liver disease with other systemic illnesses excluded
16. Polycystic liver disease with massive enlargement leading to physical impairment.

12. All other presentations not eligible for automatic MELD exception points not adequately accounted for in the MELD/PELD score may be considered. Refer to Medical Director.
13. HIV infection or AIDS, unless the following are noted:
    - On highly active antiretroviral therapy (HAART) regimen and documented evidence of sustained viral load suppression.
    - No other complications from AIDS (for example, opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi's sarcoma or other neoplasm)
    - NEEDS INFECTIOUS DISEASE CLEARANCE
14. Anatomic abnormality that precludes liver transplantation
15. Severe cardiac disease (severe valvular disease complicated by severe pulmonary hypertension; aortic stenosis with LV dysfunction; uncorrected coronary artery disease or residual LV dysfunction)
16. Severe pulmonary disease including severe pulmonary hypertension > 59mmhg. If FEV1<1 or FVC <50% if related to cirrhosis complications and cleared by pulmonary may be considered.
17. Fulminant hepatic failure with sustained intracranial pressure >50mm Hg or Cerebral perfusion pressure < 40 mm Hg
18. Pediatric severe, life threatening extrahepatic multi-organ mitochondrial disease.
19. Pediatric Alper's syndrome.
20. Valproate-associated liver failure in a child under 10 years of age.
21. Pediatric severe portopulmonary hypertension that is not responsive to medical therapy.
22. Pediatric Niemann-Pick desease type C
23. Pediatric hemophagocytic lymphohistiocytosis presenting acute liver failure.

NOTE: Methadone-maintained opiate dependence with stable abstinence from illicit opiates is not a contraindication to transplant absent further evidence of substance abuse. Marijuana use is not an absolute contraindication and will be reviewed on a case-by-case basis.

Member Compliance with Plan of Care (applicable for ages 10 and above):

- Alcohol screen- abstinence for the past 6 months prior to actual transplant approval, if member history includes use of alcohol. If no history exists, then 1 negative alcohol screen must be submitted for members with no history of past alcohol use
- Drug screen-abstinence for the past 6 months prior to actual transplant approval if history exists of drug use. If no history exists, then 1 negative drug screen must be submitted for members with no history of positive drug screen.
- Nicotine screening- abstinence for the past 6 months prior to actual transplant approval if history of smoking. If no history exists, then 1 negative cotinine level must be submitted

Refusal or failure to undergo monthly testing for those members with a history of alcohol, tobacco, and/or drug use will be interpreted as a positive test result.

Six month abstinence period may be shortened in cases where patient's condition is sufficiently advanced that mortality is reasonably expected before the full abstinence period can be completed. Patients granted a waiver of the six month abstinence period require documentation of participation in a formal outpatient treatment program, when practical, as well as serial blood or urine testing no less frequently than monthly. A positive test result at any time prior to the procurement phase will result in denial.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description

HCPCS ®* Codes	Description

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date		
• **Annual Review** • References were updated. • Definition of PELD and MELD were added. Additional pediatric diagnoses were added. New indication for repeat transplant was added.		3/25/2022

References

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1.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.