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Subject: Liver Transplant and Combined Liver-Kidney Transplant

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DESCRIPTION:

Liver transplantation is now routinely performed as a treatment of last resort for those 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. Candidates 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. The liver allocation system adopted includes the Model for End-stage Liver Disease (MELD) and Pediatric End-stage Liver Disease (PELD) scales. Scoring on the MELD and PELD uses a continuous disease severity scale based entirely on objective laboratory values.

Summary and Analysis of Evidence: The evidence on liver transplantation for a hepatocellular disease includes registry studies and systematic reviews. Long-term survival rates in patients with viral hepatitis are significant in a group of patients who have no other treatment options. Also, survival can be improved by the eradication of the hepatitis virus before transplantation. For patients with nonalcoholic steatohepatitis (NASH), a 2014 systematic review has indicated that overall (OS) rates are similar to other indications for liver transplantation. (Yong et al, 2023; Cholankeril et al, 2017; Wang et al, 2014).

The presence of hepatitis B virus and hepatitis C virus (HCV) have been controversial indications for liver transplantation because of the high potential for recurrence of the virus and subsequent recurrence of liver disease. However, registry data have indicated a long-term survival rate (7 years) of 47% in hepatitis B virus-positive transplant recipients, which is lower than that seen in other primary liver diseases such as primary biliary cirrhosis (71%) or alcoholic liver disease (57%). Recurrence of HCV infection in transplant recipients who are not treated pretransplant has been nearly universal, and 10% to 20% of patients will develop cirrhosis within 5 years (Sheiner, Rochon, 2012; Belle et al, 1995).

Historical data demonstrating inferior survival in transplant recipients with HCV is not applicable to the current treatment landscape with the availability of direct acting antiviral agents, which are associated

with sustained virological response rates of over 95%. Timing the receipt of direct acting antiviral agents either before or after transplantation is still controversial and the decision should be individualized based on the presence of compensated/decompensated disease, Model for End-Stage Liver Disease (MELD) score, current quality of life, and the proportion of HCV-positive donors in the local and regional areas. (Gadiparthi et al, 2018).

Use of standardized patient selection criteria, such as the Milan criteria (a solitary tumor with a maximum tumor diameter of ≤5 cm, or up to 3 tumors ≤3 cm and without extrahepatic spread or macrovascular invasion), has led to improved OS rates. A 2012 systematic review reported 5-year OS rates ranged from 65% to 94.7%. In a 2013 meta-analysis a liver transplant was shown to result in higher survival rates than resection. Similar outcomes were identified in a 2017 meta-analysis, in which transplantation showed a significantly improved survival benefit, especially for patients with early HCC. In patients who present with unresectable organ-confined disease, transplant represents the only curative approach (Murali et al, 2017; Zhu et al, 2013; Maggs et al, 2012).

The evidence on liver transplantation in patients with extrahepatic (hilar or perihilar) cholangiocarcinoma includes systematic reviews and observational studies. For patients with extrahepatic cholangiocarcinoma treated with a liver transplant and adjuvant chemotherapy, 5-year survival rates have been reported to be as high as 76%. (Cambridge et al, 2021; Gu et al, 2012; Darwish Murad et al, 2012)

The evidence on liver transplantation in patients with intrahepatic cholangiocarcinoma includes systematic reviews, as well as a systematic review of observational studies. In a registry study comparing outcomes in patients 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 patients with intrahepatic cholangiocarcinoma or in mixed populations of patients with extrahepatic and intrahepatic cholangiocarcinoma have reported 5-year survival rates of less than 30% (Ziogas et al, 2021; Hue et al, 2020).

The evidence on liver transplant for neuroendocrine tumors (NETs) includes systematic reviews of NETs for metastases of any origin. In select patients 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 there may be centers that perform liver transplantation in select patients with NETs, the available studies were limited by their heterogeneous populations. Further studies are needed to define the appropriate selection criteria (Fan et al, 2015; Mathe et al, 2011).

Hepatoblastoma is a rare malignant primary solid tumor of the liver that occurs in children. Treatment consists of chemotherapy and resection; however, tumors are often not discovered until they are unresectable. In cases of unresectable tumors, liver transplantation with pre- and/or postchemotherapy is a treatment option with reports of good outcomes and high rates of survival. The UNOS guidelines list nonmetastatic hepatoblastoma as a condition eligible for pediatric liver transplantation (UNOS, 2023; Czauderna et al, 2005)

Observational studies have evaluated the risk factors with a failed liver transplant for survival after liver retransplantation. Reported OS rates are lower after retransplantation than after initial liver

transplantation, but survival rates are acceptable in appropriately selected patients given the lack of treatment-related options (Salimi et al, 2021; Bellido et al, 2012).

The evidence on combined liver-kidney transplantation includes a systematic review of retrospective observational studies in adult patients and several registry studies that have compared combined organ transplantation with liver or with kidney transplantation alone. In adults undergoing liver transplant with kidney failure, a systematic review did not find differences in 1-, 3-, or 5-year survival when comparing combined liver-kidney transplantation to liver transplantation alone. Individual registry studies showed that combined liver-kidney transplantation resulted in a modest improvement in patient survival compared with liver transplantation alone. Liver allograft survival was also higher in the patients who received combined liver-kidney transplantation compared with patients who received a liver transplant alone. Relatively few children have received combined liver-kidney transplantation. Patient survival has been reported to be worse with combined liver-kidney transplantation than with kidney transplantation alone, but no worse than for liver transplant alone. For kidney grafts that survive the first 6 months, the organ survival rate may be better than for a kidney graft alone. Together, these results would suggest that combined liver-kidney transplantation is no worse, and possibly better, for graft and patient survival in adults and children who meet the requirements for liver transplantation and have concomitant renal failure. Indications for combined liver-kidney transplantation 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 (Bouari et al, 2021; Lunsford et al, 2017; Calinescu et al, 2014; Fong et al, 2012; de la Cerda et al, 2010; Ruiz et al, 2010).

POSITION STATEMENT:

Certificate of Medical Necessity

Submit a completed Certificate of Medical Necessity (CMN) along with your request to expedite the medical review process.

1. Click the link Solid Organ Transplant under Certificates of Medical Necessity in the side navigation of this page to access the form.
2. Complete all fields on the form thoroughly.
3. Print and submit a copy of the form with your request.

Note: Florida Blue regularly updates CMNs. Ensure you are using the most current copy of a CMN before submitting to Florida Blue.

A liver transplant, using a cadaver or living donor, **meets the definition of medical necessity** for carefully selected individuals with end-stage liver failure resulting from irreversible liver damage. Etiologies of end-stage liver disease include, but are not limited to:

A. Hepatocellular disease

- Alcoholic liver disease
- Viral hepatitis (A, B, C, or non-A, non-B)

- Autoimmune hepatitis
 - Alpha-1 antitrypsin deficiency
 - [Hemochromatosis](#)
 - Non-alcoholic steatohepatitis
 - Protoporphyrin
 - Wilson's disease
- B. Cholestatic liver disease**
- Primary biliary cirrhosis
 - Primary [sclerosing cholangitis](#) with development of secondary biliary cirrhosis
 - [Biliary atresia](#)
- C. Vascular disease**
- [Budd-Chiari syndrome](#)
- D. Primary hepatocellular carcinoma with ONE of the following:**
- A single tumor 5 cm or less, **OR** 2 to 3 tumors that are 3 cm or less (Milan criteria), **OR**
 - 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 (University of California, San Francisco Expanded Criteria), **OR**
 - 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 (UNOS Stage T2 Criteria)
- E. Inborn errors of metabolism**
- F. Trauma and toxic reactions**
- G. Miscellaneous**
- Familial amyloid polyneuropathy*

Liver transplantation **meets the definition of medical necessity** in candidates with polycystic disease of the liver who have massive hepatomegaly causing obstruction or functional impairment.

Liver transplantation **meets the definition of medical necessity** in candidates with unresectable hilar cholangiocarcinoma.

Liver transplantation **meets the definition of medical necessity** in pediatric candidates with non-metastatic hepatoblastoma.

Liver re-transplantation **meets the definition of medical necessity** in those with:

- Primary graft non-function
- 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 **meets the definition of medical necessity** in those who qualify for liver transplantation and have advanced irreversible kidney disease.

Liver transplant **does not meet the definition of medical necessity** for the following:

- Hepatocellular carcinoma that has extended beyond the liver
- The transplant candidate is not approved by the transplant committee for the institution where the transplant will be performed

Liver transplant is considered **experimental or investigational** for the following conditions, as available clinical evidence does not support safety and effectiveness:

- Intrahepatic cholangiocarcinoma
- Neuroendocrine tumors metastatic to the liver

Potential contraindications to liver transplant (subject to the judgment of the transplant center) include:

- 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 disease 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

BILLING/CODING INFORMATION:

CPT Coding:

47133	Donor hepatectomy (including cold preservation), from cadaver donor
47135	Liver allograft transplantation ; orthoptic; partial or whole, from cadaver or living donor, any age
47140	Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)
47141	Donor hepatectomy, with preparation and maintenance of allograft, from living donor; total left lobectomy (segments II, III and IV)

47142	Donor hepatectomy, with preparation and maintenance of allograft, from living donor; total right lobectomy (segments V, VI, VII and VIII)
47143	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without tri-segment 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 tri-segment split of whole liver graft into 2 partial liver grafts (i.e., left lateral segment (segments II and III) and right tri-segment (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	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each

REIMBURSEMENT INFORMATION:

None applicable.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage: The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date: Adult Liver Transplantation (260.1) and Pediatric Liver Transplantation (260.2), located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

Allotransplantation: transplantation of tissue from one individual to another of the same species, but of different genotypes.

Biliary atresia: obliteration of one or more components of the bile ducts due to arrested fetal development resulting in persistent jaundice and liver damage ranging from biliary stasis to cirrhosis, with spleen enlargement as portal hypertension progresses.

Budd-Chiari syndrome: symptomatic obstruction or occlusion of the hepatic veins eventually resulting in liver failure; death can occur within days in cases of complete occlusion.

Hemochromatosis: disorder where deposits of intercellular storage of iron in the parenchymal cells of the liver, causing tissue damage and dysfunction of the liver.

Hepatectomy: excision of all or part of the liver.

Sclerosing cholangitis: fibrosing inflammation of the bile ducts of unknown cause, most commonly in young men and frequently associated with chronic ulcerative colitis.

UNOS: United Network of Organ Sharing.

Wilson's disease: inherited disease involving metabolism of copper and resulting in accumulation of copper in the liver, brain, kidney, cornea, and other tissues; characterized by cirrhosis of the liver and generative changes in the brain.

RELATED GUIDELINES:

[Isolated Small Bowel Transplant, 02-40000-18](#)

[Small Bowel, Liver and Multivisceral Transplant, 02-40000-19](#)

[Kidney Transplant, 02-50300-01](#)

[Allogeneic Pancreas Transplant, 02-40000-17](#)

OTHER:

Florida Statute 765.523 Discrimination in access to anatomical gifts and organ transplants prohibited. (excerpt)

(3)(d) "Organ transplant" means the transplantation or transfusion of a part of a human body into the body of another individual for the purpose of treating or curing a medical condition.

Florida Statute 627.64197 Coverage for organ transplants. —A health insurance policy issued, delivered, or renewed on or after July 1, 2020, in this state by an insurer which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be construed to require such insurer to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

Florida Statute 627.65736 Coverage for organ transplants. —A group health insurance policy delivered, issued, or renewed on or after July 1, 2020, in this state by an insurer or nonprofit health care services plan which provides coverage for organ transplants on an expense-incurred basis may not deny coverage for an organ transplant solely on the basis of an insured's disability. This section may not be

construed to require such insurer or nonprofit health care service plan to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

Florida Statute 641.31075 Coverage for organ transplants. - A health maintenance contract issued or renewed on or after July 1, 2020, in this state by a health maintenance organization which provides coverage for organ transplants may not deny coverage for an organ transplant solely on the basis of a subscriber's disability. This section may not be construed to require such health maintenance organization to provide coverage for an organ transplant that is not medically necessary. For purposes of this section, the term "organ transplant" has the same meaning as in s. 765.523.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 07/25/24.

GUIDELINE UPDATE INFORMATION:

02/15/01	Medical Coverage Guideline Developed.
03/15/02	Reviewed investigational status – maintained.
09/26/02	Revised to include new MELD and PELD scoring system criteria.
01/01/04	Annual HCPCS coding update.
03/15/04	Scheduled reviewed with formatting revisions; no change in coverage statement.
01/01/05	HCPCS coding update: added new codes for liver transplantation; revised 47133 and 47140 descriptors.
06/15/05	Revision to guideline, consisting of removal of investigational statement regarding HIV-positive recipients.
06/15/06	Scheduled review; no change in coverage statement.
06/15/07	Scheduled review; reformatted guideline; updated references.
09/15/07	Revision consisting of removal of criteria restricting coverage to patients over the age of 70 years.
07/15/08	Scheduled review; no change in position statement. Update references.
07/15/09	Scheduled review; no change in position statement. Update description section.
01/01/10	Annual HCPCS coding update: revise descriptors for CPT codes 47144 & 47145.
10/01/10	4th Quarter HCPCS coding update: ICD-9 diagnosis code 275.0 deleted; ICD-9 diagnosis codes 275.01, 275.02, 275.03 and 275.09 added.
10/15/10	Revision; related ICD-10 codes added.
04/01/12	Revision; updated ICD10 coding with new and revised codes.
08/15/12	Revision; added Medicare Advantage program exception in accordance with CMS Decision Memo (CAG-00091R).
06/15/14	Scheduled review. Revised description section, position statement and program exceptions section. Updated references.
01/01/16	Annual CPT/HCPCS coding update. Deleted code 47136.
12/15/19	Scheduled review. Revised description and position statement (added MELD/PELD scoring criteria; revised re-transplantation criteria; added coverage statement for liver/kidney transplant). Updated references.
02/15/20	Revision: Deleted (informational) statements regarding “liver specific criteria” and MELD/PELD scores.
07/01/20	Revision: added Florida statute language regarding discrimination in access to anatomical gifts and coverage of organ transplants. Updated references.
03/15/20	Revision. Revised alcohol and/or drug abuse criterion. Updated references.
09/15/21	Scheduled review. Maintained position statement and updated references.

05/25/23	Update to Program Exceptions section.
09/15/23	Scheduled review. Maintained position statement and updated references.
08/15/24	Scheduled review. Revised description, maintained position statement and updated references.