MEDICAL POLICY

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MEDICAL POLICY DETAILS	
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and review of the peer-reviewed literature, liver transplantation for selected individuals with end-stage liver disease has been medically proven to be effective and therefore **medically appropriate** for **ANY** of the following indications when criteria are met:

A. Hepatocellular diseases:
   1. Alcoholic cirrhosis;
   2. Viral hepatitis;
   3. Autoimmune hepatitis;
   4. Alpha-1 antitrypsin deficiency;
   5. Hemochromatosis;
   6. Non-alcoholic steatohepatitis cirrhosis;
   7. Protoporphyria; or
   8. Wilson's disease.

B. Cholestatic liver diseases:
   1. Primary biliary cirrhosis;
   2. Primary sclerosing cholangitis with development of secondary biliary cirrhosis; or
   3. Biliary atresia.

C. Vascular disease:
   1. Budd-Chiari syndrome.

D. Primary hepatocellular carcinoma when:
   1. Disease is organ confined, and the patient is not a candidate for subtotal liver resection.

E. Inborn errors of metabolism.
F. Trauma and toxic reactions.
G. Nonresectable hilar cholangiocarcinoma and as part of a neoadjuvant chemoradiation protocol when:
   1. Absence of metastatic disease, and
   2. For localized hilar tumors Stage I or II.
H. Nonresectable intrahepatic cholangiocarcinoma when:
   1. Absence of metastatic disease confirmed by a staging laparoscopy or laparotomy; and
   2. When combined with neoadjuvant chemoradiation.
I. Hepatoblastoma (non-metastatic):
J. Miscellaneous:
   1. Polycystic disease of the liver; or
   2. Familial amyloid polyneuropathy.

II. Recipient Selection Guidelines:
A. Cadaver Liver Recipient:
   1. MELD score equal to or greater than 9 (UNOS adjusts the MELD score for patients with hepatocellular cancer by adding points to their scores).
   2. Patients with polycystic disease of the liver do not always develop progressive liver failure but may require transplantation due to the anatomic complications of a hugely enlarged liver. The MELD/PELD score may not apply to these cases. One of the following complications should be present:
      a. Enlargement of liver impinging on respiratory function;
      b. Extremely painful enlargement of liver; or
      c. Enlargement of liver significantly compressing and interfering with function of other abdominal organs.
   3. The MELD/PELD score may apply to patients with amyloid polyneuropathy. Candidacy for liver transplant is an individual consideration based on the morbidity of the polyneuropathy. Many patients may not be candidates for liver transplant alone due to coexisting cardiac disease.
B. Living Donor Recipient:
   1. MELD score equal to or greater than 9 and less than or equal to 25; and
   2. Listed on the cadaveric liver transplant waiting list; and
   3. Has suffered at least one significant complication related to his or her liver disease (e.g., variceal hemorrhage, spontaneous bacterial peritonitis, encephalopathy, or severe impairment to his or her quality of life due to, for example, fatigue, pruritis).

III. Contraindications to Liver Transplantation:
A. Cadaveric Organ Recipient:
   1. Relative contraindications include:
      a. Major co-morbid illnesses such as ischemic heart disease, severe peripheral vascular disease, congestive cardiomyopathy, moderately severe COPD;
      b. HIV infection unless ALL of the following criteria are met:
         i. CD4 count greater than 100 cells/mm^3 for non-hepatitis C patients, greater than 200 cells/mm^3 for patients with hepatitis C;
         ii. HIV-1RNA undetectable;
         iii. On stable anti-retroviral therapy greater than 3 months;
         iv. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections, Kaposi's sarcoma, or other neoplasm); and
         v. Meets all other criteria for transplantation.
      c. Presence of malignancy within 5 years of transplantation (other than non-melanoma skin cancers), or unless malignancy has been completely resected, or unless (upon medical review) it is determined that malignancy has been treated with small likelihood of recurrence and acceptable future risks;
      d. Ongoing or recurring infections that are not effectively treated;

2. Absolute contraindications: uncontrolled behavioral health disorder that manifests in behaviors that that interfere with the patient's capacity to comply with surgical and follow-up management including but not limited to alcohol or substance abuse and major thought disorder.

B. Living Donor Organ Recipient:
   1. Hepatocellular carcinoma if:
      a. There is evidence of metastatic disease;
      b. The recipient can expect less than a one-year disease-free outcome;
   2. Simultaneous combined liver/kidney transplantation (however, in cases involving hyperoxalosis or other specific metabolic disorders, special consideration should be given to allowing simultaneous liver/kidney transplantation from two different donors).

IV. Living Donation Guidelines:
   A. Donor selection must be consistent with the New York State Department of Health, updates to that report, and relevant regulatory requirements.
   B. Donor should be "Emotionally related" to recipient (e.g., relative, previous known or current acquaintance).

POLICY GUIDELINES

I. Prior authorization is contract dependent. Approvals for all transplants, including arrangements with an approved transplant center, may be required.

II. Pre-transplant evaluation documentation could include the following clinical information. If testing is unable to be performed, the rationale for not performing the testing must be included in the documentation.
   A. Clinical Evaluation:
      1. Confirmation of diagnosis;
      2. Identification of comorbidities;
      3. Treatment of co-morbidities;
      4. Current assessment of co-morbidities;
      5. Consult notes (if applicable).
   B. Psycho-Social Evaluation:
      1. Karnofsky performance score; and/or Palliative Performance Scale (PPS) score.
      2. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol or substance abuse).
   C. Oral Health Evaluation
   D. Lab Tests:
      1. CBC, metabolic profile;
      2. Serologies: CMV, Hepatitis B and C;
      3. HIV Testing.
   E. Cardiac Assessment:
      1. 12 Lead EKG;
      2. Stress (exercise, nuclear, or dobutamine);
      3. Echo or Muga Scan.
   F. Pulmonary Assessment:
      1. Chest x-ray;
      2. Pulmonary function tests (PFTs) for high-risk for respiratory failure (COPD, emphysema, a-1-antritrypsin deficiency, hepatopulmonary syndrome, or significant smoking history);
      3. Low dose screening CT for individuals considered high-risk for lung cancer (e.g., 20-30 pack history of smoking).
   G. Age-Appropriate Screening Tests: Please refer to the U.S Preventive Services Task Force (USPSTF) website for list of age-appropriate screening guidelines. [https://uspreventiveservicestaskforce.org/uspstf/]

III. Re-authorization

Transplant re authorization must be completed annually while actively waiting for a transplant. Re-authorization documentation must be within the past eleven months (11) (unless specified) and include the following clinical information (if testing is unable to be performed, the rationale must be included in the documentation). If your health condition has not changed from the previous year some testing would not be applicable.

A. Clinical Evaluation:
   1. Updated list of diagnoses to include identification of comorbidities, current assessment and treatment plan.
   2. Specialty consultation notes (if applicable)

B. Current functional ability as evidence by current Karnofsky performance score (KPS); and/or Palliative Performance Scale (PPS) score.

C. Follow-up Oral Health Evaluation.

D. Lab Tests:
   1. CBC, metabolic profile;
   2. Serologies: CMV Hepatitis B and C; and
   3. HIV testing (If applicable)

E. Cardiac Assessment:
   1. 12 Lead EKG (If applicable); and
   2. Stress (exercise, nuclear, or dobutamine) (If applicable),
   3. Echo or Muga scan (If applicable).

F. Pulmonary Assessment:
   1. Chest x-ray (If applicable);
   2. Pulmonary function tests (PFTs) for high-risk for respiratory failure (COPD, emphysema, a-1-antritrypsin deficiency, hepatopulmonary syndrome, or significant smoking history) (If applicable)
   3. Low-dose screening CT for individuals considered high-risk for lung cancer (e.g., 20- to 30-pack history of smoking

G. Age-appropriate Screening Tests: Please refer to the U.S Preventive Services Task Force (USPSTF) website for list of age-appropriate screening guidelines. [https://www.uspreventiveservicestaskforce.org/uspstf/].

IV. Candidates who have end stage disease related to or impacted by alcohol consumption, including viral hepatitis, must demonstrate a period of abstinence through clinical treatment records (e.g., PCP, alcohol treatment programs). If the patient has been abstinent less than one month**s**, medical director consultation with the transplant center behavioral health team is required which includes an assessment by a trained Alcohol and Addiction Professional. The assessment should include history of addiction, harmful drinking patterns, awareness of harmful drinking by the patient, social environment along with family support, any identifiable psychiatric issues, and post-transplantation rehabilitation planning.

V. Candidates may be waitlisted at more than one transplant center. Since waiting time priority is first calculated among candidates at all hospitals within the local donation area, listing at transplant centers in different local allocation areas is recommended. Requirements for multiple-listed candidates may vary among transplant centers. When possible, results of tests used in the evaluation for the transplant at one center should be used at subsequent centers where the patient is listed.

DESCRIPTION

A liver transplant consists of replacing a diseased liver with a healthy liver or a segment of a healthy liver. Transplanted organs are harvested from either a cadaver (brain-dead donor) or from a living donor. In the latter case, a segment of the liver is typically transplanted. In a living donor liver transplantation (LDLT) a portion of the liver is surgically removed from a healthy living person and placed into someone whose liver is no longer working properly. The donor's remaining liver regrows and returns to its normal size, volume and capacity within a couple of months after the surgery. At the same time, the transplanted liver portion grows and restores normal liver function in the recipient. Liver transplantation is currently the treatment of last resort for patients with end-stage liver disease.

The United Network for Organ Sharing (UNOS) uses the Model for End-stage Liver Disease (MELD) and Pediatric End-stage Liver Disease (PELD) criteria. Candidates who are less than 12 years old receive a PELD score, while candidates

who are at least 12 years old receive a MELD score. Candidates listed for a liver transplant receive a MELD or PELD score, which is calculated using a combination of the candidate's clinical lab values. These scores are designed to reflect the probability of death on the waitlist within a 90-day period. Higher scores indicate a higher probability of mortality and increased urgency for transplant. Candidates that are considered urgent are assigned status 1A or 1B. MELD scores range from six (6) to 40, with higher scores indicating a higher risk of waitlist mortality and therefore increased urgency for transplant. MELD and PELD score ranges from six (6) to 40 and the calculators can be found at: [https://optn.transplant.hrsa.gov/resources/allocation-calculators/meld-calculator/]

And [https://optn.transplant.hrsa.gov/resources/allocation-calculators/peld-calculator/]

Multiple listing for organs is recommended by the Organ Procurement Transplant Network (OPTN). Multiple listing does not guarantee a shorter waiting time for an organ. Waiting time is affected by the type of organ, the number of organs donated that year as well as factors such as body size and blood type. Since some centers will not consider multiple listing of the patient at their center, the requirements for multiple-listed candidates should be investigated prior to an evaluation at the transplant center. Before acceptance into a transplant program an evaluation must be performed. To avoid duplicate testing from listing at more than one transplant center, many transplant centers will accept testing from another transplant center or allow specific tests to be obtained by the patient's in area physician.

Hepatoblastoma:

A malignant liver neoplasm that occurs almost exclusively in infants, although isolated cases in older children and adults have been reported. Grossly, hepatoblastoma (HB) is solid, well circumscribed, and more often solitary than multiple. Microscopically, most of the tumors are composed exclusively of immature hepatocytic elements. About a fourth of hepatoblastomas contain a stromal component that may be undifferentiated or develop into bone or cartilage. The treatment of choice for hepatoblastoma is surgical excision with adjuvant therapy. Liver transplantation is being increasingly used as well, with overall survival in primary liver transplantation at 80–90%.

Organ allocation in children under the age of 11 is based on the PELD Score. Because patients with HB have no underlying liver disease, their PELD scores are low and, as a result, these patients would rarely have access to a donor organ. In 2010, the United Network of Organ Sharing (UNOS) addressed this challenge by assigning a child with HB listed for liver transplantation a PELD exception score of 30. If after 30 days the child had not been transplanted, 1B status was assigned. In 2012, access to deceased-donor organs expanded further as all patients with HB were listed Status 1B without an obligatory wait period. Overall, since 2010, wait times have decreased by over forty percent. This modification has potentially prevented poor outcomes associated with disease progression while awaiting organ allocation.

RATIONALE

Transplantation represents the only curative approach for many patients with end-stage hepatic-disease. The limited availability of liver grafts demands a system that selects the best recipient of a transplant rather than one that selects the best treatment for a patient. To justify organ allocation, candidacy must be restricted to those whose survival is likely to be similar to that of other transplant recipients.

The MELD score's ability to predict risk of waitlist mortality has decreased since the time it was developed. A primary concern highlighted in recent literature is a disparity in access to transplant and waitlist outcomes for female candidates under the previous MELD system. The Organ Procurement Transplant Network (OPTN) made a set of improvements to MELD and PELD scores. The updated MELD score better predicts risk of waitlist mortality for all candidates and provide priority to female candidates to address these issues. On July 13, 2023, MELD 3.0 went into effect. MELD 3.0 improved the MELD formula by, incorporating additional variables (albumin and sex), updated coefficients for existing variables, introduced interaction terms, and lower the maximum creatinine value from 4.0 to 3.0 mg/dL. The new PELD score also referred to as PELD Creatinine or PELD Cr improved the PELD formula score by incorporating a creatinine variable to capture renal function, updated parameters for existing coefficients, and converted age and growth failure from categorical to continuous variables. The risk of waitlist mortality at a given PELD Cr scores aligns with the risk of waitlist mortality for an 18-year-old candidate with an equivalent MELD score.

Effective March 25, 2021, the Organ Procurement and Transplantation Network implemented a new policy to establish a system for the expedited placement of deceased donor whole livers in the event of a late turndown by an intended candidate. This policy clarifies how to place these organs and provides requirements for organ procurement organizations (OPOs) and transplant hospitals when there is a need to expedite placement of deceased donor livers. It also provides a consistent process which can be practiced across the country and regulated by policy.

For recipients with alcoholic cirrhosis, usually a 6-month period of abstinence is required prior to the liver transplant evaluation based on UNOS recommendations (1997). The impact of the 6-month rule on abstinence after transplant has been controversial however there is strong consensus for requiring this period of abstinence prior to listing for a liver transplant. During this time, the liver may recover from the acute inflammatory effects of recent alcohol exposure and improve enough that a transplant may no longer be needed. In addition, this period of abstinence may reinforce the patient's commitment to sobriety and allow for preventive strategies against future recidivism to be implemented. Waiving the 6-month period of abstinence may be based on multiple psycho-social factors such as, patient awareness of the cause of the disease from their alcohol intake and the toxic effects from alcohol dependence, past attempts at abstinence, any anxiety or depression, whether or not the patient is in a stable relationship, any family support, and if the patient has underlying psychiatric issues. Careful evaluation by a trained alcohol and addiction specialist with assessment of harmful drinking patterns, the potential recipient's family support, and insight of the patient regarding his disease. A plan for post- transplant rehabilitation should be included with the assessment and should include any behavior modification or support programs the patient will receive while awaiting transplant and after. The patient should also be monitored for relapse during the evaluation and waiting period.

Donor morbidity and mortality are prime concerns in adult donors undergoing partial hepatectomy. Subjecting healthy donors to the risks of surgery, especially in light of uncertain long-term outcomes, can be justified only in clinical circumstances in which the potential recipient has a compelling need for a living donor transplant; such as when a liver transplantation is the only therapeutic option, and a cadaveric transplantation is impossible or problematic for reasons such as anticipated waiting times. Due to the scarcity of donor organs and the success of living donation between parent and child, adult-to-adult living donor liver transplantation offers an option for appropriately screened recipients and donors.

Liver transplantation for candidates that are HIV positive has been controversial due to the long-term prognosis for HIV positivity, the impact of immunosuppression on HIV disease, and the interactions of immunosuppressive therapy with antiretroviral therapy in the setting of a transplanted liver. Additionally, the HIV candidates are frequently co-infected with hepatitis B or C, and viral co-infection can further exacerbate drug related hepatotoxicity's. Due to the advent of highly active antiretroviral therapy (HAART), which has markedly changed the natural history of the disease, and the increasing experience with liver transplant in HIV positive patients, HIV positive status is no longer an absolute contraindication. Currently UNOS states that asymptomatic HIV+ patients should not necessarily be excluded from candidacy for organ transplantation, stating, "A potential candidate for organ transplantation whose test for HIV is positive but who is in an asymptomatic state should not necessarily be excluded from candidacy for organ transplantation, but should be advised that he or she may be at increased risk of morbidity and mortality because of immunosuppressive therapy." The 2001 Clinical Practice Committee of the American Society of Transplantation proposed the presence of AIDS could be considered a contraindication to kidney transplant unless certain criteria were present. These criteria are listed in this policy regarding HIV status and liver transplants.

On June 25, 2020, the U.S. Department of Health and Human Services and the U.S. Public Health Service published an updated solid organ transplant guideline to assess donors and monitor recipients for human immunodeficiency virus (HIV), hepatitis B virus, and hepatitis C virus infections. This guideline reflects advances in transplant technology and safety that can increase the number of organs available for transplants.

Cholangiocarcinoma is an uncommon, aggressive malignancy of the biliary tract whose incidence and mortality rate has been increasing. Nonsurgical treatment of cholangiocarcinoma results are disappointing with the majority of patients surviving less than 1 year after diagnosis. Surgical resection of the liver provides improved 5-year survival rates of up to 50%. For those patients with nonresectable intrahepatic cholangiocarcinoma, liver transplant was unsatisfactory with poor outcomes. However recently liver transplant combined with neoadjuvant chemoradiation has proven to be a promising

option. Small studies from the Mayo Clinic have shown 5-year survival rates of up to 82% which is comparable to the overall survival rate for liver transplants.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN)*

CPT Codes

Code	Description
44132	Donor enterectomy (including cold preservation), open; from cadaveric donor
44133	Donor enterectomy (including cold preservation), open, partial, from living donor
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age
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 2 partial liver grafts (i.e., 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 2 partial liver grafts (i.e., left lobe [segments II, III, and IV] and right lobe [segments I and V through VIII])
47146	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each
47147	arterial anastomosis, each

HCPCS Codes

Code	Description
No code(s)	

ICD10 Codes

Code	Description
A52.15	Late syphilitic neuropathy

Code	Description
B15.0-B15.9	Acute hepatitis A (code range)
B16.0-B16.9	Acute hepatitis B (code range)
B17.10-B17.11	Acute hepatitis C (code range)
B17.8-B19.9	Other acute viral hepatitis (code range)
B25.1	Cytomegaloviral hepatitis
B66.1	Clonorchiasis
B66.3	Fascioliasis
C22.0	Liver cell carcinoma
C22.2-C22.9	Malignant neoplasm of liver and intrahepatic bile ducts (code range) (includes hepatoblastoma)
D64.0-D64.3	Other anemias (code range)
D81.810	Biotinidase deficiency
D84.1	Defects in the complement system
E70.0-E71.30	Disorders of aromatic amino-acid metabolism (code range)
E72.00-E73.1	Other disorders of amino-acid metabolism (code range)
E74.39	Other disorders of intestinal carbohydrate absorption (code range)
E74.4-E74.9	Other disorders of carbohydrate metabolism (code range)
E75.21-E75.3	Disorders of sphingolipid metabolism and other lipid storage disorders (code range)
E75.5-E75.6	Lipid storage disorders (code range)
E77.0-E77.9	Disorders of glycoprotein metabolism (code range)
E78.0-E78.9	Pure hypercholesterolemia (code range)
E80.0-E80.29	Disorders of porphyrin and bilirubin metabolism (code range)
E83.00-E83.19	Disorders of mineral metabolism (code range)
E88.89	Other specified metabolic disorders
E88.9	Metabolic disorder, unspecified
G60.0	Hereditary motor and sensory neuropathy
G60.2	Neuropathy in association with hereditary ataxia
G63	Polyneuropathy in diseases classified elsewhere
G65.0-G65.2	Sequelae of inflammatory and toxic polyneuropathies (code range)
G80.1-G80.9	Cerebral palsy (code range)
I82.0	Budd-Chiari syndrome
I99.9	Unspecified disorder of circulatory system
K71.0-K71.9	Toxic liver disease (code range)

Code	Description
K74.0	Hepatic fibrosis
K74.3-K74.69	Fibrosis and cirrhosis of liver (code range)
K75.2-K75.3	Other inflammatory liver diseases (code range)
K75.81-K75.89	Other specified inflammatory liver diseases (code range)
K75.9	Inflammatory liver disease, unspecified
K76.4	Peliosis hepatitis
K77	Liver disorders in diseases classified elsewhere
K80.30-K80.37	Calculus of bile duct with cholangitis (code range)
K83.0-K83.8	Other diseases of biliary tract (code range)
K87	Disorders of gallbladder, biliary tract and pancreas in diseases classified elsewhere
M34.83	Systemic sclerosis with polyneuropathy
Q44.2-Q44.3	Congenital malformations of gallbladder, bile ducts and liver (code range)
Q44.6	Cystic disease of liver
S31.609A	Unspecified open wound of abdominal wall, unspecified quadrant with penetration into peritoneal cavity, initial encounter
S36.112A	Contusion of liver, initial encounter

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*Key Article

KEY WORDS

Hepatic transplant, Liver Transplant, Living donor liver transplant.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) #260.1 Adult Liver Transplantation. Please refer to the following Adult Liver Transplantation website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=70&ncdver=3&bc=AgAAgAAAAAAAAA%3d%3d&] accessed 09/18/24.