MEDICAL POLICY – 7.03.509
Liver Transplant and Combined Liver-Kidney Transplant

Introduction

An organ transplant is the surgical process of replacing a severely diseased organ with a healthy one from a donor. The donated organ can come from a living person or a person who passed away from an accident or illness. Organ failure is the most common reason a transplant is needed. Organ failure can occur because of illness, injury, or birth defect. There are many factors that go into finding a donor organ that matches. These include blood type and the size of the organ. Other factors include how long a person has been on the waiting list, the level of illness, and the distance the donated organ must be transported. This policy describes when transplanting a liver or a liver/kidney combined may be considered medically necessary. This policy notes that a plan physician will review solid organ transplant requests together with the criteria of the transplant center.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Transplant</th>
<th>Medical Necessity</th>
</tr>
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</table>
| **Liver transplant using a cadaver or living donor** | 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, the following:  
  A. Hepatocellular diseases  
    - Alcoholic liver disease  
    - Viral hepatitis (either A, B, C, or non-A, non-B)  
    - Autoimmune hepatitis  
    - α1-Antitrypsin deficiency  
    - Hemochromatosis  
    - Nonalcoholic steatohepatitis  
    - Protoporphyria  
    - Wilson disease  
  B. Cholestatic liver diseases  
    - Primary biliary cirrhosis  
    - Primary sclerosing cholangitis with development of secondary biliary cirrhosis  
    - Biliary atresia  
  C. Vascular disease  
    - Budd-Chiari syndrome  
  D. Primary hepatocellular carcinoma (see Related Information for individual selection criteria)  
  E. Inborn errors of metabolism  
  F. Trauma and toxic reactions  
  G. Miscellaneous  
    - Familial amyloid polyneuropathy |

| **Liver transplantation** | 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 (see Related Information for individual selection criteria). |
### Transplant Medical Necessity

Liver transplantation may be considered medically necessary in pediatric individuals with nonmetastatic hepatoblastoma.

**Liver transplantation is considered not medically necessary in the following individuals:**

- Individuals with hepatocellular carcinoma that has extended beyond the liver (see Related Information for individual selection criteria)
- Individuals with ongoing alcohol and/or drug abuse except for those with:
  - Objective failure of therapy for severe acute alcoholic hepatitis.69 (See Appendix for Lille protocol).
  - Critical decompensation in alcohol related cirrhotic individuals as judged by MELD score (MELD-Na ≥21)\(^{59}\) predicting mortality prior to completion of required abstinence

**Note:** Evidence for abstinence may vary among liver transplant programs, but generally a minimum of 3 months is required.

### Liver retransplantation

Liver retransplantation may be considered medically necessary in individuals with:

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

### Combined liver-kidney transplantation

Combined liver-kidney transplantation may be considered medically necessary in individuals who qualify for liver transplantation and have advanced irreversible kidney disease.

### Transplant Investigational

Liver transplantation is investigational in the following situations:

- Individuals with intrahepatic cholangiocarcinoma
- Individuals with neuroendocrine tumors metastatic to the liver
Transplant | Investigational
---|---
Liver transplantation is considered investigational in all other situations not described above.

| HCV (hepatitis C) viremic solid organs |
The transplantation of HCV-viremic solid organs (kidney, lung, heart, liver, small bowel, pancreas) to an HCV non-viremic recipient combined with direct-acting antiviral treatment for HCV is considered investigational.

Documentation Requirements
The individual’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:
- Office visit notes that contain the relevant history and physical supporting that the individual has end stage liver disease due to irreversibly damaged livers from one of the listed etiologies. Request for liver transplant, combined liver/kidney transplant, or liver retransplantation is specified.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td>Liver allotransplantation; orthotopic; partial or whole, from cadaver or living donor, any age</td>
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<tr>
<td>47135</td>
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<tr>
<td>HCPCS</td>
<td>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 posttransplant care in the global definition</td>
</tr>
<tr>
<td>S2152</td>
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</table>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).
Contraindications

Potential contraindications for solid organ transplant are subject to the judgment of the transplant center and include the following:

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

Liver-Specific Criteria

The Model for End-stage Liver Disease (MELD) and Pediatric End-stage Liver Disease (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
- Extremely painful enlargement of liver
- 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.

**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.

**Milan Criteria**

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

**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.

**UNOS Stage T2 Criteria**

A single tumor 2 cm or greater and up to 5 cm or less or two to three tumors 1 cm or greater and up to 3 cm or less and without extrahepatic spread or macrovascular invasion. UNOS criteria were updated in 2022 (https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_09) Accessed September 7, 2022.

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 transplantation 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 transplantation 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 consists 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 (>1 cm and <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.

Cholangiocarcinoma

According to the Organ Procurement and Transplantation Network (OPTN) 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 three months:

- Centers must submit a written protocol for individual care to the OPTN and UNOS Liver and Intestinal Organ Transplantation Committee before requesting a MELD score exception for a candidate with cholangiocarcinoma. This protocol should include selection criteria, administration of neoadjuvant therapy before transplantation, 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 Transplantation Committee.

- 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 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).
• If cross-sectional imaging studies (computed tomography scan, ultrasound, magnetic resonance imaging) demonstrate a mass, the mass should be less than 3 cm.

• 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.

• Regional hepatic lymph node involvement and peritoneal metastases should be assessed by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude individuals with obvious metastases before neoadjuvant therapy is initiated.

• 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.

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 transplantation. 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 transplantation. Liver Transplant. 2000;6(6):815-817. PMID 11084076):

• 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

• They should undergo evaluation to ensure that they fully understand the procedure and associated risks

• They should be of legal age and have sufficient intellectual ability to understand the procedures and give informed consent

• They should be emotionally related to the recipients

• They must be excluded if the donor is felt or known to be coerced

• They need to have the ability and willingness to comply with long-term follow-up.
Benefit Application

Transplants, such as a liver or a liver-kidney transplant, should be considered for coverage under the transplant benefit and should be evaluated for a charge in accordance with traditional transplant benefits.

See member’s plan contract language for organ transplant benefits and specific benefits related to transport, lodging, and donor services. Please note limitations in coverage based on the transplant benefit, if applicable.

Evidence Review

Description

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 and the United Network of Organ Sharing. The severity of illness is determined by the Model for End-stage Liver Disease (MELD) and Pediatric End-stage Liver Disease (PELD) scores.

Background

Solid organ transplantation offers a treatment option for individuals with different types of end stage organ failure that can be lifesaving or provide significant improvements to a individual’s quality of life.1 Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Individuals are prioritized for transplant by mortality risk and severity of illness criteria developed by Organ Procurement and Transplantation Network and United Network of Organ Sharing.
Liver Transplantation

Liver transplantation is routinely performed as a treatment of last resort for individuals with end-stage liver disease. Liver transplantation may be performed with liver donation after a brain or cardiac death or with a liver segment donation from a living donor. Certain populations are prioritized as Status 1A (e.g., acute liver failure with a life expectancy of fewer than 7 days without a liver transplant) or Status 1B (pediatric individuals with chronic liver disease). Following Status 1, donor livers are prioritized to those with the highest scores on the Model for End-stage Liver Disease (MELD) and Pediatric End-stage Liver Disease (PELD) scales. Due to the scarcity of donor livers, a variety of strategies have been developed to expand the donor pool. For example, a split graft refers to dividing a donor liver into 2 segments that can be used for 2 recipients. Living donor liver transplantation (LDLT) is now commonly performed for adults and children from a related or unrelated donor. Depending on the graft size needed for the recipient, either the right lobe, left lobe, or the left lateral segment can be used for LDLT. In addition to addressing the problem of donor organ scarcity, LDLT allows the procedure to be scheduled electively before the recipient's condition deteriorates or serious complications develop. LDLT also shortens the preservation time for the donor liver and decreases disease transmission from donor to recipient.

Summary of Evidence

For individuals who have a hepatocellular disease who receive a liver transplant, the evidence includes registry studies and systematic reviews. The relevant outcomes include overall survival (OS), morbid events, and treatment-related morbidity and mortality. Studies on liver transplantation for viral hepatitis have found that survival is lower than for other liver diseases. Although these statistics raise questions about the most appropriate use of a scarce resource (donor livers), the long-term survival rates are significant in a group of individuals who have no other treatment options. Also, survival can be improved by the eradication of the hepatitis virus before transplantation. For individuals with nonalcoholic steatohepatitis (NASH), OS rates have been shown to be similar to other indications for liver transplantation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have primary hepatocellular carcinoma (HCC) who receive a liver transplant, the evidence includes systematic reviews of observational studies. The relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. In the past, long-term outcomes in individuals with primary hepatocellular malignancies had been poor (19%) compared with the OS of liver transplant recipients. However, the recent use of standardized
individual selection criteria (e.g., the Milan criteria diameter) has dramatically improved OS rates. In the appropriately selected individuals, a liver transplant has been shown to result in higher survival rates than resection. In individuals who present with unresectable organ-confined disease, transplant represents the only curative approach. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have extrahepatic cholangiocarcinoma who receive a liver transplant, the evidence includes systematic reviews of observational studies and individual registry studies. The relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. For individuals with extrahepatic (hilar or perihilar) cholangiocarcinoma who are treated with adjuvant chemotherapy, 5-year survival rates have been reported as high as 76%. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have intrahepatic cholangiocarcinoma who receive a liver transplant, the evidence includes registry studies and a systematic review of observational studies. The relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. In a registry study comparing outcomes in individuals with intrahepatic cholangiocarcinoma who received liver transplantation to those who received surgical resection of the liver, no differences were found in OS, length of stay, or unplanned 30-day readmission rates between groups. Additional studies reporting survival rates in individuals with intrahepatic cholangiocarcinoma or in mixed populations of individuals with extrahepatic and intrahepatic cholangiocarcinoma have reported 5-year survival rates of less than 30%. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have metastatic neuroendocrine tumors (NETs) who receive a liver transplant, the evidence includes systematic reviews of case series. The relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. In select individuals with nonresectable, hormonally active liver metastases refractory to medical therapy, liver transplantation has been considered as an option to extend survival and minimize endocrine symptoms. While some centers may perform liver transplants on select individuals with neuroendocrine tumors, the available studies are limited by their heterogeneous populations. Further studies are needed to determine the appropriate selection criteria. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have pediatric hepatoblastoma who receive a liver transplant, the evidence includes case series. The relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. The literature on liver transplantation for pediatric hepatoblastoma is limited, but case series have demonstrated good outcomes and high rates of long-term survival.
Additionally, nonmetastatic pediatric hepatoblastoma is among the United Network for Organ Sharing criteria for individuals eligible for liver transplantation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a failed liver transplant who receive a liver retransplant, the evidence includes observational studies. The relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. Case series have demonstrated favorable outcomes with liver retransplantation in certain populations, such as when criteria for original liver transplantation are met for retransplantation. While some evidence has suggested outcomes after retransplantation may be less favorable than for initial transplantation in some individuals, long-term survival benefits have been demonstrated. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with indications for liver and kidney transplant who receive a combined liver-kidney transplantation (CLKT), the evidence includes a systematic review of retrospective observational studies in adults and several individual registry studies. The relevant outcomes include OS, morbid events, and treatment-related morbidity and mortality. Most of the evidence involves adults with cirrhosis and kidney failure. Indications for CLKT in children are rare and often congenital and include liver-based metabolic abnormalities affecting the kidney, along with structural diseases affecting both the liver and kidney. In both adults and children, comparisons with either liver or kidney transplantation alone would suggest that CLKT is no worse, and possibly better, for graft and individual survival. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who require a liver transplant and are HCV non-viremic and receive a liver transplant from an HCV viremic donor combined with direct-acting antiviral agents (DAA), the evidence consists of multiple prospective and retrospective cohort studies. Relevant outcomes are overall survival, disease-specific survival, change in disease status, treatment-related mortality, treatment-related morbidity, morbid events, quality of life and resource utilization. The timing, duration and specific DAA regimens used in the published studies were different. Reported sustained virologic response at 12 weeks (SVR12) rates in these studies were 100%. Additionally, a retrospective analysis from a transplant registry reported similar 1- and 3-year graft survival among recipients who received liver transplant from HCV viremic donors versus those who received organs from HCV non-viremic donors. These studies enrolled a limited number of subjects as they intended to examine the feasibility of transplanting livers from HCV viremic donors into HCV non-viremic recipients and are informative in concluding that such a strategy is feasible; multicenter trials with standardized protocols, and rigorous adjudication of outcomes and adverse events are needed to confirm these promising results and demonstrate
their generalizability to settings outside of academic centers. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Ongoing and Unpublished Clinical Trials**

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
<thead>
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<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>NCT03500315</td>
<td>HOPE in Action Prospective Multicenter, Clinical Trial of Deceased HIV+ Kidney Transplants for HIV+ Recipients</td>
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<td>Dec 2022</td>
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<tr>
<td>NCT02878473</td>
<td>Liver Transplantation for the Treatment of Early Stages of Intrahepatic Cholangiocarcinoma in Cirrhotics</td>
<td>30</td>
<td>Jan 2029</td>
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<tr>
<td>NCT03819322</td>
<td>The Use of Hepatitis C Positive Livers in Hepatitis C Negative Liver Transplant Recipients</td>
<td>20</td>
<td>May 2024</td>
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<tr>
<td><strong>Unpublished</strong></td>
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<tr>
<td>NCP03650920</td>
<td>Hepatitis C Virus (HCV) Positive Liver Grafts in HCV Negative Recipients</td>
<td>89</td>
<td>Feb 2021 Completed</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

**Clinical Input Received from Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from three physician specialty societies and five academic medical centers while this policy was under review in 2012. There was a consensus
among reviewers that liver transplantation may be medically necessary for end-stage liver failure due to irreversibly damaged livers from various disease states such as those considered during the report update. There was also a consensus among reviewers that liver retransplantation is appropriate in individuals with acute or chronic liver failure such as primary graft nonfunction, ischemic-type biliary injury after donation after cardiac death, hepatic artery thrombosis, chronic rejection or recurrent diseases such as primary sclerosing cholangitis, autoimmune hepatitis, and hepatitis C resulting in end-stage liver failure. There was general support for the use of liver transplantation as a treatment for cholangiocarcinoma in individuals who meet strict eligibility criteria. In general, there was no support for the use of liver transplantation for a neuroendocrine tumor metastatic to the liver.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

International Consensus Conference
In 2010, an International Consensus Conference, including representation from the U.S., convened with the goal of reviewing current practice regarding liver transplantation in individuals with hepatocellular carcinoma (HCC). The Conference ultimately came up with recommendations beginning from the assessment of candidates with HCC for liver transplantation and managing individuals on waitlists, to the role of liver transplantation and post-transplant management. Some notable recommendations are described.

The Milan criteria were recommended for use as the benchmark for individual selection, although it was suggested that the Milan criteria might be modestly expanded based on data from expansion studies that demonstrated outcomes are comparable with outcomes from studies using the Milan criteria. Candidates for liver transplantation should also have a predicted survival of five years or more. The consensus criteria indicate alpha-fetoprotein concentrations may be used with imaging to assist in determining individual prognosis.

Regarding liver retransplantation, the consensus criteria issued a weak recommendation for retransplantation after graft failure of a living donor transplant for hepatocellular carcinoma.
(HCC) in individuals meeting regional criteria for a deceased donor liver transplant. A strong recommendation was issued against liver retransplantation with a deceased donor for graft failure for individuals exceeding regional criteria. Also, the consensus criteria issued a strong recommendation that liver retransplantation for recurrent HCC would not be appropriate. However, a de novo case of HCC may be treated as a new tumor, and retransplantation may be considered even though data to support this is limited.

**American Association for the Study of Liver Diseases and American Society of Transplantation**

In 2013, the American Association for the Study of Liver Diseases and the American Society of Transplantation issued joint guidelines on evaluating individuals for a 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
  - α1-Antitrypsin deficiency
  - Familial amyloidosis
  - Glycogen storage disease
  - Hemochromatosis
  - Primary oxaluria
  - Wilson disease
- 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."
"Patients with HIV [Human Immunodeficiency Virus] 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 < 15
- Severe cardiac or pulmonary disease
- AIDS [acquired immunodeficiency syndrome]
- 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."

In 2014, 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. 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 patients, 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.

The American Association for the Study of Liver Diseases

In 2019, the American Association for the Study of Liver Diseases guideline on alcohol-associated liver disease provided recommendations on the timing of referral and selection of candidates for liver transplant. The guidance notes that the individual's history of addiction to alcohol is a primary driver in selecting appropriate candidates for liver transplantation. Clinical characteristics that should trigger an evaluation and consideration for liver transplant include decompensated alcohol-associated cirrhosis, Child-Pugh-Turcotte class C cirrhosis, or a MELD-Na score ≥21. Additionally, the guideline notes that candidate selection "should not be based solely on a fixed interval of abstinence" and instead a formal psychological evaluation can help stratify individuals into higher- or lesser-risk strata for relapse.

The American Association for the Study of Liver Diseases and the Infectious Diseases Society of America have published online HCV guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. The recommendation for treatment of HCV-uninfected transplant recipients receiving organs from HCV viremic donors are summarized in Table 2. These guidelines were last updated on September 29, 2021.

Table 2. American Association for the Study of Liver Diseases
Recommendations When Considering Use of Hepatitis C Virus Viremic Donor Organs in Hepatitis C Virus Uninfected Recipients

<table>
<thead>
<tr>
<th>Recommendation When Considering Use of HCV Viremic Donor Organs in HCV Uninfected Recipients</th>
<th>Rating</th>
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<tbody>
<tr>
<td>Informed consent should include the following elements:</td>
<td>I, C</td>
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<tr>
<td>• Risk of transmission from an HCV viremic donor (and with a PHS-defined increased risk donor, the potential risks for other viral infections)</td>
<td></td>
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<tr>
<td>• Risk of liver disease if HCV treatment is not available or treatment is unsuccessful</td>
<td></td>
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<tr>
<td>• Risk of graft failure</td>
<td></td>
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<tr>
<td>• Risk of extrahepatic complications, such as HCV-associated renal disease</td>
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<tr>
<td>• Risk of HCV transmission to partner</td>
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</tbody>
</table>
### Recommendation When Considering Use of HCV Viremic Donor Organs in HCV Uninfected Recipients

**Benefits, specifically reduced waiting time and possibly lower waiting list mortality**
- Other unknown long-term consequences (hepatic and extrahepatic) of HCV exposure (even if cure is attained)

**Transplant programs should have a programmatic strategy to:**
- Document informed consent
- Assure access to HCV treatment and retreatment(s), as necessary
- Ensure long-term follow-up of recipients (beyond SVR12)

### Recommendation Regarding Timing of DAA Therapy for HCV Negative Recipients of HCV Viremic Liver Transplant

**Rating**

**Early** treatment with a pangenotypic DAA regimen is recommended when the patient is clinically stable.

### Recommendations for Treatment of HCV Uninfected Recipients of Liver Grafts from HCV Viremic Donors

<table>
<thead>
<tr>
<th>DAA Combination</th>
<th>Rating</th>
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<tbody>
<tr>
<td>Glecaprevir (300 mg)/Pibrentasvir (120 mg)</td>
<td>I, C</td>
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<tr>
<td>Sofosbuvir (400 mg)/Velpatasvir (100 mg)</td>
<td>I, C</td>
</tr>
</tbody>
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### Recommendation Regarding Timing of DAA Therapy for HCV Negative Recipients of HCV Viremic Non-Liver Solid Organ Transplant

**Rating**

**Prophylactic**/preemptive treatment with a pangenotypic DAA regimen is recommended

### Recommendations for Treatment of HCV Uninfected Recipients of Non-Liver Organs from HCV Viremic Donors

<table>
<thead>
<tr>
<th>DAA Combination</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glecaprevir (300 mg)/Pibrentasvir (120 mg)</td>
<td>I, C</td>
</tr>
<tr>
<td>Sofosbuvir (400 mg)/Velpatasvir (100 mg)</td>
<td>I, C</td>
</tr>
</tbody>
</table>

---

**DAA:** direct acting antiviral; **HCV:** hepatitis C virus; **SVR12:** sustained virologic response; **PHS:** United States Public Health Service

**Early treatment refers to starting within the first month after liver transplant, preferably within the first week when the patient is clinically stable.**

**Listed by evidence level and alphabetically. Other considerations in selection of the DAA regimen:**
- Presence of liver dysfunction (e.g., elevated bilirubin) as protease inhibitors should be avoided
- Specific drugs that are contraindicated or not recommended with specific DAA agents, including but not limited to:
  - High-dose antacid therapy (e.g., twice daily proton pump inhibitor)
  - Amiodarone (contraindicated with sofosbuvir-inclusive regimens; see prescribing information)
  - Specific statins (e.g., atorvastatin)
  - Consideration of immunosuppressive drugs and DAA interactions
c Dosing is 3 coformulated tablets (glecaprevir [100 mg]/pibrentasvir [40 mg]) taken once daily. Refer to the prescribing information.
d Prior to HCV RNA results, typically immediately pre-transplant or day 0 post-transplant
e Day 0 to within the first week post-transplant, typically as soon as the individual is deemed clinically stable

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) guidelines on hepatobiliary cancers (v.1.2022) 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 two to three tumors 3 cm or less with no macrovascular involvement or extrahepatic disease. 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, the 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 individual is a transplant candidate, then referral to a transplant center should be given or bridge therapy should be considered. The NCCN guidelines on hepatobiliary cancers also indicate that individuals with unresectable disease who are not a transplant candidate should receive locoregional therapy with ablation, arterially directed therapies, or external beam radiation therapy (preferred) or may receive systemic therapy, best supportive care, or be enrolled in a clinical trial. These are level 2A recommendations based on lower-level evidence and uniform consensus.

The NCCN guidelines on neuroendocrine tumors (v.1.2022) indicate that liver transplantation for neuroendocrine liver metastases is considered investigational despite "encouraging" 5-year survival rates.

The American Society of Transplantation

The American Society of Transplantation (2017) convened a consensus conference of experts to address issues related to the transplantation of hepatitis C virus (HCV) viremic solid organs into HCV non-viremic recipients. Key findings and recommendations are summarized in Table 3.
Table 3. American Society of Transplantation Consensus Conference - Use of Hepatitis C Virus Viremic Donors

<table>
<thead>
<tr>
<th>Content Area</th>
<th>Key Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition of HCV positive</td>
<td>HCV viremic reflecting a positive NAT should be adopted</td>
</tr>
<tr>
<td>Data interpretation</td>
<td>HCV antibody status alone limits interpretation of outcomes of transplantation of HCV “positive” organs</td>
</tr>
<tr>
<td>Transmission and Treatment</td>
<td>Highest risk for unexpected HCV transmission is associated with organ donation from a person who injected drugs within the eclipse or pre-viremic period</td>
</tr>
<tr>
<td>OPTN policy</td>
<td>No current policies prevent transplantation of HCV-viremic organs into HCV non-viremic recipients</td>
</tr>
<tr>
<td>Ethical considerations</td>
<td>Transplantation of HCV-viremic organs into HCV non-viremic recipients should be conducted under site specific IRB approved protocols with multi-step informed consent.</td>
</tr>
</tbody>
</table>

HCV: hepatitis-C virus; NAT: nucleic acid test; OPTN: Organ Procurement and Transplantation Network

Medicare National Coverage

Medicare covers adult liver transplantation for end-stage liver disease and HCC when performed in a facility approved by the Centers for Medicare & Medicaid Services as meeting institutional coverage criteria for liver transplants.69,70 The following conditions must be met for coverage of HCC:

- "The patient is not a candidate for subtotal liver resection;
- The patient's tumor(s) is less than or equal to 5 cm in diameter;
- There is no macrovascular involvement; and
- There is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone; and
- The transplant is furnished in a facility that is approved by CMS [Centers for Medicare & Medicaid Services] ..."

Beginning in June 2012, on review of this national coverage decision for new evidence, Medicare began covering adult liver transplantation, at Medicare administrative contractor discretion, for extrahepatic unresectable cholangiocarcinoma, liver metastases due to a neuroendocrine tumor, and hemangioendothelioma. Adult liver transplantation is excluded from other malignancies.
Pediatric liver transplantation is covered for children (<18 years of age) when performed at pediatric hospitals approved by the Centers for Medicare & Medicaid Services. Coverage includes extrahepatic biliary atresia or any other form of end-stage liver disease, except for children with a malignancy extending beyond the margins of the liver or those with persistent viremia.

**Regulatory Status**

Solid organ transplants are a surgical procedure and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA).

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation Title 21, parts 1270 and 1271. Solid organs used for transplantation are subject to these regulations.

**References**


Appendix

Lille Protocol


- Non-responsive to medical therapy defined as a Lille model score > 0.45 or more after 7 days of medical therapy. Calculation available at: https://www.mdcalc.com/lille-model-alcoholic-hepatitis Accessed September 7, 2022.
  - Medical therapy consists of standard medical care for liver insufficiency and use of glucocorticoids (40 mg per day of prednisolone for at least 7 days); OR
  - As a continuous increase in the Model for End-Stage Liver Disease (MELD) score
- Severe alcoholic hepatitis as the first liver-decompensating event
- Presence of close supportive family members
- Absence of severe coexisting or psychiatric disorders
- Agreement by individuals (with support from family members) to adhere to lifelong total abstinence
- Selection process consists of 4 medical teams who independently meet the individual and family members
  - Team 1: (closest to the individual): nurses, one resident, one fellow
  - Team 2: specialist in addiction
  - Team 3: senior hepatologists


- Team 4: anesthesiologist and transplant surgeon

- The 4 evaluating teams have to reach complete consensus on selection


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/01/02</td>
<td>Add to Surgery Section - New Policy. Replaces other transplant policies (PR.7.03.100, 102, 103, 104, 105, and 106)</td>
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<tr>
<td>05/13/03</td>
<td>Replace Policy - Scheduled review. References added and CPT code table updated.</td>
</tr>
<tr>
<td>01/01/04</td>
<td>Replace Policy - CPT code updates only.</td>
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<tr>
<td>05/11/04</td>
<td>Replace Policy - Policy reviewed by Nancy Aceto no changes needed at this time; new review date only. Appendices removed—no value.</td>
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<tr>
<td>09/01/04</td>
<td>Replace Policy - Policy renumbered from PR.7.03.109. No changes to dates.</td>
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<tr>
<td>05/10/05</td>
<td>Replace Policy - Scheduled review. References added. No change to policy statement.</td>
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<td>02/06/06</td>
<td>Codes updated - No other changes.</td>
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<tr>
<td>05/09/06</td>
<td>Replace Policy - Scheduled review. References added; no change to policy statement.</td>
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<tr>
<td>05/26/06</td>
<td>Scope and Disclaimer Updates - No other changes.</td>
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<tr>
<td>02/26/07</td>
<td>Codes Updated - No other changes.</td>
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<td>05/08/07</td>
<td>Replace Policy - Policy updated with literature review; reference added. No change in policy statement.</td>
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<tr>
<td>05/21/07</td>
<td>References Updated - Policy updated with information on Medicare coverage of heart transplants.</td>
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<tr>
<td>05/13/08</td>
<td>Replace Policy - Policy updated with literature search. Policy statement to include using a cadaver or living donor under kidney transplants as a medically necessary indication. Also to include “imminent end-stage liver failure” for patients under liver transplants as medically necessary.</td>
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<td>03/10/09</td>
<td>Replace Policy - Policy updated with literature search; references added. No change to policy statement.</td>
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<td>02/09/10</td>
<td>Replace Policy - Policy updated with literature search. No change to policy statement.</td>
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<tr>
<td>01/11/11</td>
<td>Replace Policy - Policy updated with literature search. No change to policy statement.</td>
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<td>Comments</td>
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<td>------------</td>
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<td>12/03/12</td>
<td>Update title to Related Policy 7.03.11.</td>
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<td>01/29/13</td>
<td>Replace policy. Policy updated with literature search. No change to policy statement. References updated.</td>
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<tr>
<td>02/12/13</td>
<td>Update Related Policies, change title for 8.02.02.</td>
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<tr>
<td>05/30/13</td>
<td>Update Related Policies. Change title for 7.03.510.</td>
</tr>
<tr>
<td>02/10/14</td>
<td>Replace policy. Retransplant policy statements added to kidney, heart, heart/lung. Literature updated. References 35-39 added. ICD-9 Diagnosis codes were listed for informational purposes only and have been removed from the policy.</td>
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<td>03/11/14</td>
<td>Coding Update. Codes 33.50, 33.51, 33.52, 33.6, 37.5, 50.4, 50.51, 50.59, 52.80, 52.81, 52.82, 52.83, and 55.69 were removed per ICD-10 mapping project; these codes are not utilized for adjudication of policy.</td>
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<td>03/31/15</td>
<td>Annual Review. Alphabetized names of organ transplants in policy statements. Related policy 7.03.05 added. Rationale section extensively reorganized by alphabetizing organ transplants and updated based on a literature review through December, 2014. References extensively renumbered and some references removed. Policy statements unchanged.</td>
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<td>08/19/15</td>
<td>Update Related Policies. Remove 7.03.510 and 8.02.02 then add 8.03.05 and 7.03.04.</td>
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<td>09/24/15</td>
<td>Coding update. ICD-9 Procedure codes removed; these are informational only.</td>
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<td>01/12/16</td>
<td>Annual Review. Policy updated with literature search; references added. No change to the policy statement.</td>
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<tr>
<td>01/29/16</td>
<td>Coding update. Added HCPCS code S2152.</td>
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<tr>
<td>11/01/16</td>
<td>Update related policies. Removed 7.03.05 from related policies section as it was deleted (contents moved to 7.03.04).</td>
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<tr>
<td>01/01/17</td>
<td>Coding Update. Transplant benefit-related codes removed. Coding table moved to Policy Guidelines section. Updated titles of some Related Policies.</td>
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<td>03/01/17</td>
<td>Annual Review, approved February 14, 2017. Policy updated with literature review through October 25, 2016; references renumbered. Policy statements unchanged.</td>
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<td>04/14/17</td>
<td>Coding update; added HCPCS code S2060.</td>
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<tr>
<td>04/18/17</td>
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<tr>
<td>09/01/17</td>
<td>Policy moved to new format. No changes to policy statement.</td>
</tr>
<tr>
<td>07/27/18</td>
<td>Coding update; added CPT 33935 to policy as it was inadvertently removed.</td>
</tr>
<tr>
<td>11/01/18</td>
<td>Annual Review, approved October 26, 2018. Policy updated with literature review through June 2018; references 42, 51, 56, 82, 87, 89, 94, 109, 111, 118, 120,136, 158, 164, 178,183, 184, and 201 added. Examples of end-stage cardiac and pulmonary</td>
</tr>
</tbody>
</table>
diseases added for clarity under heart and lung transplant. Etiologies of end-stage liver disease added for clarity, polycystic disease of the liver, unresectable hilar cholangiocarcinoma, pediatric patients with nonmetastatic hepatoblastoma are added as medically necessary indications for liver transplantation. Indications for liver retransplantation were added. Indications where liver transplantation is not medically necessary or is considered investigational were added, otherwise policy statements unchanged.

04/01/19 Minor update, added Documentation Requirements section.

11/01/19 Annual Review approved October 8, 2019. Policy title changed from “Solid Organ Transplants” to “Liver Transplant and Combined Liver-Kidney Transplant”. Previous content of Solid Organ Transplants is now addressed in individual policies (7.03.01, 7.03.02, 7.03.07, 7.03.08, 7.03.09) except for liver and combined liver-kidney transplant. Policy updated with literature review through June 2019. References added. Added exception criteria for patients with ongoing alcohol abuse. Added policy statement on transplantation of HCV viremic organs which is taken from BCBSA policy 7.03.14.

04/01/20 Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.

06/10/20 Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.


11/01/22 Annual Review, approved October 24, 2022. Policy updated with literature review through June 27, 2022; references added and updated. Minor editorial refinements to policy statements; intent unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2022 Premera All Rights Reserved.

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