

Liver Transplant

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Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary benefits.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

POLICY POSITION

1. Prior authorization is required.
2. Liver transplantation is currently the treatment of last resort for individuals with end-stage liver disease. Liver transplantation may be performed with a liver donation after a brain or cardiac death or with a liver segment donation from a living donor. Individuals are prioritized for transplant by mortality risk and severity of illness criteria developed by the Organ Procurement and Transplantation Network (OPTN) and the United Network of Organ Sharing (UNOS). The severity of illness is determined by the Model for End-stage Liver Disease (MELD) and Pediatric End-stage Liver Disease (PELD) scores.

3. A liver transplant using a cadaver or living donor may be considered medically necessary for carefully selected individuals with end-stage liver failure due to irreversibly damaged livers. Etiologies of end-stage liver disease include, but are not limited to ANY of the following:
- Hepatocellular Diseases
 - Alcoholic liver disease; or
 - Viral hepatitis (either A, B, C, or non-A, non-B); or
 - Autoimmune hepatitis; or
 - α_1 -Antitrypsin deficiency; or
 - Hemochromatosis; or
 - Nonalcoholic steatohepatitis; or
 - Protoporphyrria; or
 - Wilson disease; or
 - Cholestatic liver diseases
 - Primary biliary cirrhosis; or
 - Primary sclerosing cholangitis with development of secondary biliary cirrhosis; or
 - Biliary atresia; or
 - Vascular disease
 - Budd-Chiari syndrome; or
 - Primary Hepatocellular Carcinoma
 - Inborn Errors of Metabolism
 - Trauma and toxic reactions
 - Miscellaneous
 - Familial amyloid polyneuropathy

Liver transplantation may be considered medically necessary in individuals with polycystic disease of the liver who have massive hepatomegaly causing obstruction or functional impairment.

Liver transplantation may be considered medically necessary in individuals with unresectable hilar cholangiocarcinoma.

Liver transplantation may be considered medically necessary in pediatric individuals with nonmetastatic hepatoblastoma as per UNOS and OPTN guidelines.

Liver retransplantation may be considered medically necessary in individuals with ANY of the following:

- Primary graft nonfunction; or
- Hepatic artery thrombosis; or
- Chronic rejection; or
- Ischemic type biliary lesions after donation after cardiac death; or
- Recurrent non-neoplastic disease-causing late graft failure.

Liver transplantation is experimental and investigational and therefore noncovered because the safety/and/or effectiveness of this service cannot be established by the available published peer-reviewed literature for the following situations:

- Individuals with intrahepatic cholangiocarcinoma; or
- Individuals with neuroendocrine tumors metastatic to the liver.

Liver transplantation is considered not medically necessary in ANY of the following individuals;

- Individuals with hepatocellular carcinoma that has extended beyond the liver; or
- Individuals with ongoing alcohol and/or drug abuse:
 - Note: Evidence for abstinence may vary among liver transplant programs, but generally a minimum of 3 months is required.

Liver transplantation not meeting the criteria as indicated in this policy is considered not medically necessary.

In addition to the above criteria and subject to the discretion of the transplant center, a Hepatitis C Virus (HCV) positive donor organ may be considered an acceptable organ option for an HCV negative adult recipient 18 years of age or older.

4. Contraindications

Potential contraindications for solid organ transplant are subject to the judgment of the transplant center and may include, but is not limited to, the following:

- Known current malignancy, including metastatic cancer; or
- Recent malignancy with high risk of recurrence; or
- Untreated systemic infection making immunosuppression unsafe, including chronic infection; or
- Other irreversible end-stage diseases not attributed to liver disease; or
- History of cancer with a moderate risk of recurrence; or
- Systemic disease that could be exacerbated by immunosuppression; or
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

5. Liver-specific criteria

The MELD and PELD scores range from 6 (less ill) to 40 (gravely ill). The MELD and PELD scores will change during an individual's tenure on the waiting list.

Individuals with liver disease related to alcohol or drug abuse must be actively involved in a substance abuse treatment program.

Tobacco consumption is a contraindication.

Individuals with polycystic disease of the liver do not develop liver failure but may require transplantation due to the anatomic complications of a hugely enlarged liver. The MELD and PELD score may not apply to these cases. One of the following complications should be present:

- Enlargement of liver impinging on respiratory function; or
- Extremely painful enlargement of liver; or
- Enlargement of liver significantly compressing and interfering with function of other abdominal organs.

Individuals with familial amyloid polyneuropathy do not experience liver disease per se, but develop polyneuropathy and cardiac amyloidosis due to the production of a variant transthyretin molecule by the liver. MELD and PELD exception criteria and scores may apply to these cases. Candidacy for liver transplant is an individual consideration based on the morbidity of the polyneuropathy. Many individuals may not be candidates for liver transplant alone due to coexisting cardiac disease; or

a. Hepatocellular Carcinoma

Criteria used for individual selection of hepatocellular carcinoma (HCC) individuals eligible for liver transplant include the Milan criteria, which is considered the criterion standard, the University of California, San Francisco expanded criteria, and United Network of Organ Sharing (UNOS) criteria.

b. Milan Criteria

A single tumor 5 cm or less or 2 to 3 tumors 3 cm or less.

c. University of California, San Francisco Expanded Criteria

A single tumor 6.5 cm or less or up to 3 tumors 4.5 cm or less, and a total tumor size of 8 cm or less.

d. UNOS Stage T2 Criteria

A single tumor 2 cm or greater and up to 5 cm or less or 2 to 3 tumors 1 cm or greater and up to 3 cm or less and without extrahepatic spread or macrovascular invasion.

Individuals with HCC are appropriate candidates for liver transplant only if the disease remains confined to the liver. Therefore, the individual should be periodically monitored while on the waiting list, and if metastatic disease develops, the individual should be removed from the transplant waiting list. Also, at the time of transplant, a backup candidate should be scheduled. If locally extensive or metastatic cancer is discovered at the time of exploration before hepatectomy, the transplant should be aborted, and the backup candidate scheduled for transplant.

Note that liver transplant for those with T3 HCC is not prohibited by UNOS guidelines, but such individuals do not receive any priority on the waiting list. All individuals with HCC awaiting transplant are reassessed at 3 month intervals. Those whose tumors have progressed and are no longer stage T2 will lose the additional allocation points.

Additionally, nodules identified through imaging of cirrhotic livers are given a class 5 designation. Class 5B and 5T nodules are eligible for automatic priority. Class 5B criteria consist of a single nodule 2 cm or larger and up to 5 cm (T2 stage) that meets specified imaging criteria. Class 5T nodules have undergone subsequent locoregional treatment after being automatically approved on initial application or extension. A single class 5A nodule (greater than 1 cm and less than 2 cm) corresponds to T1 HCC and does not qualify for automatic priority. However, combinations of class 5A nodules are eligible for automatic priority if they meet stage T2 criteria. Class 5X lesions are outside of stage T2 and ineligible for automatic exception points. Nodules less than 1 cm are considered indeterminate and are not considered for additional priority. Therefore, the UNOS allocation system provides strong incentives to use locoregional therapies to downsize tumors to T2 status and to prevent progression while on the waiting list.

e. Cholangiocarcinoma

According to the Organ Procurement and Transplant Network policy on liver allocation, candidates with cholangiocarcinoma meeting the following criteria will be eligible for a MELD or PELD exception with a 10% mortality equivalent increase every 3 months:

- Centers must submit a written protocol for individual care to the OPTN and UNOS Liver and Intestinal Organ Transplant Committee before requesting a MELD score

exception for a candidate with cholangiocarcinoma. This protocol should include selection criteria, administration of neoadjuvant therapy before transplant, and operative staging to exclude individuals with regional hepatic lymph node metastases, intrahepatic metastases, and/or extrahepatic disease. The protocol should include data collection as deemed necessary by the OPTN and UNOS Liver and Intestinal Organ Transplant Committee; or

- Candidates must satisfy diagnostic criteria for hilar cholangiocarcinoma: malignant-appearing stricture on cholangiography and one of the following: carbohydrate antigen 19-9 100 U/mL, or and biopsy or cytology results demonstrating malignancy, or aneuploidy. The tumor should be considered unresectable on the basis of technical considerations or underlying liver disease (e.g., primary sclerosing cholangitis); or
- If cross-sectional imaging studies (computed tomography scan, ultrasound, magnetic resonance imaging) demonstrate a mass, the mass should be 3 cm or less; or
- Intra- and extrahepatic metastases should be excluded by cross-sectional imaging studies of the chest and abdomen at the time of initial exception and every 3 months before score increases; or
- Regional hepatic lymph node involvement and peritoneal metastases should be assessed by operative staging after completion of neoadjuvant therapy and before liver transplant; or endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude individuals with obvious metastases before neoadjuvant therapy is initiated; or
- Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative, or percutaneous approaches) should be avoided because of the high risk of tumor seeding associated with these procedures.

f. Living Donor Criteria

Donor morbidity and mortality are prime concerns in donors undergoing right lobe, left lobe, or left lateral segment donor partial hepatectomy as part of living donor liver transplant. Partial hepatectomy is a technically demanding surgery, the success of which may be related to the availability of an experienced surgical team. The American Society of Transplant Surgeons proposed the following guidelines for living donors (American Society of Transplant Surgeons: Ethics Committee. American Society of Transplant Surgeons' position paper on adult-to-adult living donor liver transplant):

- They should be healthy individuals who are carefully evaluated and approved by a multidisciplinary team including hepatologists and surgeons to assure that they can tolerate the procedure; or
- They should undergo evaluation to ensure that they fully understand the procedure and associated risks; or
- They should be of legal age and have sufficient intellectual ability to understand the procedures and give informed consent; or
- They should be emotionally related to the recipients; or
- They must be excluded if the donor is felt or known to be coerced; or
- They need to have the ability and willingness to comply with long-term follow-up.

6. Professional statements and societal positions guidelines

a. American Association for the Study of Liver Diseases et al-2013

The American Association for the Study of Liver Diseases and the American Society of Transplantation (2013) issued joint guidelines on evaluating [individuals] for liver transplant.

These guidelines indicated liver transplantation for severe acute or advanced chronic liver disease after all effective medical treatments have been attempted. The formal evaluation should confirm the irreversible nature of the liver disease and lack of effective alternative medical therapy.

The guidelines also stated that liver transplant is indicated for the following conditions:

- Acute liver failure complications of cirrhosis
- Liver-based metabolic condition with systemic manifestations
- Systemic complications of chronic liver disease.

The guidelines also included 1-A recommendations (strong recommendation with high-quality evidence) for a liver transplant that:

- “Tobacco consumption should be prohibited in LT [liver transplant] candidates.”
- “[Individuals] with HIV infection are candidates for LT if immune function is adequate and the virus is expected to be undetectable by the time of LT.”
- “LT candidates with HCV [hepatitis C virus] have the same indications for LT as for other etiologies of cirrhosis.”
- Contraindications to liver transplant included:
 - MELD [Model for End-stage Liver Disease] score less than 15
 - Severe cardiac or pulmonary disease
 - AIDS
 - Ongoing alcohol or illicit substance abuse
 - Hepatocellular carcinoma with metastatic spread
 - Uncontrolled sepsis
 - Anatomic abnormality that precludes liver transplantation
 - Intrahepatic cholangiocarcinoma
 - Extrahepatic malignancy
 - Fulminant hepatic failure
 - Hemangiosarcoma
 - Persistent noncompliance
 - Lack of adequate social support system

The American Association for the Study of Liver Diseases, the American Society of Transplantation, and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition issued joint guidelines on the evaluation of the pediatric [individuals] for liver transplant in 2014. The guidelines stated that “disease categories suitable for referral to a pediatric LT program are similar to adults: acute liver failure, autoimmune, cholestasis, metabolic or genetic, oncologic, vascular, and infectious. However, specific etiologies and outcomes differ widely from adult [individuals], justifying independent pediatric guidelines.” The indications listed for liver transplantation included biliary atresia, Alagille syndrome, pediatric acute liver failure, hepatic tumors, HCC, hemangioendothelioma, cystic fibrosis-associated liver disease, urea cycle disorders, immune-mediated liver disease, along with other metabolic or genetic disorders.

b. National Comprehensive Cancer Network-2020

The National Comprehensive Cancer Network (NCCN) guidelines on hepatobiliary cancers (v.5.2020) recommend referral to a liver transplant center or bridge therapy for [individuals] with HCC meeting United Network of Organ Sharing criteria of a single tumor measuring 2 to 5 cm, or 2 to 3 tumors 3 cm or less with no macrovascular involvement or extrahepatic disease. [Individuals] should be referred to the transplant center. [Individuals] should be

referred to the transplant center before the biopsy. In [individuals] who are ineligible for transplant and in select [individuals] with Child-Pugh class A or B liver function with tumors that are resectable, NCCN indicates resection is the preferred treatment option; locoregional therapy may also be considered. [Individuals] with unresectable HCC should be evaluated for liver transplantation; if the [individuals] is a transplant candidate, then referral to a transplant center should be given or bridge therapy should be considered. NCCN guidelines on hepatobiliary cancers also indicate that. These are level 2A recommendations based on lower-level evidence and uniform consensus.

The NCCN guidelines on neuroendocrine tumors (v.5.2020) indicate that liver transplantation included for neuroendocrine liver metastases is considered investigational despite “encouraging” 5-year survival rates.

ELIGIBLE PROCEDURE CODES

CPT codes	Description
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age.
47399	Unlisted procedure, liver.

1. Prior Authorization for above codes are required.

Heart, heart/lung, liver, cornea, bone marrow, pancreas, kidney with prior authorization and documentation that the following conditions were met:

- Current medical therapy has failed and will not prevent progressive disability and death;
- The patient does not have any other major systemic disease that would compromise that transplant outcome;
- There is every reasonable expectation, upon considering all circumstances involving the patient, that there will be strict adherence by the patient to the long term difficult medical regimen which is required;
- The transplant is likely to prolong life for at least two years and restore a range of physical and social function suited to the ADLs;
- The patient is not both in an irreversible terminal state (moribund) and on a life support system;
- The patient has a diagnosis appropriate for the transplant; and
- The patient does not have multiple uncorrectable severe major system congenital anomalies.

ELIGIBLE DIAGNOSIS CODES FOR PROCEDURE CODES 47135 AND 47399

Codes						
B15.0	B15.9	B16.0	B16.1	B16.2	B16.9	B17.10
B17.11	B17.8	B17.9	B18.0	B18.1	B18.2	B18.8
B18.9	B19.0	B19.10	B19.11	B19.20	B19.21	B19.9
B25.1	B66.1	B66.3	C22.0	C22.1	C22.2	C22.3
C22.4	C22.7	C22.8	C22.9	E70.0	E70.1	E70.20
E70.21	E70.29	E70.30	E70.310	E70.311	E70.318	E70.319

E70.320	E70.321	E70.328	E70.329	E70.330	E70.331	E70.338
E70.339	E70.39	E70.40	E70.41	E70.49	E70.5	E70.9
E71.0	E71.110	E71.111	E71.118	E71.120	E71.121	E71.128
E71.19	E71.2	E71.30	E71.310	E71.311	E71.312	E71.313
E71.314	E71.318	E71.32	E71.39	E71.40	E71.41	E71.42
E71.43	E71.440	E71.448	E71.50	E71.510	E71.511	E71.518
E71.520	E71.521	E78.0	E71.522	E71.528	E71.529	E71.53
E71.540	E71.541	E71.542	E71.548	E72.00	E72.01	E72.02
E72.03	E72.04	E72.09	E72.10	E72.11	E72.12	E72.19
E72.20	E72.21	E72.22	E72.23	E72.29	E72.3	E72.4
E72.50	E72.51	E72.52	E72.53	E72.59	E72.81	E72.89
E72.9	E74.00	E74.01	E74.02	E74.03	E74.04	E74.09
E74.10	E74.11	E74.12	E74.19	E74.20	E74.21	E74.29
E74.31	E74.39	E74.4	E74.9	E78.01	E78.1	E78.2
E78.3	E78.41	E78.49	E78.5	E78.6	E78.70	E78.79
E78.81	E78.89	E78.9	E80.0	E80.1	E80.20	E80.21
E80.29	E83.00	E83.01	E83.09	E83.10	E83.110	E83.111
E83.118	E83.119	E83.19	E85.0	E85.1	E85.2	E85.3
E85.4	E85.81	E85.82	E85.89	E85.9	E88.09	E88.1
E88.2	E88.3	E88.40	E88.41	E88.42	E88.49	E88.89
E88.01	G63	I74.8	I82.0	K70.2	K70.30	K70.31
K70.40	K70.41	K70.9	K71.0	K71.10	K71.11	K71.2
K71.3	K71.4	K71.50	K71.51	K71.6	K71.7	K71.8
K71.9	K72.00	K72.01	K71.10	K72.11	K72.90	K72.91
K73.2	K73.9	K74.00	K74.01	K74.02	K74.3	K74.4
K74.5	K74.60	K74.69	K75.2	K75.3	K75.4	K75.81
K76.0	K76.2	K76.3	K76.4	K76.5	K76.7	K76.89
K77	K83.1	K83.5	K83.8	Q44.1	Q44.2	Q44.3
Q44.4	Q44.5	Q44.6	Q44.7	S36.112A	S36.112D	S36.112S
S36.113A	S36.113D	S36.113S	S36.114A	S36.114D	S36.114S	S36.115A
S36.115D	S36.115S	S36.116A	S36.116D	S36.116S	S36.118A	S36.118D
S36.118S	S36.119A	S36.119D	S36.119S	T86.40	T86.41	T86.42
T86.43	T86.49	Z52.6	K83.0			

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POLICY UPDATE HISTORY

07/27/2022	Approved in Medical Policy Committee
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08/2022	Approved in QI/UM