# Medical Coverage Policy

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**Coverage Policy Number..... 0355**

# Liver and Liver-Kidney Transplantation

## Table of Contents



## Related Coverage Resources

Kidney Transplantation, Pancreas-Kidney Transplantation, and Pancreas Transplantation Alone
Intestinal and Multivisceral Transplantation
Transplantation Donor Charges

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## Overview

This Coverage Policy addresses liver transplantation and simultaneous liver-kidney (SLK) transplantation.

Cigna Omnibus Reimbursement Policy R24 addresses donor organ procurement and transport.

## Coverage Policy

**Transplant wait listing (including model for end-stage liver disease [MELD] exceptions) for liver oncology diagnoses must meet 2/27/2025 National Liver Review Board (NLRB) Adult Transplant Oncology Review Board guidelines.**

**Liver transplantation is considered medically necessary for an individual with ANY of the following indications:**

- end-stage liver failure
- hepatocellular carcinoma and ONE of the following:
  - presented with stage T2 (LI-RADS 5 or biopsy proven; one lesion >2 cm and <5 cm in size, two or three lesions >1 cm and <3 cm in size) which was treated by locoregional therapy or resected but developed T1 or T2 (LI-RADS 5 or biopsy proven) recurrence
  - downstaged to T2 and no evidence of metastasis outside the liver, or macrovascular invasion, or AFP >1,000
- hepatoblastoma which is confined to the liver
- metabolic disease (urea cycle disorder or organic acidemia)
- unresectable perihilar or hilar cholangiocarcinoma and BOTH of the following:
  - administration of neoadjuvant therapy before transplantation
  - absence of regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease
- unresectable solitary intrahepatic cholangiocarcinoma (iCCA) or mixed hepatocellular carcinoma/intrahepatic cholangiocarcinoma (mixed HCC-iCCA) and BOTH of the following:
  - less than or equal to 3 cm
  - 6 months of tumor stability after locoregional or systemic therapy
- neuroendocrine tumors (NET) of gastro-entero-pancreatic (GEP) origin and BOTH of the following:
  - resection of primary malignancy and extra-hepatic disease without any evidence of recurrence for at least six months
  - neuroendocrine liver metastasis (NLM) limited to the liver, bi-lobar, not amenable to resection
- colorectal cancer metastatic to the liver and ALL of the following:
  - primary colorectal cancer was resected with negative resection margins and there is no evidence of local recurrence by colonoscopy within 12 months prior to time of initial exception request
  - no extrahepatic disease or local recurrence, based on CT/MRI (chest, abdomen and pelvis) and PET scan within one month of initial model for end-stage liver disease (MELD) exception request

  - received or receiving first-line chemotherapy/immunotherapy
  - relapse of liver metastases after liver resection or liver metastases not eligible for curative resection
  - no hepatic lesion should be greater than 10 cm before start of treatment
  - must have stability or regression of disease with systemic and/or locoregional therapy for at least 6 months
- unresectable hepatic epithelioid hemangioendothelioma (HEHE)
- hepatic adenomas (HA) and ONE of the following:
  - adenoma in the presence of glycogen storage disease
  - unresectable β Catenin (+) adenoma
  - adenoma(s) and ALL of the following:
    - unresponsive to medical management
    - unresectable
    - progressive or with complication such as hemorrhage or malignant transformation
- cystic fibrosis and BOTH of the following:
  - diagnosis has been confirmed by genetic analysis
  - a forced expiratory volume at one second (FEV1) below 40 percent of predicted FEV1 within 30 days prior to submission of the initial MELD exception request
- familial amyloid polyneuropathy (FAP) and ALL of the following:
  - registered and active on the waiting list for a heart transplant at that transplant hospital, OR has an echocardiogram performed within 30 days prior to submission of the initial MELD exception request showing the candidate has an ejection fraction greater than 40%
  - can walk without assistance.
  - a transthyretin (TTR) gene mutation
  - a biopsy-proven amyloid
- hepatopulmonary syndrome (HPS) and ALL of the following:
  - ascites, varices, splenomegaly, or thrombocytopenia.
  - a shunt, shown by either contrast echocardiogram or lung scan.
  - PaO2 less than 60 mmHg on room air within 30 days prior to submission of the initial MELD exception request
  - no clinically significant underlying primary pulmonary disease
- portopulmonary hypertension and ALL of the following:
  - document via heart catheterization initial mean pulmonary arterial pressure (MPAP) level greater than or equal to 35 mmHg and initial pulmonary vascular resistance (PVR) level greater than or equal to 240 dynes*sec/cm5 (or greater than or equal to 3 Wood units (WU)). These values must be from the same test date.
  - other causes of pulmonary hypertension have been assessed and determined to not be a significant contributing factor
  - initial transpulmonary gradient to correct for volume overload
  - documentation of treatment
  - document via heart catheterization within 90 days prior to submission of the initial exception either of the following:
    - post-treatment MPAP less than 35 mmHg and post-treatment PVR less than 400 dynes*sec/cm5 (or less than 5 Wood units (WU)). These values must be from the same test date.
    - post-treatment MPAP greater than or equal to 35 mmHg and less than 45 mmHg and post-treatment PVR less than 240 dynes*sec/cm5 (or less than 3 Wood units (WU)). These values must be from the same test date.
  - documentation of portal hypertension at the time of initial exception
- primary hyperoxaluria and ALL of the following:
  - on the waiting list for a kidney transplant at that transplant hospital

- alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample analysis or genetic analysis
- glomerular filtration rate (GFR) less than or equal to 25 mL/min on 2 occasions at least 42 days apart

**Liver retransplantation is considered medically necessary for an individual considered to have a significant chance of success and who still meet eligibility criteria for primary transplantation for ANY of the following indications:**

- primary graft failure
- severe rejection
- recurrence of the disease which prompted the initial liver transplantation
- adult hepatic artery thrombosis (HAT) within 7 days of transplant, with AST greater than or equal to 3,000 U/L and at least ONE of the following:
  - INR greater than or equal to 2.5
  - Arterial pH less than or equal to 7.30
  - Venous pH less than or equal to 7.25
  - Lactate greater than or equal to 4 mmol/L
- adult hepatic artery thrombosis within 14 days of transplant but does not meet criteria for status 1A
- pediatric hepatic artery thrombosis within 14 days of transplant

**Simultaneous liver-kidney (SLK) transplantation is considered medically necessary for an individual 18 years or older who meets medical necessity criteria for liver transplantation with ANY of the following indications:**

- chronic kidney disease (CKD) with a measured or calculated glomerular filtration rate (GFR) ≤ 60 mL/min for more than 90 consecutive days and ANY of the following:
  - receiving regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting
  - at the time of registration on the kidney waiting list, the individual's most recent measured or calculated creatinine clearance (CrCl) or GFR is ≤ 30 mL/min
  - on a date after registration on the kidney waiting list, the individual's measured or calculated CrCl or GFR is ≤ 30 mL/min
- sustained acute kidney injury and at least ONE of the following for the previous 6 weeks:
  - receiving dialysis at least once every 7 days
  - individual has a measured or calculated CrCl or GFR that is consistently ≤ 25 mL/min
- a diagnosis of ANY of the following:
  - hyperoxaluria
  - atypical hemolytic uremic syndrome (HUS) from mutations in factor H or factor I
  - familial non-neuropathic systemic amyloidosis
  - methylmalonic aciduria

**Pediatric simultaneous liver-kidney (SLK) transplantation is considered medically necessary for an individual who meets medical necessity criteria for liver transplantation and when BOTH of the following criteria are met:**

- individual was less than 18 years old when registered on the liver waiting list
- individual is registered for both a liver and a kidney transplantation

**Liver transplantation, liver retransplantation, or a simultaneous liver-kidney (SLK) transplantation is considered medically necessary if an individual with a history of malignancy:**

- meets the above criteria for liver transplantation, liver retransplantation, or a simultaneous liver-kidney (SLK) transplantation AND
- has oncology clearance in accordance with published guidelines (See Appendix) and does not have a contraindication as noted below.

**Liver transplantation is considered not medically necessary for an individual with ANY of the following contraindications to transplant surgery:**

- ongoing alcohol abuse
- a history of the following malignancies (See Appendix):
  - Breast cancer, Stage IV
  - Prostate cancer, metastatic and castration-resistant
  - Renal cell carcinoma:
    - with sarcomatoid and/or rhabdoid histologic features
    - duct or medullary
  - Bladder cancer, muscle invasive
  - Gynecological cancer:
    - Endometrial cancer:
      - Stage IV
      - recurrent or metastatic
    - Ovarian cancer:
      - epithelial, Stage IV
      - recurrent
    - Cervical cancer:
      - Squamous cell/adenocarcinoma, Stage IV
      - recurrent or metastatic
  - Lung cancer, Stage IIIA or higher
  - Skin cancer:
    - Cutaneous squamous cell carcinoma with distant metastasis
    - Merkel cell carcinoma with distant metastasis
    - Malignant melanoma, Stage III or IV
- persistent, recurrent or unsuccessfully treated major or systemic infections
- systemic illness or comorbidities that would be expected to substantially negatively impact the successful completion and/or outcome of transplant surgery
- a pattern of demonstrated noncompliance which would place a transplanted organ at serious risk of failure
- human immunodeficiency virus (HIV) disease unless ALL of the following are noted:
  - cluster determinant (CD)4 count >100 cells/$mm^3$
  - HIV-1 ribonucleic acid (RNA) undetectable
  - stable antiretroviral therapy for more than three months
  - absence of serious complications associated with HIV disease (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; or resistant fungal infections; or Kaposi's sarcoma or other neoplasm)
- donor with:
  - ongoing alcohol abuse
  - active malignancy, with the exception of non-melanotic skin cancer
  - persistent, recurrent or unsuccessfully treated infections, including hepatitis A, B or C or HIV
  - active systemic illness or serious comorbidities that would be expected to substantially negatively impact the successful completion and/or outcome of transplant surgery
  - active systemic illness that is likely to negatively affect survival

## Coding Information

**Notes:**

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Liver Transplant/Liver Retransplantation**

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

| CPT®* Codes | Description |
|---|---|
| 47133 | Donor hepatectomy (including cold preservation), from cadaver donor |
| 47135 | Liver allotransplantation, orthotopic, 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 (including cold preservation), from living donor; total left lobectomy (segments II, III and IV) |
| 47142 | Donor hepatectomy (including cold preservation), 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 trisegment or lobe split |
| 47144 | Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into 2 partial liver grafts (ie, left lateral segment [segments II and III] and right trisegment [segments I and IV through VIII]) |
| 47145 | Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into 2 partial liver grafts (ie, 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 |

| HCPCS Codes | Description |
|---|---|
| S2152 | Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; |

| HCPCS Codes | Description |
|---|---|
| | supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and post-transplant care in the global definition |

**Simultaneous Liver-Kidney (SLK) Transplantation**

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

| CPT®* Codes | Description |
|---|---|
| 47133 | Donor hepatectomy (including cold preservation), from cadaver donor |
| 47135 | Liver allotransplantation, orthotopic, 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 (including cold preservation), from living donor; total left lobectomy (segments II, III and IV) |
| 47142 | Donor hepatectomy (including cold preservation), 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 trisegment or lobe split |
| 47144 | Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into 2 partial liver grafts (ie, left lateral segment [segments II and III] and right trisegment [segments I and IV through VIII]) |
| 47145 | Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into 2 partial liver grafts (ie, 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 |
| 50300 | Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral |
| 50320 | Donor nephrectomy (including cold preservation); open, from living donor |
| 50323 | Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary |

| CPT®* Codes | Description |
|---|---|
| 50325 | Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary |
| 50327 | Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each |
| 50328 | Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; arterial anastomosis, each |
| 50329 | Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; ureteral anastomosis, each |
| 50340 | Recipient nephrectomy (separate procedure) |
| 50360 | Renal allotransplantation, implantation of graft; without recipient nephrectomy |
| 50365 | Renal allotransplantation, implantation of graft; with recipient nephrectomy |
| 50370 | Removal of transplanted renal allograft |
| 50547 | Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor |

| HCPCS Codes | Description |
|---|---|
| S2152 | 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 post-transplant care in the global definition |



## General Background

Liver transplantation (LT) is a complex operation requiring vascular reconstruction of the hepatic artery, the portal vein, and the hepatic venous system. Surgical techniques, which continue to evolve, include the orthotopic approach, involving replacement of the recipient liver with the donor liver, and the heterotopic approach in which the recipient liver is left in place and the donor liver is transplanted to an ectopic site. The whole liver, a reduced liver, or a liver segment may be transplanted depending on whether the donor is deceased or living.

Living-donor liver transplantation was introduced as an alternative to deceased donor transplantation in response to the shortage of available deceased donor organs and is used for both adults and children. The graft from a living donor is more commonly from a relative of the recipient. The success of this type of transplantation is based on the ability of the liver to regenerate in both the donor and the recipient. The graft must be of adequate size in order to function in the recipient. The risks and benefits of using a living-donor graft must be considered as there are surgical risks to both the recipient and the donor. Benefits to the recipient include a reduced chance of mortality related to waiting for a deceased donor organ, a reduced likelihood of primary non-function of the graft, and a potential decrease in the chance of graft rejection and the need for immunosuppression. Ethical concerns regarding living donor liver transplantation (LDLT) are related to the potential for donor morbidity and mortality. Opponents argue that it is unacceptable to place a healthy donor at risk of long-term debility or death. Donation of the left lateral segment or left lobe, used primarily in pediatric transplantation, is associated with a 5 to

10 percent chance of surgical complications and a mortality rate of less than 1 percent. The estimated mortality for right lobe donation, used in adult-to-adult LDLT, is around 0.5 percent.

In 2024, 94.7% of liver transplants were from deceased donors and 5.3% were from living donors; 5% were pediatric transplants, 95% adult. There were 785 simultaneous liver-kidney transplants in 2024.

**Indications for Liver Transplantation**
The major indications for liver transplantation are irreversible hepatic failure or liver cancer**.** Each liver transplant candidate is assigned a score that reflects the probability of death within a 3-month period as determined by the Model for End-Stage Liver Disease (MELD) scoring system or the Pediatric End Stage Liver Disease (PELD) scoring system. Liver candidates can also be assigned a priority status if the candidate meets the requirements for that status. If a candidate's transplant program believes that a candidate's current MELD or PELD score does not appropriately reflect the candidate's medical urgency for transplant, the transplant program may submit a MELD or PELD score exception request to the National Liver Review Board (NLRB).

A liver distribution system based on acuity circles went into effect in February 2020. Since implementation of this policy change, waiting times have decreased for patients with a MELD score of ≥29, while waiting times have increased for those patients with a MELD score of ≤28. This has placed pressure on transplant programs to increasingly pursue DCD and other "marginal" livers for patients listed with a MELD score of ≤28. HCC patients no longer have a "ladder" model of increasing exception scores over time. This has significantly reduced access to standard criteria livers for patients with HCC. As a result, the utilization of DCD livers for patients with HCC has significantly increased.

**Donor Health**
The health of the donor is also an important factor in liver transplantation outcomes. Hepatitis C virus (HCV) infection in the donor can affect the health of the donor liver, making individuals with persistent, recurrent, or untreated HCV infection unacceptable donors. Likewise, donor candidates who are hepatitis B surface antigen- (HbsAg) positive are also generally excluded from living-donor liver transplant donation to prevent transmission of disease to recipients. Factors which may negatively affect recipient outcomes after liver transplantation including ongoing alcohol abuse, active systemic illness, and malignancy, are also considered contraindications to donation.

**Retransplantation of the Liver**
Retransplantation may be appropriate for carefully selected patients experiencing graft loss if an improvement in survival is expected; however, liver retransplantation should be used with discretion in the emergency setting and avoided in patients with little chance of success. In adults, the most common condition resulting in the need for retransplantation of the liver is recurrent infection with hepatitis C virus (HCV). Retransplantation in patients with HCV is controversial due to concerns of aggressive disease recurrence post retransplantation, and decreased patient and graft survival. Several retrospective cohort studies have examined the outcomes of patients retransplanted for recurrent HCV demonstrating lower patient and graft survival in some studies.

**Professional Societies/Organizations**

**Organ Procurement & Transplantation Network (OPTN)**
The National Liver Review Board (NLRB) released 'Updates Related to Transplant Oncology' (2/27/25) available at https://optn.transplant.hrsa.gov/policies-bylaws/policies/.

- The purpose of the National Liver Review Board (NLRB) is to provide equitable access to transplant for liver transplant candidates whose calculated model for end-stage liver

disease (MELD) score or pediatric end-stage liver disease (PELD) score does not accurately reflect the candidate's medical urgency for transplant.

- The 2/27/25 'Updates Related to Transplant Oncology' is not OPTN Policy. It is not an official guideline for clinical practice, nor is it intended to be clinically prescriptive or to define a standard of care. It is intended to provide guidance to transplant programs and the review board.

- Some of the changes in the Update include:
  - The addition of OPTN guidance specific to colorectal liver metastases and intrahepatic cholangiocarcinoma (iCCA) for the NLRB:
    - Individuals with colorectal liver metastasis (CRLM) may be considered for MELD exception points according to MELD Exception Criteria and MELD Exception Extension Criteria detailed in the Update document.
    - Individuals with intrahepatic cholangiocarcinoma (iCCA) or mixed hepatocellular carcinoma/ intrahepatic cholangiocarcinoma (mixed HCC-iCCA) may be considered for MELD exception points according to MELD Exception Criteria and MELD Exception Extension Criteria detailed in the Update document.
  - Expanding the purview of the Adult HCC Review Board to review non-standard exception cases related to liver cancers and tumors. The Adult HCC Review Board will now be broadened and renamed the Adult Transplant Oncology Review Board.
  - The proposed Adult Transplant Oncology guidance document includes guidance for HCC, iCCA, neuroendocrine tumors, colorectal liver metastases, hepatic epithelioid hemangioendothelioma, and hepatic adenomas. The Adult Transplant Oncology Review Board will review non-standard exception cases for these diagnoses as well as any non-standard exception requests for CCA, and any other liver cancer or tumor-related request.

- The Update document summarizes available evidence to assist clinical reviewers in approving candidates for MELD exceptions in the specific setting of hepatic neoplasms. It contains guidance for specific clinical situations for use by the review board to evaluate common exception case requests for adult candidates with the following diagnoses:
  - Hepatocellular Carcinoma (HCC)
  - Hepatic Epithelioid Hemangioendothelioma (HEHE)
  - Hepatic Adenomas
  - Neuroendocrine Tumors (NET)
  - Colorectal Liver Metastases (CRLM)
  - Intrahepatic Cholangiocarcinoma (iCCA) (OPTN/NLRB, 2025).

The OPTN Policies document (OPTN, 2/27/25) addresses Allocation of Livers and Liver-Intestines in Policy 9. Sections within the Policy address many topics related to liver transplant including Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions.

OPTN Policy 9.5 Specific Standardized MELD or PELD Score Exceptions
Candidates are eligible for MELD or PELD score exceptions or extensions that do not require evaluation by the NLRB if they meet any of the following requirements for a specific diagnosis of any of the following:

- Hilar Cholangiocarcinoma (CCA)
- Cystic fibrosis
- Familial amyloid polyneuropathy
- Hepatic artery thrombosis
- Hepatopulmonary syndrome
- Metabolic disease

- Portopulmonary hypertension
- Primary hyperoxaluria
- Hepatocellular carcinoma

OPTN Policy 9.5.I.ii Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions / Eligible Candidates Definition of T2 Lesions
Candidates with T2 HCC lesions are eligible for a standardized MELD or PELD exception if they have an alpha-fetoprotein (AFP) level less than or equal to 1000 ng/mL. T2 stage is defined as candidates with either of the following:

- One class 5 lesion greater than or equal to 2 cm and less than or equal to 5 cm in size.
- Two or three class 5 lesions each greater than or equal to 1 cm and less than or equal to 3 cm in size.

Note: The NLRB 'Updates Related to Transplant Oncology' (2/27/25) document states Patients who presented with stage T2 HCC (LI-RADS 5 or biopsy proven; one lesion >2 cm and <5 cm in size, two or three lesions >1 cm and <3 cm in size) which was treated by locoregional therapy or resected but developed T1 or T2 HCC (LI-RADS 5 or biopsy proven) recurrence and the transplant program is requesting an initial HCC exception more than 6 months but less than 60 months following initial treatment or resection are eligible for a MELD score exception without a six month delay period" (NLRB/ 2025).

A candidate who has previously had an AFP level greater than 1000 ng/mL at any time must qualify for a standardized MELD or PELD exception according to Policy 9.5.I.iv: Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000.

OPTN Policy 9.5.I.iii Lesions Eligible for Downstaging Protocols
Candidates are eligible for a standardized MELD or PELD exception if, before completing local-regional therapy, they have lesions that meet *one* of the following criteria:

- One class 5 lesion greater than 5 cm and less than or equal to 8 cm
- Two or three class 5 lesions that meet all of the following:
  - at least one lesion greater than 3 cm
  - each lesion less than or equal to 5 cm, and
  - a total diameter of all lesions less than or equal to 8 cm
- Four or five class 5 lesions each less than 3 cm, and a total diameter of all lesions less than or equal to 8 cm

For candidates who meet the downstaging criteria above and then complete local-regional therapy, their viable lesions must subsequently meet the requirements for T2 stage according to Policy 9.5.I.ii: Eligible Candidates Definition of T2 Lesions to be eligible for a standardized MELD or PELD exception. Downstaging to meet eligibility requirements for T2 stage must be demonstrated by dynamic-contrast enhanced CT or MRI performed after local-regional therapy. Candidates with lesions that do not initially meet the downstaging protocol inclusion criteria who are later downstaged and then meet eligibility for T2 stage are not automatically eligible for a standardized MELD or PELD exception and must be referred to the NLRB for consideration of a MELD or PELD exception.

OPTN Policy 9.5.I.iv Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000
Candidates with lesions meeting T2 stage according to Policy 9.5.I.ii Eligible Candidates Definition of T2 Lesions but with an alpha-fetoprotein (AFP) level greater than 1000 ng/mL may be treated with local-regional therapy. If the candidate's AFP level falls below 500 ng/mL after treatment, the candidate is eligible for a standardized MELD or PELD exception

as long as the candidate's AFP level remains below 500 ng/mL. Candidates with an AFP level greater than or equal to 500 ng/mL following local-regional therapy at any time must be referred to the NLRB for consideration of a MELD or PELD exception.

OPTN Policy 9.9 Liver-Kidney Allocation
Unless otherwise stated, all mentions of MELD in this section reference a candidate's allocation MELD score.

When an OPO is offering a liver, and a kidney is also available from the same deceased donor, then before allocating the kidney to kidney alone candidates, the OPO must offer the kidney to a potential transplant recipient (PTR) who is registered for a liver and a kidney at the same transplant hospital, and who meets *one* of the following criteria:

- PTR was less than 18 years old when registered on the liver waiting list
- PTR is registered at a transplant hospital at or within 150 nautical miles of the donor hospital and has a MELD of 15 or greater and meets eligibility criteria according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*
- PTR is registered at a transplant hospital at or within 500 nautical miles of the donor hospital and has a MELD of 29 or greater and meets eligibility criteria according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*
- PTR is registered at a transplant hospital at or within 500 nautical miles of the donor hospital and is adult status 1A and meets eligibility criteria according to *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*

The OPO may then offer the kidney and liver to any PTRs who meet eligibility in *Table 9-17: Medical Eligibility Criteria for Liver-Kidney Allocation*, or offer the liver and the kidney separately according to policy.

OPTN Table 9-17: Medical Eligibility Criteria for **Liver-Kidney Allocation** (2/27/25) OPTN Policy)

| If the candidate's transplant nephrologist confirms a diagnosis of: | Then the transplant program must report to the OPTN and document in the candidate's medical record: |
|---|---|
| Chronic kidney disease (CKD) with a measured or calculated glomerular filtration rate (GFR) less than or equal to 60 mL/min for greater than 90 consecutive days | At least *one* of the following:<br>• That the candidate has begun regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.<br>• At the time of registration on the kidney waiting list, that the candidate's most recent measured or calculated creatinine clearance (CrCl) or GFR is less than or equal to 30 mL/min.<br>• On a date after registration on the kidney waiting list, that the candidate's measured or calculated CrCl or GFR is less than or equal to 30 mL/min. |
| Sustained acute kidney injury | At least *one* of the following, or a combination of *both* of the following, for the last 6 weeks:<br>• That the candidate has been on dialysis at least once every 7 days.<br>• That the candidate has a measured or calculated CrCl or GFR less than or equal to 25 mL/min at least once every 7 days. |

| If the candidate's transplant nephrologist confirms a diagnosis of: | Then the transplant program must report to the OPTN and document in the candidate's medical record: |
|---|---|
| | If the candidate's eligibility is not confirmed at least once every seven days for the last 6 weeks, the candidate is not eligible to receive a liver and a kidney from the same donor. |
| Metabolic disease | A diagnosis of at least *one* of the following:<br><br>• Hyperoxaluria<br>• Atypical hemolytic uremic syndrome (HUS) from mutations in factor H or factor I<br>• Familial non-neuropathic systemic amyloidosis<br>• Methylmalonic aciduria |

**National Comprehensive Cancer Network Guidelines™ (NCCN Guidelines™)**
The NCCN Guidelines (Version 2.2025—October 22, 2025) for Hepatocellular Carcinoma states the NCCN Guidelines recommend that patients with disease meeting the UNOS criteria be considered for transplantation using either cadaveric or living donation. Patients with tumor characteristics that are marginally outside of the UNOS guidelines may be considered for transplantation at select institutions. For patients with initial tumor characteristics beyond the Milan criteria who have undergone successful downstaging therapy (ie, tumor currently meeting Milan criteria), transplantation can also be considered.

The NCCN Guidelines (Version 2.2025—July 2, 2025) for Biliary Tract Cancers notes the following:

- Intrahepatic Cholangiocarcinoma: There are clinical trials investigating whether liver transplantation would be beneficial for patients with intrahepatic cholangiocarcinoma (CCA) (NCT04195503). Very highly selected candidates may meet the criteria for referral. However, these trials are only available at a small subset of centers.

- Extrahepatic Cholangiocarcinoma: Liver transplantation is a potentially curative option for selected patients with lymph node-negative, non-disseminated, locally advanced hilar CCAs. Liver transplantation should be considered only for highly selected patients (ie, tumor ≤3 cm in radial diameter, no intrahepatic or extrahepatic metastases, no nodal disease) with either unresectable disease with otherwise normal biliary and hepatic function or underlying chronic liver disease precluding surgery. The Panel encourages continuation of clinical research in this area, and referral of patients with unresectable disease to a transplant center with a United Network for Organ Sharing-approved protocol for transplant of CCA should be considered.

The NCCN Guidelines (Version 5.2025— October 30, 2025) for Colon Cancer does not address liver transplant. Hepatic resection is the treatment of choice for resectable liver metastases from CRC. When hepatic metastatic disease is not optimally resectable based on insufficient remnant liver volume, approaches using preoperative portal vein embolization, staged liver resection, or yttrium-90 radioembolization can be considered

**American Association for the Study of Liver Disease (AASLD)/ American Society of Transplantation (AST):** The AASLD and AST have published numerous joint guidelines, including some specific to liver transplantation for adults and pediatrics.

**Liver Transplant in Adults:**

Liver transplantation (LT) is an established, lifesaving therapy for selected adults with acute or chronic liver dysfunction that is not responsive to medical management, and it may also be appropriate for certain malignancies or metabolic conditions independent of etiology. Contemporary guidance from the American Association for the Study of Liver Diseases (AASLD) and the American Society of Transplantation (AST) emphasizes that the indication for LT is driven by prognosis and clinical trajectory rather than the mere presence of cirrhosis. Many individuals with compensated cirrhosis may remain stable for prolonged periods, whereas the development of hepatic decompensation signals a marked decline in survival and the need for transplant consideration. Individuals with chronic liver disease should be referred for liver transplant evaluation following a decompensating event such as ascites (with or without spontaneous bacterial peritonitis), hepatic encephalopathy, variceal or portal hypertensive gastrointestinal bleeding, hepatocellular carcinoma, or other complications reflecting progressive hepatic failure and synthetic dysfunction. Although a specific MELD score threshold for referral in the absence of decompensation is not definitively established, referral is supported when the anticipated survival benefit of transplantation outweighs continued medical therapy, and MELD score alone should not be used as a barrier to evaluation. In addition, all individuals with acute liver failure warrant urgent referral to a liver transplant center to allow timely assessment, advanced supportive care, and determination of transplant candidacy, given the potential for rapid clinical deterioration (Dove, et al., 2025).

**Pediatrics:**

While the overarching principles of timely referral and individualized risk–benefit assessment apply across all ages, pediatric liver transplantation involves distinct diseases, developmental considerations, and outcomes that require dedicated guidance. In children, liver transplantation (LT) is an established, lifesaving therapy for selected infants, children, and adolescents with acute or chronic liver disease who are unlikely to survive or achieve acceptable quality of life with medical or surgical management alone. Pediatric indications for LT include biliary atresia (32%), metabolic/genetic conditions (22%), acute liver failure (11%), cirrhosis (9%), liver tumor (9%), immune-mediated liver and biliary injury (4%), and other miscellaneous conditions (13%); within these broad categories are many rare disorders with varied presentations that can influence the timing and urgency of referral (Squires et al., 2014). Referral for pediatric transplant evaluation may be emergent, urgent, or anticipatory depending on diagnosis and clinical course. Acute liver failure and acute decompensation of established liver disease warrant immediate referral because of the risk of rapid progression to death or irreversible neurologic injury. Children with chronic liver disease should be referred when there is evidence of progressive hepatic dysfunction or complications such as growth failure, malnutrition, intractable pruritus, recurrent cholangitis, ascites, portal hypertensive bleeding, encephalopathy, hepatopulmonary or portopulmonary syndromes, or substantial quality-of-life impairment despite optimized therapy. In pediatrics, transplantation may also be pursued to prevent irreversible extrahepatic sequelae—particularly neurodevelopmental injury in certain metabolic disorders—even when conventional markers of liver synthetic failure are relatively preserved.

The AASLD/AST adult and pediatric liver transplant evaluation guidelines were developed through structured, multidisciplinary, evidence-based processes designed to promote consistency, equity, and clinical benefit in candidate evaluation and selection. Expert writing groups conducted systematic reviews of peer-reviewed literature using predefined search strategies and explicit criteria for study inclusion, while also incorporating national transplant registry data and organ allocation policies administered through the Organ Procurement and Transplantation Network (OPTN) and implemented by the United Network for Organ Sharing (UNOS). Recommendations were graded using established evidence-rating frameworks (including the Oxford Centre for

Evidence-Based Medicine approach in the adult guideline and GRADE methodology in the pediatric guideline), with strength determinations reflecting the quality of evidence, anticipated benefits and harms, and practical considerations. Draft recommendations were refined through structured consensus processes and subjected to organizational and peer review, followed by formal approval through the relevant sponsoring societies to ensure alignment with current clinical practice standards, ethical principles, and national allocation policy (Dove, et al., 2025, Squires, et al., 2014).

**American Society of Transplantation (AST):** The AST has several Key Position Statements, including but not limited to Deceased Organ Donation, Insurance Coverage for Living Donors, and Insurance Coverage for Transplant Recipients, and Living Organ Donation.

**Kidney Disease: Improving Global Outcomes (KDIGO):** The KDIGO 2020 Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation guideline included recommendations regarding liver-kidney transplantation:

- Hyperoxaluria (oxalosis), primary and secondary 9.16.1: We suggest that candidates with primary hyperoxaluria type 1 be considered for combined or sequential liver-kidney transplantation (2C).
- Hepatitis C virus (HCV) 10.5.2.4.2: We recommend referring patients with HCV and decompensated cirrhosis for combined liver-kidney transplantation (1B) and deferring HCV treatment until after transplantation (1D).
- Liver disease 16.7.3: We recommend that candidates with cirrhosis or suspected cirrhosis be referred to a specialist with expertise in combined liver-kidney transplantation for evaluation (1B).

Description for grading recommendations:
Level 1: "We recommend". Most patients should receive the recommended course of action.
Level 2: "We suggest". Different choices will be appropriate for different patients. Each patient needs help to arrive at a management decision consistent with her or his values and preferences.
A: High Quality of Evidence. We are confident that the true effect lies close to that of the estimate of the effect.
B: Moderate Quality of Evidence. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
C: Low Quality of Evidence. The true effect may be substantially different from the estimate of the effect.
D: Very low Quality of Evidence. The estimate of effect is very uncertain, and often will be far from the truth (Chadban, et al., 2020).

## Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Liver transplants in the United States in 2024:

| | |
|---|---|
| | 11,458 All races/ethnicities |
| 65.8% | 7,542 White, Non-Hispanic |
| 19.3% | 2,216 Hispanic/Latino |
| 6.3% | 730 Black, Non-Hispanic |
| 3.6% | 420 Asian, Non-Hispanic |

According to Nagesh et al. (2025), liver transplantation remains the standard of care for patients with end-stage liver disease in the United States; however, disparities exist in referral and access to the liver transplant (LT) waitlist. Social determinants of health (SDOH) such as income, lack of private insurance and education are increasingly recognized as important drivers of health inequities in both liver and liver-kidney transplantation. These liver transplantation disparities manifest through differences in waitlist mortality, transplantation rate, and post-transplant outcomes.

Studies further suggest that socioeconomic factors at time of transplant may also influence long-term post-transplant survival. Lower socioeconomic status and minority race and ethnicity have been associated with poorer health outcomes, likely due to unequal distribution of and access to healthcare resources. As noted in the table above, White individuals consistently account for the majority of liver transplant recipients, and Hispanic (Latinix) individuals represented the second-largest group, followed by Black individuals. While these proportions closely mirror the racial distribution of hepatic failure admissions, the persistent underrepresentation of Black and Hispanic (Latinix) individuals relative to disease burden underscores ongoing inequities in referral, evaluation, and waitlisting processes.

Additionally, some studies have shown that documentation status, unstable housing, unemployment, and reliance on public insurance are associated with increased risks of delayed waitlisting, waitlist removal, and mortality and are linked to worse post-LT patient survival and graft survival. Lower educational attainment, including lack of a college education, has also been shown to negatively impact both patient survival and graft outcomes (Nagesh et al., 2025; Mansour et al., 2022; Huang et al., 2021; Yilma et al., 2023).

# Appendix

**Recommended wait time for SOT candidates with a prior history of breast cancer**

| Risk/stage | 5-year disease-specific survival (%) | Time interval to transplant | Additional considerations |
|---|---|---|---|
| **Low risk**<br>DCIS<br>Stage I | 97 to 99 | No wait time necessary* | Hormone receptor negative disease may have a slightly higher risk of recurrence in the first 2 to 3 years. |
| **Intermediate risk**<br>Stage II | 90 to 99 | 1 to 2 years NED* | Hormone receptor negative disease may have a slightly higher risk of recurrence in the first 2 to 3 years. |
| **High risk**<br>Stage III | 66 to 97 | 3 to 5 years NED* | Hormone receptor negative disease may have a slightly higher risk of recurrence in the first 2 to 3 years.<br>Inflammatory breast cancer likely has a higher risk of recurrence and worse survival. |
| **Prohibitive risk**<br>Stage IV | 32 to 38 | Not an SOT candidate | |

Standard oncologic treatments are based on those recommended in the National Comprehensive Cancer Network Breast Cancer guidelines. Breast cancer stages are based on the prognostic stage groups specified in the AJCC's Staging Manual, 8th edition. Anatomic stage groups are not necessarily equivalent to the corresponding prognostic stage groups and should not be applied here.

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DCIS: ductal carcinoma in situ; NED: no evidence of disease.

* After completion of all standard treatments. Endocrine therapy does not need to be completed prior to transplant, as this is an oral medication that is fairly well tolerated with few serious side effects and often continues for 5 to 10 years.

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*From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.*

**Recommended wait time for SOT candidates with a prior history of colon cancer**

| Risk/stage | Recurrence-free survival 5 years (%) | Time interval to transplant | Additional considerations |
|---|---|---|---|
| **Low risk**<br>▪ Stage I (T1 or T2, N0, M0) | 91 | 1 year | Low-risk features:<br>▪ Deficient DNA mismatch repair (as reflected by high levels of MSI) without BRAF mutation<br>High-risk features:<br>▪ LVI or PNI<br>▪ Mucinous or signet histology<br>▪ Poorly differentiated histology<br>▪ Bowel obstruction<br>▪ Tumor perforation<br>▪ <12 lymph nodes examined<br>Tumor deposits considered as N+ disease.<br>Consider chemotherapy prior to transplantation for high-risk stage II disease.<br>Patients with stage III disease should complete chemotherapy. |
| **Low intermediate risk**<br>▪ Stage II (T3, N0, M0) | 72 | 2 years, consider longer if high-risk features present | |
| **High intermediate risk**<br>▪ Stage II (T4, N0, M0)<br>▪ Stage III (Any T, N+, M0) | | 3 years, 5 years if high-risk features present | |
| **High risk**<br>▪ Stage IV (Any T, Any N, M+) | 13 | 5 years NED | SOT not recommended prior to 5 years; refer to special consideration regarding resectable CRC metastasis |

LVI: lymphovascular invasion; PVI: perineural invasion; MSI: microsatellite instability; CT: computed tomography; CAP: chest, abdomen and pelvis; CEA: carcinoembryonic antigen; NED: no evidence of disease.

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*From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.*

**Recommended wait time for SOT candidates with a prior history of rectal cancer**

| Risk/stage | Recurrence-free survival 5 years (%) | Time interval to transplant | Additional considerations |
|---|---|---|---|
| **Low risk**<br>▪ Stage I (T1 or T2, N0, M0)<br>▪ Full oncologic resection | 85 to 88 | 1 year, consider 2 years if high-risk features present | Low-risk features:<br>▪ Deficient DNA mismatch repair (as reflected by high levels of MSI) without BRAF mutation<br>▪ Upper 1/3 rectum or rectosigmoid<br>High-risk features:<br>▪ LVI or PNI<br>▪ Mucinous or signet histology<br>▪ Poorly differentiated histology<br>▪ Bowel obstruction<br>▪ Tumor perforation<br>▪ <12 lymph nodes examined<br>▪ Lower 1/3 of rectum<br>▪ Incomplete mesorectal excision<br>Tumor deposits considered as N+ disease.<br>Patients with stage II and III disease should complete trimodality treatment (chemoradiotherapy, surgery and chemotherapy) unless elimination of one of these is deemed appropriate after multidisciplinary discussion.<br>For patients who have undergone preoperative radiotherapy, response to treatment is highly prognostic. Complete and nearly complete responders have much lower risk for recurrence than those with poor response. |
| **Low intermediate risk**<br>▪ Stage I (T1, N0, M0)<br>▪ Local excision | 78 to 88 | 2 years | |
| **High intermediate risk**<br>▪ Stage II (T3 or T4, N0, M0)<br>▪ Stage III (Any T, N+, M0) | 70 | 3 years, 5 years if high-risk features present | |
| **High risk**<br>▪ Stage IV (Any T, Any N, M+) | 14 | 5 years NED | SOT not recommended prior to 5 years; refer to special consideration regarding resectable CRC metastasis |

RFS: recurrence-free survival; LVI: lymphovascular invasion; PNI: perineural invasion; MSI: microsatellite instability; CT: computed tomography; CAP: chest, abdomen, and pelvis; CEA: carcinoembryonic antigen; NED: no evidence of disease.

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*From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.*

**Recommended wait time for SOT candidates with a prior history of prostate cancer**

| Risk/stage | Survival | Time interval to transplant | Additional considerations |
|---|---|---|---|
| **Very low risk** | <1% risk of mets/death over 15 years | None | Surveillance is strongly recommended |
| ▪ PSA <10 ng/mL | | | |
| ▪ 3 or fewer cores of Gleason 6 (grade group 1); no greater than 50% of individual core | | | Extenuating circumstances may require treatment |
| ▪ T1c to T2a | | | |
| **Low risk** | ~2 to 3% risk of mets/death over 15 years | None | Surveillance is strongly recommended |
| ▪ PSA <10 ng/mL | | | |
| ▪ Gleason 6 (not meeting very low-risk criteria) | | | Extenuating circumstances may require treatment |
| ▪ T1c to T2a | | | |
| **Low-volume intermediate risk**<br>▪ One of the following criteria: PSA >10 ng/mL, Gleason 7 (grade group 2 or 3), T2b | <5% risk of mets/death over 15 years | If surveillance, no wait time<br>If treatment initiated, and nomogram predicts cancer-specific death over the next 15 years <10%, no wait time | Surveillance or treatment, depending on patient and cancer characteristics |
| **High-volume intermediate risk, high risk, or very high risk**<br>▪ PSA >20 ng/mL or high-volume Gleason 7 or any Gleason 8 to 10, T3 | 20 to 70% risk of mets/death over 15 years | If treatment initiated, and nomogram predicts cancer-specific death over the next 15 years <10%, no wait time | Treatment |
| **Metastatic castration-sensitive** | Median survival ~5 to 6 years | If stable disease for 2 years with prolonged estimated life expectancy, may consider transplant | Best systemic therapy ± local treatment |
| **Metastatic castration-resistant** | Median survival 2 to 3 years | Not a SOT candidate | Best systemic therapy |

PSA: prostate specific antigen.

*From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.*

**Recommended wait time for SOT candidates with a prior history of renal cell carcinoma**

| Stage | Recurrence-free survival 5 years (%) | Time interval to transplant |
|---|---|---|
| T1a (≤4 cm), N0, M0 | 95 to 98 | No wait time |
| T1b (>4 cm to ≤7 cm), N0, M0 | 91 for FG 1/2 | No wait time |
| | 80 to 82 for FG 3/4 | 1 to 2 years |
| T2 (7 to 10 cm), N0, M0 | 80 | 2 years |
| T3, N0, M0 | 43 to 80 | Minimum of 2 years, then reassess |
| T4, N0, M0 | 28 to 55 | Minimum of 2 years, then reassess |
| Any T, node positive, metastatic disease | 0 to 32 | Not a candidate (if solitary metastasis +resected, tumor board discussion on candidacy) |
| Any T with sarcomatoid and/or rhabdoid histologic features | 15 to 27 | Not a SOT candidate |
| Collecting duct or medullary RCC | <10 | Not a SOT candidate |

RCC: renal cell carcinoma; FG: Fuhrman grade (grade 1: inconspicuous nucleoli at ×400 magnification and basophilic, grade 2: clearly visible nucleoli at ×400 magnification and eosinophilic, grade 3: clearly visible nucleoli at ×100 magnification, grade 4: extreme pleomorphism or rhabdoid and/or sarcomatoid morphology).

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*From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.*

**Recommended wait time for SOT candidates with a prior history of bladder cancer**

| Bladder cancer history | 2-year local recurrence from baseline transurethral resection of bladder tumor (%) | Time interval to transplant |
|---|---|---|
| NMIBC low risk* | 19 | 6 months |
| Intermediate risk¶ | 39 | 6 months |
| High risk$^{\Delta}$ | 38 | 2 years |
| MIBC, postradical cystectomy | 25 to 37 | 2 years |
| MIBC, postchemoradiation | 25 to 30 (10-year) | Not an SOT candidate |

NMIBC: nonmuscle invasive bladder cancer; MIBC: muscle invasive bladder cancer.

* Low risk: Solitary, ≤3 cm, low-grade, Ta tumor, absence of carcinoma in situ (CIS).

¶ Intermediate risk: Solitary tumor >3 cm, recurrence within 12 months with low-grade Ta tumor, multifocal low-grade Ta tumor, low-grade T1 tumor, or high-grade tumor <3 cm.

Δ High risk: Any CIS, high-grade Ta tumor >3 cm, high-grade T1 tumor, multifocal high-grade Ta tumor, any recurrent high-grade Ta tumor, CIS, variant histology, lymphovascular invasion, high-grade prostatic urethral involvement, recurrence after BCG intravesical therapy. Although 2-year recurrence rate is lower than intermediate risk, the progression rate to muscle invasion is higher.

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*From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.*

**Recommended wait time for SOT candidates with a prior history of gynecological cancer**

| 5-year recurrence risk | Type and stage | Time interval to transplant |
|---|---|---|
| **Low risk**<br><5% risk of recurrence | Stage IA/IB, grade 1 to 2 endometrial cancer without lymph-vascular space invasion | No waiting period after completion of primary treatment |
| | Stage IA/IB/IC grade 1 to 2 epithelial ovarian cancer | |
| | Stage IA1, IA2 squamous/adenocarcinoma of the cervix | |
| **Intermediate risk**<br>5 to 15% risk of recurrence | Stage I/II endometrial cancer +risk factors* | 2 to 3 years after completion of treatment |
| | Stage IB squamous/adenocarcinoma of the cervix | |
| **High risk**<br>>30% risk of recurrence | Serous, clear cell, or carcinosarcoma of uterus (all stages) | 5 years after completion of treatment |
| | Stage III grade 1 to 3 endometrioid cancer of the uterus | |
| | Stage II/III epithelial ovarian cancer | |
| | Stage II/III squamous cell/adenocarcinoma cervical cancer | |
| **Very high risk**<br>>80% risk of recurrence | Stage IV endometrial cancer (all grades) | Not a SOT candidate |
| | Recurrent or metastatic endometrial cancer | |
| | Stage IV epithelial ovarian cancer (any grade) | |
| | Recurrent ovarian cancer | |
| | Stage IV squamous cell/adenocarcinoma of the cervix | |
| | Metastatic or recurrent cervical cancer | |

* Risk factors: Older age, lymph-vascular space invasion, grade 2 or 3 endometrioid, deeply invasive tumor.

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*From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.*

**Recommended wait time for SOT candidates with a prior history of lung cancer**

| Stage | Tumor and node | 5-year survival (%) | Work-up pre-SOT | Time interval to transplantation | Additional considerations |
|---|---|---|---|---|---|
| I | T1aN0 | 92 | PET-CT; consider biopsy post-SBRT | ≥3 years | |
| | T1bN0 | 83 | PET-CT; consider biopsy post-SBRT | ≥3 years | |
| | T1cN0 | 77 | PET-CT; consider biopsy post-SBRT | 3 to 5 years | 5-year recurrence-free survival is safest |
| IB | T2aN0 | 68 | PET-CT | 5 years | |
| IIA | T2bN0 | 60 | PET-CT | 5 years | |
| IIB | T3 N0 | 53 | PET-CT | 5 years | |
| IIIA | | 36 | PET-CT | 5 years | Special caution with N2 disease |
| IIIB | | 26 | N/A | N/A | Not an SOT candidate |
| IIIC | | 13 | N/A | N/A | Not an SOT candidate |
| IVA | | 10 | N/A | N/A | Not an SOT candidate |
| IVB | | 0 | N/A | N/A | Not an SOT candidate |

SOT: solid organ transplantation; PET-CT: positron emission tomography-computed tomography; SBRT: stereotactic body radiation therapy.

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*From: Al-Adra DP, Hammel L, Roberts, J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant 2021; 21:460.*

**Recommended wait times pretransplantation for patients with a history of skin cancer before transplantation**

| Skin malignancy | Appropriate treatment pretransplantation | Wait time before transplantation after treatment |
|---|---|---|
| **cSCC** | | |
| No history of SCC but at risk for development of SCC | Treatment of field disease | No delay necessary |
| Low risk | Surgical excision with clear margins or Mohs micrographic surgery | No delay necessary |
| High-risk SCC* (not including perineural invasion) | Surgical excision with clear margins or Mohs micrographic surgery | 2 years |
| High-risk SCC with:<br>▪ Perineural invasion<br>or<br>▪ ≥2 Risk factors | Surgical excision with clear margins or Mohs micrographic surgery ± ART | 2 to 3 years |
| High risk with local nodal metastatic disease | Surgical excision with appropriate lymph node dissection plus ART | 5 years |
| Distant metastasis | Refer for oncology opinion | Not eligible for transplantation |
| **MCC** | | |
| Local with negative SLN biopsy | Wide local excision ± ART | 2 years |
| Local with nodal metastasis | Wide local excision, lymph node dissection, ART | 3 to 5 years |
| Distant metastasis | Refer for oncology opinion | Not eligible for transplantation |
| **MM** | | |
| In situ melanoma | Wide local excision | No wait necessary, follow-up posttransplantation 3 months |
| Stage Ia melanoma | Wide local excision | 2 years |
| Stage Ib/IIa melanoma | Wide local excision ± sentinel lymph node biopsy | 2 to 5 years |
| Stage IIb/IIc melanoma | Wide local excision + sentinel lymph node biopsy | 5 years |
| Any stage III or IV melanoma | Refer for oncology opinion | Not eligible for transplantation |

ART: adjuvant radiation therapy; cSCC: cutaneous squamous cell carcinoma; MCC: Merkel cell carcinoma; MM: malignant melanoma; SCC: squamous cell carcinoma; SLN: sentinel lymph node biopsy.

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*From: Zwald F, Leitenberger J, Zeitouni N, et al. Recommendations for Solid Organ Transplantation for Transplant Candidates With a Pretransplant Diagnosis of Cutaneous Squamous Cell Carcinoma, Merkel Cell Carcinoma and Melanoma: A Consensus Opinion From the International Transplant Skin Cancer Collaborative (ITSCC). Am J Transplant 2016; 16:407.*

**Recommended wait time for SOT candidates with a prior history of melanoma**

| Pathological stage | 5-year MS (%) | Appropriate treatment pretransplantation | Time interval to transplant | Additional considerations |
|---|---|---|---|---|
| In situ | 99 | Wide local excision | No wait time necessary | Follow-up 3 months post-SOT |
| Stage IA (T1a) | 99 | Wide local excision | 1 year | |
| Stage IB (T1b or T2a) | 97 | Wide local excision plus SLNB | 1 year | If positive SLNB at time of diagnosis, imaging as for Stage IIA disease |
| Stage IIA (T2b or T3a) | 94 | Wide local excision plus SLNB | 1 year | Imaging of the brain, CAP<br>Imaging of the neck for those with head/neck melanoma primary |
| Stage IIB (T3b or T4a) | 87 | Wide local excision plus SLNB | 2 to 4 years | Imaging as above |
| Stage IIC (T4b) | 82 | Wide local excision plus SLNB | 2 to 4 years | Imaging as above |
| Stage IIIA (T1-2a, N1a or 2a) | 93 | Wide excision plus SLNB plus lymph node dissection | 1 ton 2 years | Imaging as above<br>Oncology referral |
| Stage IIIB (T0-3a and N1a/b/c, N2a/b) | 83 | Wide excision plus SLNB plus lymph node dissection<br>Adjuvant therapy with CKI | 2 to 4 years | Imaging as above<br>Oncology referral |
| Stage IIIC (T3b-4b and N2b/c-N3b/c) | 69 | Wide excision plus SLNB plus lymph node dissection<br>Adjuvant therapy with CKI | At least 5 years | Imaging as above<br>Oncology referral (no consensus was possible for this group) |
| Stage IIID (T4b and N3a-3c) | 32 | Wide excision plus SLNB plus lymph node dissection<br>Adjuvant therapy with CKI | At least 5 years | Oncology referral (no consensus was possible for this group) |
| Stage IV | 15 to 20 | Wide excision plus SLNB plus lymph node dissection<br>Adjuvant therapy with CKI | At least 5 years | Oncology referral (no consensus was possible for this group) |

MSS: melanoma-specific survival; SLNB: sentinel lymph node biopsy; CKI: checkpoint inhibitor; CAP: chest, abdomen, and pelvis.

*From: Al-Adra DP, Hammel L, Roberts J, et al. Preexisting melanoma and hematological malignancies, prognosis, and timing to solid organ transplantation: A consensus expert opinion statement. Am J Transplant 2021; 21:475.*

**Recommended wait time for SOT candidates with a prior history of hematological malignancies**

| Histology | Survival/relapse data | Time interval to transplant | Additional considerations |
|---|---|---|---|
| Diffuse large B cell lymphoma | Survival is equivalent to age- and sex-matched general population after EFS24 and PFS24 achieved | 2 years | |
| Follicular lymphoma | No added mortality when compared with age- and sex-matched general population after EFS24 achieved | 2 years | |
| Peripheral T cell lymphoma, NOS | 23% relapse within 5 years of EFS24, 78% 5-year survival after EFS24 achieved | 2 years | |
| Burkitt lymphoma | 0.6% relapse after EFS24 achieved | 2 years | |
| Hodgkin lymphoma | 10% relapse at 10 years after EFS24 achieved | 2 years | PET scan negative patients after initial treatment have a low rate of relapse |
| Monoclonal B cell lymphocytosis | N/A | No wait time | |
| Chronic lymphocytic leukemia | 83% 5-year survival untreated | 2 to 3 years after treatment | Consider if in remission with no CLL-IPI scores >4 |

EFS24: event-free survival at 24 months; PFS24: progression-free survival at 24 months; PET: positron emission tomography.

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*From: Al-Adra DP, Hammel L, Roberts J, et al. Preexisting melanoma and hematological malignancies, prognosis, and timing to solid organ transplantation: A consensus expert opinion statement. Am J Transplant 2021; 21:475.*

## Criteria for safe SOT candidates with a prior history of myeloma (top) or amyloidosis (bottom)

| Criteria for safe renal transplantation in myeloma |
|---|
| ▪ Stringent complete response |
| • No monoclonal protein in serum or urine by immunofixation |
| • Normal free light chain ratio |
| • Bone marrow plasma cells <1% by flow or immunohistochemistry |
| ▪ Performance status 0 or 1 |
| ▪ FISH at diagnosis fail to demonstrate deletion (17p), t(4;14), t(14;16) |
| ▪ Hematologic remission >6 months |
| **Criteria for organ transplantation in amyloidosis** |
| ▪ Therapeutic response with dFLC of <4 mg/dl |
| ▪ Only one organ involved with amyloidosis |
| ▪ Does not fulfill criteria for symptomatic myeloma |
| ▪ Must be a candidate for stem cell transplantation following organ transplantation |

dFLC: difference between involved minus uninvolved serum free light chains.

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*From: Al-Adra DP, Hammel L, Roberts J, et al. Preexisting melanoma and hematological malignancies, prognosis, and timing to solid organ transplantation: A consensus expert opinion statement. Am J Transplant 2021; 21:475.*

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## Revision Details

| Type of Revision | Summary of Changes | Date |
|---|---|---|
| Annual Review | • Added policy statement for pediatric simultaneous liver-kidney transplantation (SLKT) | 4/15/2026 |
| Focused review | • Added policy statements regarding history of malignancy | 10/15/2025 |
| Annual review | • Added a disclaimer statement for transplant wait listing<br>• Added policy statements for:<br>➢ intrahepatic cholangiocarcinoma<br>➢ colorectal cancer metastatic to the liver (CRLM)<br>➢ hepatic epithelioid hemangioendothelioma (HEHE)<br>➢ hepatic adenomas<br>➢ cystic fibrosis<br>➢ familial amyloid polyneuropathy (FAP)<br>➢ hepatopulmonary syndrome<br>➢ portopulmonary hypertension<br>➢ primary hyperoxaluria<br>• Revised policy statements for hepatocellular carcinoma (HCC), metabolic disease, perihilar or hilar cholangiocarcinoma, and neuroendocrine tumors.<br>• Revised the policy statement for liver retransplantation, specific to hepatic artery thrombosis.<br>• Revised the liver transplant contraindications policy statement.<br>• Removed policy statement addressing mechanical preservation machine | 4/15/2025 |
| Annual review | • Revised policy statement for liver transplantation<br>• Revised policy statement for mechanical preservation machines | 5/15/2024 |