Medical Coverage Policy

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Intestinal and Multivisceral Transplantation

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Related Coverage Resources

Liver and Liver-Kidney Transplantation
Infant Nutritional Formula

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses primary and repeat intestinal organ transplantation from both deceased and living donors and deceased donor multivisceral organ transplantation. Contraindications for transplantation are also addressed.

Coverage Policy

Primary and repeat deceased donor intestinal transplantation and primary and repeat deceased donor multivisceral organ transplantation are considered medically necessary in an individual with total irreversible intestinal failure for ANY of the following indications:

- failure, contraindication, or intolerance to parenteral nutrition with ANY of the following:
  - impending or overt liver failure
  - impending loss of central vein access (e.g., thrombosis)
  - recurrent, life-threatening sepsis
  - frequent episodes of dehydration
- high risk of death
- severe short bowel syndrome
- frequent hospitalizations for complications directly related to intestinal failure
- pseudo-obstruction

Primary and repeat deceased donor intestinal transplantation and primary and repeat deceased donor multivisceral organ transplantation are considered medically necessary if an individual with a history of malignancy:

- meets the above criteria for primary and repeat deceased donor intestinal transplantation and primary and repeat deceased donor multivisceral organ transplantation **AND**
- has oncology clearance in accordance with published guidelines (See Appendix) and does not have a contraindication as noted below.

Deceased donor intestinal or multivisceral transplantation are considered not medically necessary when ANY of the following absolute contraindications to transplantation exist (this list may not be all-inclusive):

- 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

- 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 patient noncompliance which would place a transplanted organ at serious risk of failure
- human immunodeficiency virus (HIV) disease unless **ALL** of the following are noted:
  - CD4 count greater than 200 cells/mm^3
  - HIV-1 ribonucleic acid (RNA) undetectable
  - stable anti-retroviral therapy for more than three months
  - absence of serious complications associated with or secondary to HIV disease (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections; or Kaposi's sarcoma or other neoplasm)

Living donor intestinal transplantation is not medically necessary.

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.

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

CPT®* Codes	**Description**
44132	Donor enterectomy (including cold preservation), open; from cadaver donor

CPT®* Codes	Description
44135	Intestinal allotransplantation; from cadaver donor
44137	Removal of transplanted intestinal allograft, complete
44715†	Backbench standard preparation of cadaver or living donor intestine allograft prior to transplantation, including mobilization and fashioning of the superior mesenteric artery and vein
44720†	Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; venous anastomosis, each
44721†	Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; arterial anastomosis, each
47133	Donor hepatectomy (including cold preservation), from cadaver donor
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age
47143	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split
47144	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into 2 partial liver grafts (i.e., left lateral segment (segments II and III) and right trisegment (segments I and IV through VIII))
47145	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into 2 partial liver grafts (i.e., left lobe (segments II, III, and IV) and right lobe (segments I, 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
47399††	Unlisted procedure, liver
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48551	Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery
48552	Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each
48554	Transplantation of pancreatic allograft
48556	Removal of transplanted pancreatic allograft

†Note: Considered Not Medically Necessary when used to report living donor intestinal transplantation.

††Note: Considered Medically Necessary when used to represent liver allotransplantation; heterotopic, partial or whole, from cadaver donor, any age.

HCPCS Codes	Description
S2053†	Transplantation of small intestine and liver allografts
S2054†	Transplantation of multivisceral organs
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

†Note: Considered Not Medically Necessary when used to report living donor intestinal transplantation.

Considered Not Medically Necessary:

CPT®* Codes	Description
44133	Donor enterectomy (including cold preservation), open; partial, from living donor
44136	Intestinal allotransplantation; from living donor

General Background

Intestinal (i.e., small bowel only), liver-intestinal, or multivisceral transplantation are accepted therapeutic options for highly selected adults with irreversible intestinal and/or multivisceral organ failure who have failure, contraindication, or intolerance to total parenteral nutrition (TPN). Irreversible gastrointestinal system failure is defined as the inability to maintain nutrition or adequate fluid and electrolyte balance without special support, when currently available medical and surgical treatments fail to improve intestinal adaptation and gut function. Causes may differ among children and adults (Reyes and Wendel, 2025; Matarese, 2007). Although TPN is the standard of care for patients with temporary or permanent intestinal failure, it severely affects quality of life and may be associated with a number of highly morbid and sometimes fatal complications (Kesseli and Sudan, 2022; Markman, 2012). Transplantation should be considered once it has been clearly shown that the bowel cannot adapt to allow full enteral autonomy from parenteral nutrition (Braun, 2007). Additional life-threatening indications include impending or overt liver failure, loss or impending loss of central venous access (e.g., thrombosis), recurrent, systemic sepsis, frequent episodes of dehydration, high risk of death, severe short bowel syndrome, frequent hospitalization, or pseudo-obstruction (Reyes and Wendel, 2025; Avitzur, 2010; American Gastroenterological Association [AGA], 2003, Kaufman, 2001).

Specific indications for intestinal and multivisceral transplantation may include the following (Reyes and Wendel, 2025; Matsumoto, 2018; Bharadwaj, 2017; Carter, 2007; Lauro, 2007; Matarese, 2007; Sudan, 2007; Reyes, 2006; Dove and Brown, 2004; AGA, 2003; Abu-Elmagd, 2001):

Common Indications for Intestinal and Multivisceral Transplantation

Children	Adults

Aganglionosis (Hirschsprung's disease) Autoimmune enteropathy Congenital epithelial mucosal disease (microvillus inclusion disease, tufting enteropathy) Crohn's disease Familial polyposis Gastroschisis Inflammatory pseudotumor Intestinal atresia Intestinal failure-associated liver disease Intestinal pseudo-obstruction Microvillus inclusion disease Necrotizing enterocolitis Pseudo-obstruction Radiation enteritis Short gut syndrome Tufting enteropathy Trauma Volvulus	Autoimmune enteritis Crohn's disease Desmoid tumors Gardner's syndrome/familial polyposis Hollow visceral myopathy Inflammatory bowel disease Ischemia Radiation enteritis Secretory diarrhea Short gut syndrome Surgical adhesions Trauma Vascular occlusion Volvulus

Intestinal and multivisceral transplantations are more challenging than other types of solid organ transplantation due to the intestine's large number of immune competent cells and colonization of the gut with microorganisms. Intestinal allografts may be transplanted alone, as in an isolated intestine graft, or as a composite graft which may include the liver, duodenum, and pancreas. If the recipient operation includes replacement of the entire gastrointestinal graft and liver, it is generally referred to as a multivisceral transplantation (Reyes and Wendel, 2025). The type and number of transplanted organs is dictated by the extent of the abdominal pathology and the functional status of the organs at the time of transplantation (Matsumoto, 2018; Bharadwaj, 2017; Matarese, 2007; Abu-Elmagd, 2006).

Isolated intestine transplantation may be indicated when there is a permanent need for total parenteral nutrition (TPN) after failure of intestinal adaptation and failed attempts of medical and surgical rehabilitation (Matarese, 2007). Combined liver-intestinal transplantation may be appropriate for individuals with combined intestinal and TPN-associated liver failure, liver failure associated with portal and mesenteric venous thrombosis, intestinal failure due to a hypercoagulable state associated with enzyme deficiencies that can be corrected by a liver graft (e.g., mesenteric vascular thrombosis secondary to protein C or S deficiency), or documented end-stage hepatic disease. In adults, such disease is associated with refractory ascites, spontaneous bacterial peritonitis, refractory variceal bleeding, chronic encephalopathy, hepatorenal syndrome, failure to thrive, or a severe compromise in the quality of life (Abu-Elmagd, 2001). In children, end-stage hepatic disease is suggested by hyperbilirubinemia persisting beyond three to four months of age, combined with features of portal hypertension, such as splenomegaly, thrombocytopenia, or prominent superficial abdominal veins.

A full multivisceral transplantation involves the en bloc transplantation of the stomach, liver, duodenum and pancreas with the intestine. In a modified procedure only one or two organs may be transplanted. It is indicated for patients with irreversible failure of their abdominal visceral organs, including the small bowel. The aims of multivisceral transplantation are to replace as many functional digestive units as possible, restore gastric emptying, ileocecal valve function, rectal continence, and improvement of surgical and oncological margins of resection (Braun, 2007). Conditions include symptomatic extensive thrombosis of the splanchnic vascular system,

massive gastrointestinal polyposis or neoplasm, and generalized hollow visceral myopathy or neuropathy (Abu-Elmagd, 2001). Multivisceral transplantation may also be indicated for diffuse gastrointestinal disorders such as dysmotility syndromes, hereditary neoplasms, and extensive vascular thrombosis (Matarese, 2007).

Contraindications to Intestinal and Multivisceral Transplantation
Contraindications for intestinal and multivisceral transplantation are similar to those for other types of solid organ transplantation. Absolute contraindications include severe uncontrolled infection, multiorgan failure, nonresectable or disseminated malignancy, significant cardiopulmonary insufficiency, acquired immunodeficiency syndrome, the existence of life-threatening uncontrollable intra-abdominal or systemic infections, and noncompliance (Braun, 2007; Matarese, 2007; Abu-Elmagd, 2001; Kaufman, 2001). In addition to the absolute contraindications noted, relative contraindications which may also negatively affect survival, may include, but not be limited to (Kaufman, 2007; Abu-Elmagd, 2001):

- current, ongoing substance abuse, including tobacco, alcohol and narcotic/other addictive pain medications
- profound neurologic disabilities
- severe congenital or acquired immunological deficiencies
- multisystem autoimmune diseases
- progressive neuropathy or myopathy that is not amenable to rehabilitation
- any active medical process that is currently not optimally treated and/or stable and that is likely to result in end-organ damage or medical emergency without appropriate management, such as active peptic ulcer disease, diverticular disease, active hepatitis, cholecystitis, pancreatitis, diabetes mellitus, hypertension, autoimmune disease, or cytopenia
- advanced age
- positive crossmatch

Deceased (Cadaver) Donor Intestinal and Multivisceral Transplantation
Intestinal and multivisceral transplantations most frequently involve the use of cadaveric, or deceased, donors. Although randomized clinical trial data are not available, there are several case reports and retrospective studies demonstrating improved outcomes.

Literature Review
Abu-Elmagd et al. (2009) reported results of a retrospective review of 453 patients who received 500 visceral transplants at a single transplant facility. Of 453 recipients, 198 (44%) received intestine, 142 (31%) received combined liver-intestine, and 113 (25%) received multivisceral grafts: 84 with liver (full) and 29 without liver (modified). Actuarial patient survival was 85% at 1-year, 61% at 5-years, 42% at 10-years, and 35% at 15-years with respective graft survival of 80%, 50%, 33%, and 29%. With a 10% retransplantation rate, second/third graft survival was 69% at 1-year and 47% at 5-years. Although limited by uncontrolled study design, long-term survival data suggest acceptable overall survival rates for primary and repeat intestinal and multivisceral transplantation.

Retransplantation
The overall effect of intestinal and multivisceral retransplantation in the United States has not been evaluated in a comprehensive manner and there are limited data in the published, peer-reviewed medical literature. Causes of graft loss may include acute cellular rejection, chronic rejection, post-transplant lymphoproliferative disorder, graft dysmotility or dysfunction, severe infection, arterial graft aneurysm, or allograft liver failure (Mazariegos, 2008). Careful patient selection, post-transplant immunosuppression, and patient management are essential for successful long-term outcomes (Mazariegos, 2008). Based on Organ Procurement Transplant

Network and the Scientific Registry of Transplant Recipients (OPTN/SRTR) data for repeat intestine transplants performed between 2008-2015 Kaplan-Meier one-, three-, and five-year patient survival rates (as of Nov 3, 2024) were 70.2%, 53.9% and 49.8%, respectively. Individuals undergoing repeat intestinal or multivisceral transplantation should meet all of the eligibility criteria for primary transplantation and should not have absolute contraindications to transplantation.

Literature Review
Desai et al. (2012) performed an analysis of United Network of Organ Sharing (UNOS) registry data relative to outcomes for intestine retransplantation performed in children and adults from 1987-2009. Of 1822 isolated intestine transplants (ITx) in 1664 patients during the study period, 149 patients (adults, n=72; children, n=77) received repeat transplantation. Nine of these were third transplants, all in children. Of 41 adult isolated ITx, patient survival was 80.1%, 47.4%, and 28.5% at 1, 3, and 5 years, respectively, which is lower than outcomes seen with primary isolated ITx (p=0.005). For combined liver/ITx retransplantation in adults (L-ITx, n=31), patient survival at one-, three-, and five-years was 63.1%, 56.1%, and 46.8%, respectively, compared with primary L-ITx retransplantation (p=0.07). Isolated ITx retransplantation in children (n=28) resulted in patient survival of 80.7%, 74%, ad 57.5% at one-, three-, and five-years, respectively. One-, three-, and five-year patient survival in children receiving L-ITX was 42%, 42%, and 42%, respectively. Although data suggests lower survival rates for retransplantation compared to primary transplantation, outcomes are acceptable in this population of individuals for which alternative treatment options are limited.

Living Donor Intestinal Transplantation
Intestinal transplantation is predominantly performed using organs from deceased donors. However, in rare instances, a segment of the intestine from a living-related donor has been used for small bowel transplantation (Khan and Selvaggi, 2024). Theoretical benefits of living donor intestinal transplantation include the elimination of waitlist time, the ability to schedule the procedure electively, improved histocompatibility, and reduced cold ischemia duration (Tzvetanov, 2018; Tzvetanov, 2010). Over the past 20 years, 44 such procedures have been performed in the United States, with no living donor cases reported since 2017 (United States Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients [OPTN/SRTR], 2025). A comparable number of procedures have also been conducted globally.

Literature Review
Existing literature on living donor cases is limited, primarily consisting of single-center retrospective case reports and small case series and are limited by the small numbers of patients, study methods, and a lack of donor and recipient long-term outcomes (Wu, et al., 2022; Garcia-Roca, et al., 2016; Gangemi, 2009).

Professional Societies/Organizations
American Society of Transplantation (AST): On behalf of the AST, Kaufman (2001) published guidelines regarding the indications for pediatric intestinal transplantation. These include progressive parenteral nutrition-associated liver disease, recurring sepsis, impending loss of central venous access, extreme short-bowel syndrome, and congenital intractable epithelial (mucosal) disorders. The Society notes that intestinal transplantation is a lifesaving therapy for the child with intestinal failure. Transplantation should be considered when intestinal failure has been, or will probably become, refractory to conventional management, the mainstay of which remains parenteral nutrition therapy.

American Gastroenterological Association (AGA): The AGA's medical position statement: Short Bowel Syndrome and Intestinal Transplantation (2003) notes the following indications for intestinal transplantation:

- impending or overt liver failure
- thrombosis of major central venous channels
- frequent central line-related sepsis
- frequent severe dehydration

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.

Demographic characteristics of 164 candidates on the intestine only transplant waiting list on Oct 12, 2025, show that 40.9% were under 17 years old, 43.3% were female, with a race/ethnicity breakdown of 54.9% white, 12.8% Black, 26.2% Hispanic and 4.3% Asian. The demographic characteristics of intestine transplant recipients to date in 2025 reported 42.2% are <17 years old, 43.8% are female, with a race/ethnicity breakdown of 64.1% white, 9.4% Black, 20.3% Hispanic and 4.7% Asian (United States Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients [OPTN/SRTR], 2025). According to national data from the OPTN/SRTR, one-, three-, and five-year patient survival outcomes for individuals undergoing initial or primary deceased donor intestinal transplantation from 2008-2015 (as of Oct 12, 2025) are 82.8%, 69.0%, and 59.1%, respectively. Neither graft nor patient survival data are available for multivisceral transplantation from the OPTN. There have been no living donor intestinal transplants since 2017.

Appendix

Solid Organ Transplant (SOT) oncology clearance in accordance with published guidelines (Al-Adra, et al, 2021a; Al-Adra, et al., 2021b; Zwald, et al., 2016):

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 DCIS 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 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 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. Inflammatory breast cancer likely has a higher risk of recurrence and worse survival.
Prohibitive risk 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.

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.

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 ▪ Stage I (T1 or T2, N0, M0)	91	1 year	Low-risk features: ▪ Deficient DNA mismatch repair (as reflected by high levels of MSI) without BRAF mutation High-risk features: ▪ LVI or PNI ▪ Mucinous or signet histology ▪ Poorly differentiated histology ▪ Bowel obstruction ▪ Tumor perforation ▪ <12 lymph nodes examined Tumor deposits considered as N+ disease. Consider chemotherapy prior to transplantation for high-risk stage II disease. Patients with stage III disease should complete chemotherapy.
Low intermediate risk ▪ Stage II (T3, N0, M0)	72	2 years, consider longer if high-risk features present	
High intermediate risk ▪ Stage II (T4, N0, M0) ▪ Stage III (Any T, N+, M0)		3 years, 5 years if high-risk features present	
High risk ▪ 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.

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 ▪ Stage I (T1 or T2, N0, M0) ▪ Full oncologic resection	85 to 88	1 year, consider 2 years if high-risk features present	Low-risk features: ▪ Deficient DNA mismatch repair (as reflected by high levels of MSI) without BRAF mutation ▪ Upper 1/3 rectum or rectosigmoid High-risk features: ▪ LVI or PNI ▪ Mucinous or signet histology ▪ Poorly differentiated histology ▪ Bowel obstruction ▪ Tumor perforation ▪ <12 lymph nodes examined ▪ Lower 1/3 of rectum ▪ Incomplete mesorectal excision Tumor deposits considered as N+ disease. 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. 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 ▪ Stage I (T1, N0, M0) ▪ Local excision	78 to 88	2 years	
High intermediate risk ▪ Stage II (T3 or T4, N0, M0) ▪ Stage III (Any T, N+, M0)	70	3 years, 5 years if high-risk features present	
High risk ▪ 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.

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 ▪ 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 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 ▪ 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).

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.

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 <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 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 >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 >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.

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.

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: ▪ Perineural invasion or ▪ ≥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.

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 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 Oncology referral
Stage IIIB (T0-3a and N1a/b/c, N2a/b)	83	Wide excision plus SLNB plus lymph node dissection Adjuvant therapy with CKI	2 to 4 years	Imaging as above Oncology referral
Stage IIIC (T3b-4b and N2b/c-N3b/c)	69	Wide excision plus SLNB plus lymph node dissection Adjuvant therapy with CKI	At least 5 years	Imaging as above Oncology referral (no consensus was possible for this group)
Stage IIID (T4b and N3a-3c)	32	Wide excision plus SLNB plus lymph node dissection 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 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.

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.

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 statements if individual has a history of malignancy • Added policy statement for non-coverage of living-donor intestinal transplantation	3/15/2026
Annual review	• No policy statement changes	12/15/2024

Annual review	• No policy statement changes	12/15/2023