Medical Coverage Policy

Effective Date.....9/15/2025
Next Review Date.....9/15/2026
Coverage Policy Number..... 0129

Heart, Lung, and Heart-Lung Transplantation

Table of Contents

Related Coverage Resources

Extracorporeal Photopheresis
Laboratory Testing for Transplantation Rejection
Ventricular Assist Devices (VADs), Percutaneous Cardiac Support Systems and Total Artificial Heart

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 transplantation of the thoracic organs (i.e., heart, lung), surgical procedures in which one or both of the diseased organs are replaced with the viable heart, lung(s), lung lobes, or combined heart and lung of an appropriate donor.

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

Coverage Policy

HEART TRANSPLANTATION

Heart transplantation in an adult is considered medically necessary for the treatment of ANY of the following:

- malignant ventricular arrhythmias unresponsive to medical and/or surgical therapy
- refractory angina that is not amenable or correctable by alternative medical or surgical therapies and leaves the individual in a New York Heart Association functional class III or IV
- end-stage heart failure with EITHER of the following:
  - disease that is not amenable or correctable by alternative medical therapies or leaves the individual in New York Heart Association functional class III or IV
  - disease that requires continuous intravenous inotropic or mechanical circulatory support

Heart transplantation in a child is considered medically necessary for the treatment of EITHER of the following:

- intractable heart failure
- congenital abnormality not amenable to surgical correction

LUNG TRANSPLANTATION

Lung transplantation is considered medically necessary when EITHER of the following criteria are met:

- end-stage disease of lung parenchyma, airway and pulmonary vasculature that is not amenable to maximum alternative medical or surgical therapies with severe, progressive symptoms despite optimal medical management, resulting in an unacceptable quality of life

- current diagnosis of lung-limited adenocarcinoma in situ, minimally invasive adenocarcinoma, or lepidic predominant adenocarcinoma and ALL of the following:

    - non-small cell lung cancer (NSCLC) Stage II or lower
    - surgical resection is not feasible either because of multifocal disease or significant underlying pulmonary disease
    - multifocal disease has resulted in significant lung restriction and respiratory compromise
    - medical oncology therapies have failed or are contraindicated
    - lung transplant is expected to be curative
    - has oncology clearance in accordance with published guidelines (See Appendix) and does not have a contraindication as noted below.

Lung transplantation is considered not medically necessary for EITHER of following:

- coronary artery disease not amenable to percutaneous intervention or bypass grafting, or associated with significant impairment of left ventricular function
- chest wall/spinal deformity that would pose a contraindication to transplantation

HEART-LUNG TRANSPLANTATION

Heart-lung transplantation is considered medically necessary when BOTH of the following criteria are met:

- end-stage cardiopulmonary disease where the replacement of either organ alone is unlikely to improve survival or quality of life
- the individual remains at a New York Heart Association functional class III or IV despite maximal medical and surgical management

Note: Selected candidates may be eligible for multi-organ transplantation. For each organ, the candidate should meet all of the criteria for selection for the individual transplant being considered. For a heart-kidney transplant, please refer to Coverage Policy 0146 Kidney Transplantation for the kidney transplant criteria.

HEART, LUNG, OR HEART-LUNG TRANSPLANTATION

Heart, lung, or heart-lung transplantation is considered medically necessary if an individual with a history of malignancy:

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

Heart, lung, or heart-lung transplantation is considered not medically necessary in an individual with ANY of the following contraindications to transplant surgery:

- 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:
    - 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)

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.

The OPTN's Equity in Access to Transplant page for heart transplant notes that overall disparities in access to deceased donor heart transplant among candidates on the waiting list have remained relatively stable over the last decade. The most noteworthy risk-adjusted differences in access to heart transplants correspond to four key factors: Blood Type; Donation Service Area, or DSA; Height; and Weight. Differences associated with other factors beyond these four are relatively small, with factor-specific standard deviations approaching zero.

The OPTN's Equity in Access to Transplant page for lung transplant notes that though the overall disparity metric for access to deceased donor lung transplants among candidates on the waiting list has fluctuated over the past decade, the overall level of disparity in 2019 remains about the same as it was in 2010. The most noteworthy risk-adjusted differences in access to lung transplants correspond to four key factors: Blood Type; Donation service area, or DSA; Height; and Age. Differences associated with other factors beyond these four are relatively small, with factor-specific standard deviations approaching zero. The transplant rate advantage experienced by pediatric candidates is "discounted" from the factor-specific standard deviation estimate for age.

General Background

Heart Transplantation

A heart transplant replaces an individual's failing heart with a donor heart. The failing heart may be a result of heart failure, coronary heart disease, irregular heartbeat or some other severe heart condition. In individuals with congenital heart disease, the surgeon might also transplant the lungs with the heart.

The Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR) 2022 Annual Data Report states that the number of heart transplants in the United States has continued to increase.

Since 2012, the overall heart transplant rate for adults increased 106.1%. The rate of transplant in Asian candidates far exceeded that in all of the other racial and ethnic categories. Despite increasing 97.7% since 2012, the transplant rate in Black candidates has tended to be the lowest of the racial and ethnic categories and remained so. In 2023, the heart transplant rate among pediatric candidates decreased to its lowest rate in the past decade, which is a 14.9% decrease from 2012. Among adult patients who underwent transplant in 2016-2018, the 5-year survival was 80.3%. Overall, 1-year and 3-year patient survival were 91.5% and 85.9%, respectively. Relatively early decline in patient survival was noted in Hispanic recipients compared with other racial and ethnic categories between 2-3 months posttransplant and declined to 91.7% at 6 months. By year 1, survival was slightly lower in Hispanic recipients, 90.3%, and highest in Black recipients, 92.4%. During year 2, Black and Asian patients had a similar decline. At year 5, survival was lowest in Black and Hispanic recipients, 77.2% and 77.3%, and highest in White recipients, 81.7% (OPTN/SRTR 2023 Annual Data Report: Heart, Colvin, et al., 2025).

Indications for Heart Transplantation

ADULT
The 2023 OPTN adult heart allocation criteria for medical urgency status states that the candidate must be at least 18 years old at the time of registration with the following requirements (OPTN, June 26, 2025):

Adult Heart Status 1 requires that the patient has at least one of the following conditions:

- is supported by veno-arterial extracorporeal membrane oxygenation (VA ECMO)
- is supported by non-dischargeable, surgically implanted, non-endovascular biventricular support device
- is supported by mechanical circulatory support device (MCSD) with life-threatening ventricular arrhythmia

Adult Heart Status 2 requires that the patient has at least one of the following conditions:

- is supported by a non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD)
- is supported by a total artificial heart (TAH), biventricular assist device (BiVAD), right ventricular assist device (RVAD), or ventricular assist device (VAD) for single ventricle patients
- is supported by a MCSD device that is malfunctioning
- is supported by a percutaneous endovascular mechanical circulatory support device
- is supported by an intra-aortic balloon pump (IABP)
- is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation

Adult Heart Status 3 requires that the patient has at least one of the following conditions:
- is supported by a dischargeable left ventricular assist device and is exercising 30 days of discretionary time
- is supported by multiple inotropes or a single high dose inotrope and has hemodynamic monitoring
- is supported by VA ECMO after 7 days; or percutaneous endovascular circulatory support device or IABP after 14 days
- is supported by non-dischargeable, surgically implanted, non-endovascular LVAD after 14 days
- is supported by an MCSD with one of the following:
  - hemolysis
  - pump thrombosis
  - device infection
  - bleeding
  - aortic insufficiency
  - right heart failure

Adult Heart Status 4 requires that the patient has at least one of the following conditions:
- is supported by dischargeable LVAD
- is supported by inotropes without hemodynamic monitoring
- is a re-transplant
- has a diagnosis of one of the following:
  - congenital heart disease (CHD)
  - ischemic heart disease with intractable angina
  - hypertrophic cardiomyopathy
  - restrictive cardiomyopathy
  - amyloidosis

Adult Heart Status 5 is for patients who are on the waitlist for at least one other organ at the same hospital and status 6 is for all remaining active candidates.

PEDIATRIC
Heart candidates less than 18 years old at the time of registration may be assigned any of the following:
- Pediatric status 1A
- Pediatric status 1B
- Pediatric status 2
- Inactive status

Pediatric Heart Status 1A includes patients less than 18 years old at the time of registration with at least one of the following conditions:
- requires continuous mechanical ventilation or assistance of an intra-aortic balloon pump and is admitted to the hospital that registered the patient

- has ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent or prostaglandin infusion and is admitted to the hospital that registered the patient
- has a hemodynamically significant congenital heart disease diagnosis, requires infusion of multiple intravenous inotropes or a high dose of a single intravenous inotrope and is admitted to the hospital that registered the patient.
- requires assistance of a mechanical circulatory support device

Pediatric Heart Status 1B includes at least one of the following criteria:

- requires infusion of one or more inotropic agents but does not qualify for pediatric status 1A
- younger than one year old at the time of the candidate's initial registration and has a diagnosis of hypertrophic or restrictive cardiomyopathy.

Pediatric Heart Status 2 Requirements: If the candidate is less than 18 years old at the time of registration and does not meet the criteria for pediatric status 1A or 1B but is suitable for transplant, then the candidate may be assigned pediatric status 2. A candidate's pediatric status 2 does not require any recertification (OPTN, June 26, 2025).

International Society for Heart and Lung Transplantation (ISHLT)
The ISHLT Guidelines for the Evaluation and Care of Cardiac Transplant Candidates (Peled, et al., 2024) lists the following:

Recommendations for Indications for Heart Transplantation (2.1.1)	**COR***	**LOE***
In patients with HF, when consistent with the patient's goals of care, the presence of clinical indicators of advanced HF (AvdHF) should trigger evaluation for AdvHF therapies, including heart transplantation.	I	B-NR
In ambulatory adult HF patients referred for transplant evaluation (and pediatric patients when age-appropriate), cardiopulmonary exercise test (CPET) should routinely be performed to quantify exertional intolerance, inform HF prognosis, and guide transplant listing.	I	B-NR
In adult HF patients evaluated for transplantation, right heart catheterization (RHC) should be performed prior to listing to assess for potentially prohibitive pulmonary hypertension and for cardiogenic shock requiring inotropic support and/or temporary mechanical circulatory support (MCS).	I	C-LD
In adult HT candidates, HF prognosis scores can be considered in the context of other data collected during transplant evaluation to guide listing decisions.	IIa	C-LD
In pediatric HT candidates, RHC may be performed prior to listing.	IIb	C-EO

Factor	Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation (2.1.2)	COR*	LOE*
Age	In patients with AdvHF aged ≤70 years, evaluation for Heart Transplantation (HT) is recommended.	I	B-NR
Age	In patients with AdvHF who are over 70 years of age, evaluation for HT may be considered in carefully selected patients depending on their functional status and control of comorbidities, taking into account the need for specialized post-transplant care for older patients, including the need for tailored immunosuppression.	IIb	B-NR
Obesity	In adult heart transplant candidates with a pre-transplant BMI ≥ 35 kg/m2, weight loss to achieve a BMI of < 35 kg/m2 is reasonable before listing for HT to improve post-transplant outcomes.	IIa	B-NR
Obesity	In pediatric heart transplant candidates, the use of a BMI threshold in assessing transplant candidacy is not well established.	IIb	C-LD
Cancer	Colorectal cancer: patients aged 50-75 years with an average risk of colorectal cancer should undergo regular screening with either a high-sensitivity stool-based test (fecal immunochemical, high-sensitivity, guaiac-based fecal occult blood test, multitarget stool DNA high sensitivity) or a structural (visual) examination (colonoscopy, computed tomography (CT) colonoscopy, flexible sigmoidoscopy), depending on patient preference and test availability. As a part of the screening process, all positive results of non-colonoscopy screening tests should be followed up with a timely colonoscopy. Prostate cancer: screening for prostate cancer is recommended with prostate-specific antigen (PSA) with or without digital rectal examination for patients beginning at age 50 years, for patients at higher risk (African American and men who have a first-degree relative diagnosis with prostate cancer before age 65 years) beginning at age 45 years, for patients at appreciably higher risk (multiple family members diagnosed with prostate cancer before age 65 years) beginning at age 40 years Breast cancer: women aged 45 to 54 years should have annual screening mammogram. Women aged 55 years and older should have a screening mammogram every 2 years but can continue annually if the patient prefers Cervical cancer: women aged 25 to 65 years should have a primary HPV test every 5 years (Class 1). If HPV testing is	I	B-R

Factor	Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation (2.1.2)	COR*	LOE*
	unavailable, screening may be done with either a co-test that combines an HPV test with a Papanicolaou (Pap) test every 5 years or a Pap test alone every 3 years. Lung cancer: patients aged 50-80 years with 20 pack-year smoking history who have quit smoking within the last 15 years should have annual low-dose chest CT. Screening should be discontinued once a patient reaches 15 years of smoking cessation. CT chest done in all heart transplant candidates should be evaluated for the early detection of lung cancer.		
Cancer	In heart transplant candidates with a history of malignancy, collaboration with oncology specialists is recommended for individualized risk stratification to assess malignancy-related survival and risk of recurrence in the context of immunosuppression. In heart transplant candidates with a history of malignancy, HT is recommended when malignancy-related survival will not impact post-transplant survival and the risk of recurrence is low based on tumor type, response to therapy, and negative metastatic evaluation.	I	C-LD
Cancer	Colorectal cancer: patients aged 45–49-year an average risk of colorectal cancer should undergo regular screening with either a high-sensitivity stool-based test (fecal immunochemical, high-sensitivity, guaiac-based fecal occult blood test, multitarget stool DNA high sensitivity) or a structural (visual) examination (colonoscopy, computed tomography (CT) colonoscopy, flexible sigmoidoscopy), depending on patient preference and test availability. As a part of the screening process, all positive results of non-colonoscopy screening tests should be followed up with a timely colonoscopy.	IIa	B-R
Cancer	Skin cancer: screening by a full-body skin examination completed by a dermatologist for all heart transplant candidates can be useful to reduce skin cancer morbidity and mortality. New technologies (i.e., circulating tumor DNA) can detect and measure microscopic residual disease in patients who have undergone definitive treatment, provide information on the status of a patient's cancer, and offer unique advantages in certain settings.	IIa	B-NR
Diabetes	In heart transplant candidates, ophthalmologic consultation to determine the presence of retinopathy can be beneficial	IIa	B-NR

Factor	Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation (2.1.2)	COR*	LOE*
	as a surrogate for duration of diabetes and degree of diabetic control and vascular/kidney involvement.		
Diabetes	In heart transplant candidates with diabetes with end-organ damage or poor glycemic control (glycosylated hemoglobin [HbA1c] > 7.5%), delay in HT evaluation and listing is reasonable until diabetic control is improved.	IIa	C-LD
Cerebral and Peripheral Vascular Disease	In heart transplant candidates with a history of stroke or neurologic signs or symptoms suggestive of cerebrovascular disease, screening for cerebrovascular disease with carotid ultrasonography is recommended. In heart transplant candidates with symptoms of peripheral arterial disease, diminished peripheral pulses, atherosclerotic disease, or the presence of risk factors, screening for peripheral vascular disease with ankle-brachial indices is recommended.	I	C-EO
Cerebral and Peripheral Vascular Disease	In heart transplant candidates with clinically severe symptomatic cerebrovascular disease not amenable to revascularization (as determined by a neurologist), the benefit of HT is uncertain due to the risks of perioperative stroke and impact on post-transplant rehabilitation efforts and QOL.	IIb	B-NR
Cerebral and Peripheral Vascular Disease	In heart transplant candidates with clinically severe symptomatic peripheral vascular disease, especially associated with nonhealing ischemic ulcers (as determined by a vascular specialist), the benefit of HT is uncertain due to the risks of perioperative limb ischemia and impact on post-transplant rehabilitation efforts and QOL.	IIb	C-LD
Pulmonary Disease	In heart transplant candidates, pulmonary evaluation with pulmonary function testing (spirometry, lung volume assessment, and diffusion capacity) and chest CT is recommended, ideally once optimized from a volume perspective.	I	C-EO
Pulmonary Disease	In heart transplant candidates with severe parenchymal lung disease, as evidenced by chronic hypoxia from a pulmonary source or significant abnormalities in pulmonary function tests (as determined by a pulmonologist), the benefit of HT is uncertain due to the increased risk of post-transplant mortality.	IIb	C-LD
Pulmonary Disease	In heart transplant candidates deemed ineligible for transplantation due to severe irreversible end-stage	IIb	C-EO

Factor	Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation (2.1.2)	COR*	LOE*
	parenchymal lung disease, evaluation for combined heart and lung transplantation may be considered.		
Pulmonary Hypertension	In adult heart transplant candidates with pulmonary artery systolic pressure (PASP) ≥ 50 mmHg and either a TPG≥ 15 mmHg or PVR≥3 Wood units while maintaining a systolic arterial blood pressure > 85 mmHg, the following stepwise evaluation is recommended to assess transplant candidacy: 1) an acute vasodilator challenge to assess for reversibility of PH (Class 1); 2) hospitalization with continuous hemodynamic monitoring as often the PVR will decline after 24 to 48 hours of treatment consisting of diuretics, inotropic support, and vasodilators (Class I); 3) temporary or durable MCS for unloading of the left ventricle (Class 2a).	I/IIa	C-LD
Pulmonary Hypertension	In pediatric heart transplant candidates, HT is reasonable if PVR indexed to body surface area (PVRI) is less than 9 Wood units m^2 on initial assessment or after treatment with diuretics, inotropic support, vasodilator therapy, or MCS.	IIa	B-NR
Pulmonary Hypertension	In heart transplant candidates deemed ineligible for transplantation due to severe irreversible PH, evaluation for combined heart and lung transplantation may be considered in carefully selected patients.	IIb	C-EO
Pulmonary Hypertension	In heart transplant candidates with severe PH not reversible with measures including diuretic therapy, inotropic support, vasodilators, and temporary or durable MCS as indicated, HT alone is not recommended.	III No benefit	B-NR
Kidney Disease	In heart transplant candidates, a comprehensive assessment of kidney function is recommended, including: 1) historical trends in kidney function; 2) kidney function as measured by estimated glomerular filtration rate (GFR) and 24-hour creatinine clearance (CrCl) when hemodynamically optimized; and 3) comorbidities known to impact kidney function. If there is abnormal kidney function, further investigation is recommended, including nephrology consultation, renal ultrasonography, and estimation of proteinuria for assessment of intrinsic renal disease. In heart transplant candidates with established GFR < 30 ml/min/1.73 m^2, evaluation for simultaneous heart-kidney transplantation (SHKT) is recommended.	I	B-NR

Factor	Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation (2.1.2)	COR*	LOE*
Kidney Disease	In heart transplant candidates with established GFR of 30–44 ml/min/1.73 m^2 and evidence of chronic kidney disease (CKD), such as small kidney size or persistent proteinuria >0.5 g/day in the presence of stable hemodynamics, evaluation for SHKT is reasonable.	IIa	B-NR
Liver Disease	In heart transplant candidates, a comprehensive assessment of liver function is recommended, including: 1) liver function tests (albumin, bilirubin, INR); 2) biochemical assays (AST, ALT, GGT), 3) MELD-XI score; and 4) abdominal imaging with ultrasound or CT and/or magnetic resonance imaging (MRI). If there is abnormal initial liver evaluation, further investigation is recommended, including hepatology consultation and liver biopsy. Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, gamma-glutamyl transferase; INR, international normalized ratio; MELD-XI, model for end-stage liver disease excluding INR.	I	B-NR
Liver Disease	In patients with biopsy-proven cirrhosis and/or severe liver fibrosis with evidence of portal hypertension, evaluation for heart-liver transplantation is reasonable.	IIa	B-NR
Connective Tissue Diseases and Sarcoidosis	In heart transplant candidates with connective tissue disease (CTD) or sarcoidosis, focused multidisciplinary collaboration is recommended to determine 1) the impact of the CTD on post-transplant survival, rehabilitation efforts, and QOL; 2) the impact of immunosuppression on the progression of the CTD; 3) the risk of cardiac recurrence; and 4) CTD-specific extracardiac manifestations such as PH, pulmonary parenchymal disease, aspiration risk, and/or arthritis.	I	B-NR
Connective Tissue Diseases and Sarcoidosis	In heart transplant candidates with CTD that is expected to shorten post-transplant survival, that is associated with severe non-cardiac disease, or that is not controlled with pre-transplant immunosuppression, HT is not recommended.	III No benefit	B-NR
Infections and Vaccinations	In heart transplant candidates, vaccine history and assessment of seroprotection (as appropriate) should be reviewed, and age-appropriate vaccinations administered ideally at least 2 weeks prior to transplantation are recommended; live-attenuated vaccines should be avoided unless transplant can be deferred for 4 weeks after receipt due to concern for ongoing viral replication.	I	B-NR
Infections and Vaccinations	In heart transplant candidates, screening for chronic or latent diseases that have the risk for post-transplant reactivation and may warrant pre-transplant treatment or	I	C-EO

Factor	Recommendations for Comorbidities and Potential Contraindications to Heart Transplantation (2.1.2)	COR*	LOE*
	post-transplant surveillance is recommended, including but not limited to human immunodeficiency viral (HIV) infection, Chagas disease, tuberculosis (TB), HBV and HCV infections; surveillance for geographically restricted specific pathogens may be warranted.		
Infections and Vaccinations	In heart transplant candidates with certain infections, HT is not recommended; these include1) active infections requiring ongoing antibiotic treatment (except for infected durable LVADs); and 2) HIV with opportunistic infections or related malignancy, lack of stable antiretroviral regimen, detectable viral load, and/or low CD4 count.	III No benefit	C-EO
Frailty	In heart transplant candidates, regular exercise as tolerated is recommended, ideally in a structured program if available, to prevent or improve frailty.	I	C-LD
Frailty	In heart transplant candidates, assessment of frailty can be beneficial to identify actionable targets for improvement in conditioning and perform risk assessment of transplant candidacy.	IIa	B-NR
Frailty	In heart transplant candidates with severe frailty that will preclude adequate post-transplant rehabilitation efforts and is not expected to improve with restoration of cardiac function, HT is not recommended.	III No benefit	C-EO
Surgical Risk	In HT candidates with prior cardiac surgery, this additional risk should be factored into the comprehensive assessment of transplant eligibility.	I	B-NR
Surgical Risk	In heart transplant candidates with circular aortic calcification ("porcelain" aorta), the benefit of HT is uncertain due to the high risk of perioperative mortality and stroke.	IIb	C-LD
Bone Disease	Heart transplant candidates should be assessed for osteoporosis and fracture risk.	I	B-NR

Population	Recommendations for Assessment of Transplant Eligibility in Special Populations (2.1.3)	COR*	LOE*
Cardiac Amyloidosis	In heart transplant candidates with cardiac amyloidosis from immunoglobulin light chain deposition (AL-CM) or transthyretin deposition (ATTR-CM) with evidence of AdvHF as indicated by amyloid-specific staging systems and	IIa	B-NR

Population	Recommendations for Assessment of Transplant Eligibility in Special Populations (2.1.3)	COR*	LOE*
	traditional risk factors, heart transplant evaluation is reasonable, including multidisciplinary collaboration to evaluate the extent and control of extracardiac disease.		
Cardiac Amyloidosis	In patients with ATTRv-CM, the role of heart-liver transplantation is not well established given the advent of TTR silencer therapy, which reduces the progression of amyloid neuropathy. In patients with AL-CM or ATTR-CM, the role of durable LVAD support is not well established, given the small left ventricular (LV) cavity size and biventricular involvement.	IIb	B-NR
Cardiac Amyloidosis	In patients with AL-CM and high-grade albuminuria, significant hepatic infiltration, significant gastrointestinal involvement with malnutrition, pulmonary amyloidosis with refractory effusions, significant peripheral neuropathy with autonomic dysfunction, and/or projected reduced survival despite plasma cell-directed therapies as determined in collaboration with hematologists and other relevant specialists, HT is not recommended.	III Harm	B-NR
Cardiac Amyloidosis	In patients with ATTR-CM with significant gastrointestinal involvement with malnutrition, significant peripheral neuropathy with autonomic dysfunction, and/or advanced age, HT is not recommended.	III No benefit	B-NR
Restrictive Cardio-myopathy	In patients with restrictive cardiomyopathy (RCM) and severe HF symptoms (NYHA ClassIII–IV), HT evaluation is recommended.	I	B-NR
Restrictive Cardio-myopathy	In patients with RCM being evaluated for HT, a diagnostic evaluation to exclude treatable or reversible causes is recommended.	I	C-LD
Restrictive Cardio-myopathy	In patients with RCM, the role of durable mechanical circulatory support (DMCS) is not well established.	IIb	C-LD
Hypertrophic Cardio-myopathy	In patients with nonobstructive hypertrophic cardiomyopathy (HCM)and AdvHF (NYHA Class III-IV despite guideline-directed medical therapy [GDMT]) or with life-threatening ventricular arrhythmias refractory to maximal GDMT, evaluation for HT is indicated.	I	B-NR
Hypertrophic Cardio-myopathy	In patients with nonobstructive HCM and persistent or progressive HF symptoms (NYHA Class III-IV) despite GDMT who are otherwise suitable for HT, continuous-flow LVAD therapy is reasonable as a bridge to HT, in those with suitable anatomy.	IIa	B-NR

Population	Recommendations for Assessment of Transplant Eligibility in Special Populations (2.1.3)	COR*	LOE*
Congenital Heart Disease	In heart transplant candidates with CHD, care at centers with established medical and surgical experience in both pediatric and adult CHD and transplantation is recommended to confirm that transplant evaluation is appropriate and that all non-transplant medical, interventional, and surgical therapies have been exhausted prior to evaluation.	I	B-NR
Congenital Heart Disease	In patients with single ventricle CHD, HT evaluation is recommended to improve QOL and survival in the following situations: a. Palliation to a shunted circulation or a superior cavo-pulmonary anastomosis (first procedure of a staged Fontan) and prohibitive risk for further single ventricle palliation; b. Cyanotic heart disease with severe atrio-ventricular valve regurgitation and prohibitive risk for operative repair; c. Pulmonary atresia with an intact ventricular septum, right ventricular dependent coronary circulation, and atresia of at least one aorto-coronary ostium; d. Neonatal hypoplastic left heart syndrome with high-risk features including HF symptoms, ventricular dysfunction, left ventricular-coronary artery fistulae.	I	B-NR
Congenital Heart Disease	In heart transplant candidates with CHD, detailed assessment is recommended, including: a. The position and anatomy of the abnormalities within the chest (via cardiac MRI and/or chest CT) to guide the surgical strategy; b. Evaluation of PH, and all potential sources of pulmonary flow; c. Patency of major veins and arteries and venous collaterals across the chest wall; d. Disease in organ systems that can affect post-transplant care and/or cannot be reversed with transplantation (including but not limited to lung, liver, gastrointestinal, and kidney disease); e. Anti-human leucocyte antigen (HLA) antibody sensitization; f. Psychosocial evaluation of the patient, family, and caregiver support.	I	C-LD
Congenital Heart Disease	In patients with single ventricle CHD and a Fontan circulation (total cavopulmonary anastomosis), HT evaluation is recommended to improve QOL and survival in the following situations: a. Symptomatic HF and reduced systolic function (Class 1);	I/IIa	B-NR

Population	Recommendations for Assessment of Transplant Eligibility in Special Populations (2.1.3)	COR*	LOE*
	b. Symptomatic HF, preserved systolic function, and abnormal systemic ventricular filling pressures (Class 1); c. Lymphatic abnormalities including plastic bronchitis and protein-losing enteropathy refractory to lymphatic interventions and medical management (Class 2a); d. Cirrhosis or CKD attributed to chronically elevated central venous pressures (Class 2a).		
Congenital Heart Disease	In patients with CHD, HT evaluation is recommended to improve QOL and survival in the following situations: a. HF symptoms or ventricular arrhythmias refractory to medical, interventional, and device therapies (Class 1). b. Reactive PH and a potential risk of developing fixed, irreversible elevation of PVR that could preclude HT in the future (Class 1) c. Neonatal cyanotic CHD with high-risk features as determined by an experienced pediatric CHD and cardiac surgery center (Class 2a).	I/IIa	B-NR
Congenital Heart Disease	The benefit of HT for CHD is not well established and may be considered as significant risk in the following CHD-specific situations: a. Increased surgical risk including multiple prior cardiac surgeries, aortopulmonary collaterals not amenable to catheter-based or surgical interventions; and/or prior mediastinitis b. Congenital absence, or near-total venous thromboembolism, of major systemic venous connections.	IIb	B-NR
Congenital Heart Disease	In patients with Fontan-associated liver disease and cirrhosis, the specific indications for heart alone versus heart-liver transplantation are not well-established and include: a. HT alone in patients with no stigmata of liver disease based on Child-Pugh Class A function and no portal hypertension; b. Heart-liver transplantation in patients with stigmata of liver disease based on Child-Pugh Class B/C function and/or portal hypertension (varices, ascites, splenomegaly, and/or thrombocytopenia). For patients with FALD score ≥ 2 combined heart-liver transplants may confer a survival advantage vs. isolated HT.	IIb	B-NR
Retransplant-ation	In heart transplant recipients with ISHLT Grade 3 CAV, evaluation for retransplantation is reasonable.	IIa	B-NR

Population	Recommendations for Assessment of Transplant Eligibility in Special Populations (2.1.3)	COR*	LOE*
Retransplanta-tion	2.In heart transplant recipients with the following, the benefit of retransplantation is not well established: a. Graft failure due to active rejection b. Advanced age c. Need for durable mechanical circulatory support (DMCS) as a bridge to retransplantation.	IIb	C-LD

Other areas of Recommendations include:
2.2. Psychosocial Evaluation
2.3. Multidisciplinary Team Approach
3. TASK FORCE II: OPTIMIZATION OF THE MEDICAL SURVEILLANCE OF PATIENTS ON THE WAITLIST
4. TASK FORCE III: CONSIDERATIONS FOR MECHANICAL CIRCULATORY SUPPORT SYSTEMS

*Class of Recommendation (COR)
Class I: is Strong
Class IIa: Moderate
Class IIb: Weak
CLASS III: No Benefit (MODERATE)
CLASS III: Harm (STRONG)

Level of Evidence (LOE):
LEVEL B-NR (Nonrandomized)
LEVEL C-LD (Limited Data)
LEVELC-EO (Expert Opinion)

The International Society for Heart and Lung Transplantation (ISHLT) 2023 Guidelines for Mechanical Circulatory Support (Saeed, et al., 2023) states the two major indications for durable mechanical circulatory support (DMCS) include bridge to cardiac transplantation (BTT) or permanent therapy for end-stage refractory heart failure, referred to as destination therapy (DT). Indications for mechanical circulatory support include:

*Class I
- Patients with advanced heart failure symptoms (New York Heart Association functional class IIIB-IV) refractory to maximal medical management, inotrope dependent or on temporary circulatory support, should be considered for durable mechanical circulatory (DMCS) support for short term support as bridge to transplantation or bridge to candidacy.
- Patients with advanced heart failure symptoms (New York Heart Association functional class IIIB-IV) refractory to maximal medical management, inotrope dependent or on temporary circulatory support, should be considered for DMCS for long-term support if transplant is unlikely to occur in the short-term, if a period of support will improve transplant candidacy, or as destination therapy for patients who are ineligible for transplant.

Class IIa

- Patients with dilated cardiomyopathy, particularly of recent onset and nonischemic etiology refractory to maximal medical therapy, should be considered for DMCS as bridge-to-recovery. Pharmacological treatment should be with maximally tolerated neurohormonal modulation, and surveillance for recovery of left ventricular function should be undertaken (ISHLT/Saeed, et al., 2023).

*Class I: Strongly supported by evidence or consensus opinion. Such a treatment is strongly recommended
Class IIa: Evidence or consensus opinion mostly in favor. Such a treatment is reasonable to consider.
Class IIb: Evidence or consensus opinion conflicting or less well established. Such a treatment may be reasonable to consider.
Class III: Evidence or consensus opinion is against as the treatment is not effective or harmful. Such a treatment should be avoided.

American College of Cardiology/American Heart Association (ACC/AHA)
The American College of Cardiology/American Heart Association (ACC/AHA) Guideline for the Management of Hypertrophic Cardiomyopathy (2024) lists some recommendations that address heart transplantation:

- In patients with nonobstructive hypertrophic cardiomyopathy (HCM) and advanced HF (NYHA functional class III to class IV), cardio-pulmonary exercise stress testing should be performed to quantify the degree of functional limitation and aid in selection of patients for heart transplantation or mechanical circulatory support (COR I*).
- In patients with nonobstructive HCM and advanced HF (NYHA functional class III to class IV despite guideline-directed management and therapy [GDMT]), cardiopulmonary exercise test (CPET) should be performed to quantify the degree of functional limitation and aid in selection of patients for heart transplantation or mechanical circulatory support (COR I).
- In patients with nonobstructive HCM and advanced HF (NYHA functional class III to class IV despite GDMT) or with life-threatening ventricular arrhythmias refractory to maximal GDMT, assessment for heart transplantation in accordance with current listing criteria is recommended (COR I).
- In patients with nonobstructive HCM and advanced HF (NYHA functional class III to class IV despite GDMT) who are candidates for heart transplantation, continuous-flow LVAD therapy is reasonable as a bridge to heart transplantation (COR IIa).
- In patients with HCM and recurrent, poorly tolerated life-threatening ventricular tachyarrhythmias refractory to maximal antiarrhythmic drug therapy and ablation, heart transplantation assessment is indicated in accordance with current listing criteria (COR I).

*Class of Recommendation (COR)
Class I: is recommended
Class IIa: is reasonable
Class IIb: may be reasonable
Class III: is not recommended (Writing Committee Members/ACC, 2024).

The 2023 ACC Expert Consensus Decision Pathway on Comprehensive Multidisciplinary Care for the Patient With Cardiac Amyloidosis notes:

- 7.6.2. Indications for heart transplantation
  In select patients with amyloid transthyretin cardiomyopathy (ATTR-CM) and amyloid monoclonal immunoglobulin light chain cardiomyopathy (AL-CM) with advanced/stage D HF, heart transplantation may be an option, and the current adult donor allocation system

provides priority as Status 4 to amyloid CM, given the lack of durable mechanical circulatory support (MCS) support options.

- 7.6.3. Contraindications to heart transplantation
  As multiorgan amyloid infiltration is common, the contraindications to heart transplantation in patients with cardiac amyloidosis center around the degree of extracardiac involvement and the impact of this involvement on post-transplant morbidity and mortality (Writing Committee/ACC, 2023).

The 2022 ACC/AHA/HFSA guideline for the management of heart failure (Heidenreich, et al., 2022) noted that heart transplantation is the established treatment for eligible patients with stage D heart failure that is refractory to guideline-directed medical therapy (GDMT), device, and surgical management. Heart transplantation provides a mortality and morbidity benefit to selected patients with stage D HF.

The 2018 ACC/AHA guideline for the management of adults with congenital heart disease (ACHD) stated that cardiac transplantation is reasonable in adults with Fontan palliation with signs and symptoms of protein-losing enteropathy. Additionally, in patients with ACHD and Eisenmenger syndrome exhibiting deteriorating functional ability, mechanical circulatory and pulmonary support, lung transplantation with concomitant repair of anatomic cardiovascular defects, and heart–lung transplantation have been applied (Stout, et al., 2019).

The 2016 AHA scientific statement on chronic heart failure in congenital heart disease stated that transplantation is a reasonable consideration in pediatric patients with heart failure associated with systemic ventricular dysfunction with previously repaired or palliated chronic heart disease (CHD) when it is associated with significant growth failure attributable to the heart disease and CHD with severe limitation of exercise and activity. Additional indications included: CHD with normal ventricular function if the following anatomic and physiological conditions are present and not amenable to surgical intervention (Stout, et al., 2016):

- proximal coronary arteries have severe stenosis or atresia
- atrioventricular or systemic semilunar valve(s) with moderate to severe stenosis or insufficiency
- symptomatic arterial oxygen desaturation (cyanosis)
- persistent protein-losing enteropathy despite optimal medical-surgical therapy

The 2024 AHA scientific statement on Evaluation and Management of Chronic Heart Failure in Children and Adolescents With Congenital Heart Disease does not make any specific recommendations regarding transplant (Amdani, et al., 2024).

Lung Transplantation

Lung transplantation is the surgical replacement of the lung(s) of an individual with end-stage pulmonary disease. The type of lung transplantation procedure used (i.e., lobar, single, or double) and donor type (i.e., deceased or living) are based upon the candidate's condition and indication for transplantation, and the availability of donor organs. For most recipients, lung transplantation is a palliative, rather than curative treatment, the primary goal being the projected survival benefit. It is an accepted treatment of last resort for persons with end-stage lung disease who do not respond to alternative medical or surgical treatment. Improvements in quality of life, in addition to survival, should be used to assess the effectiveness of the procedure.

The OPTN/SRTR 2022 Annual Data Report states in the year 2023, there were 3,049 adult and 31 pediatric lung transplants performed in the United States, continuing the trend of increasing lung transplants every year. The annual number of new candidates added to the waiting list also

increased, with 3,385 adult and 42 pediatric candidates added. Although White candidates remained the majority, the proportion of individuals of minority race and ethnicity have increased over time. Hispanic candidates made up 14.1% of the waiting list in 2023, a 117.2% increase since 2013; Black candidates made up 11.1% of the list in 2023, a 16.3% increase since 2013. Survival trends after lung transplant remained stable over the past decade, with 88.5% of recipients in 2022 surviving to 1 year, 71.3% of recipients in 2020 surviving to 3 years, 59.7% of recipients in 2018 surviving to 5 years, and 31.8% of recipients in 2013 surviving to 10 years. Patient survival was similar across sex and racial and ethnic groups (OPTN/SRTR 2023 Annual Data Report: Lung; Valapour, et al., 2025).

Indications for Lung Transplantation
According to the OPTN Administrative Rules and Definitions policy (June 26, 2025), the lung composite allocation score (section 10.1) is the combined total of the candidate's lung medical urgency score, post-transplant outcomes score, lung biological disadvantages score, lung patient access score and lung placement efficiency score. The lung composite allocation score is awarded on a scale from 0 to 100. Candidates will be rank-ordered by lung composite allocation score. If two or more candidates have the same lung composite allocation score, the tied candidates will be ranked by order of their registration date (oldest to newest).

Each candidate is assigned a diagnosis group (section 10.1.F) based on their lung disease diagnosis, which is used in the calculation of their medical urgency score and their post-transplant survival score.

Group A
A candidate is in Group A if the candidate has any of the following diagnoses:

- Allergic bronchopulmonary aspergillosis
- Alpha-1 antitrypsin deficiency
- Bronchiectasis
- Bronchopulmonary dysplasia
- Chronic obstructive pulmonary disease/emphysema
- Ehlers-Danlos syndrome
- Granulomatous lung disease
- Inhalation burns/trauma
- Kartagener's syndrome
- Lymphangioleiomyomatosis
- Obstructive lung disease
- Primary ciliary dyskinesia
- Sarcoidosis with either Pulmonary artery (PA) mean pressure of 30 mm Hg or less, or PA mean pressure missing
- Tuberous sclerosis
- Wegener's granuloma – bronchiectasis

Group B
A candidate is in Group B if the candidate has any of the following diagnoses:

- Congenital malformation
- CREST – pulmonary hypertension
- Eisenmenger's syndrome: atrial septal defect (ASD)
- Eisenmenger's syndrome: multi-congenital anomalies
- Eisenmenger's syndrome: other specify
- Eisenmenger's syndrome: patent ductus arteriosus (PDA)
- Eisenmenger's syndrome: ventricular septal defect (VSD)

- Portopulmonary hypertension
- Pulmonary hypertension/pulmonary arterial hypertension
- Pulmonary capillary hemangiomatosis
- Pulmonary telangiectasia – pulmonary hypertension
- Pulmonary thromboembolic disease
- Pulmonary vascular disease
- Pulmonary veno-occlusive disease
- Pulmonic stenosis
- Right hypoplastic lung
- Scleroderma – pulmonary hypertension
- Secondary pulmonary hypertension
- Thromboembolic pulmonary hypertension

Group C
A candidate is in Group C if the candidate has any of the following diagnoses:

- Common variable immune deficiency
- Cystic fibrosis
- Fibrocavitary lung disease
- Hypogammaglobulinemia
- Schwachman-Diamond syndrome

Group D
A candidate is in Group D if the candidate has any of the following diagnoses:

- ABCA3 transporter mutation
- Alveolar proteinosis
- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchioloalveolar carcinoma (BAC)
- Carcinoid tumorlets
- Chronic pneumonitis of infancy
- Combined pulmonary fibrosis and emphysema (CPFE)
- Constrictive bronchiolitis
- COVID-19: acute respiratory distress syndrome
- COVID-19: pulmonary fibrosis
- CREST – Restrictive
- Eosinophilic granuloma
- Fibrosing Mediastinitis
- Graft versus host disease (GVHD)
- Hermansky Pudlak syndrome
- Hypersensitivity pneumonitis
- Idiopathic interstitial pneumonia,
- Idiopathic pulmonary hemosiderosis
- Lung retransplant or graft failure
- Lupus
- Mixed connective tissue disease
- Obliterative bronchiolitis: non-retransplant
- Occupational lung disease: other specify
- Paraneoplastic pemphigus associated Castleman’s disease
- Polymyositis
- Pulmonary fibrosis: other specify cause
- Pulmonary hyalinizing granuloma

- Pulmonary lymphangiectasia (PL)
- Pulmonary telangiectasia – restrictive
- Rheumatoid disease
- Sarcoidosis with PA mean pressure greater than 30 mm Hg
- Scleroderma – restrictive
- Silicosis
- Sjogren's syndrome
- Surfactant protein B deficiency
- Surfactant protein C deficiency
- Teratoma
- Wegener's granuloma – restrictive (OPTN, June 26, 2025).

International Society for Heart and Lung Transplantation (ISHLT)
The International Society for Heart and Lung Transplantation (ISHLT) 2021 consensus document for the selection of lung transplant candidates (Leard, et al., 2021) indicated that:

ADULT
Lung transplantation should be considered for adults with chronic, end-stage lung disease who meet all the following general criteria:

- high (> 50%) risk of death from lung disease within 2 years if lung transplantation is not performed
- high (> 80%) likelihood of 5-year post-transplant survival from a general medical perspective provided that there is adequate graft function

PEDIATRIC
In addition to general recommendations for adults, considerations for referring children for lung transplant evaluation include the following:

- Patients with cystic fibrosis < 18 years of age should be referred when:
  - FEV1 is < 50% predicted with markers of increased disease severity
  - FEV1 is < 50% predicted with rapidly declining FEV1
  - FEV1 is <40% predicted
- Patients with PAH < 18 years of age should be referred when despite optimal PAH therapy:
  - EPPVDN intermediate or high-risk category
  - Need for IV or SC prostacyclin therapy
  - Significant RV dysfunction
  - WHO functional class > III
  - Elevated or rising BNP or NTproBNP
  - Diminished growth
  - Progressive disease despite appropriate therapy or recent hospitalization for worsening of PAH
  - Signs of secondary liver or kidney dysfunction due to PAH
  - Potentially life-threatening complications such as recurrent hemoptysis or syncope
  - Being considered for atrial septostomy or reverse Potts shunt as a palliative procedure (footnote: transplantation may be an option post procedure)
- Patients with alveolar capillary dysplasia, pulmonary vein stenosis refractory to intervention, and pulmonary venoocclusive disease should be referred for urgent evaluation and listing.

In addition to general recommendations for adults, considerations for listing children for lung transplant include the following:

- Patients with CF < 18 years of age should be listed when FEV1 < 30% predicted
- Patients with PAH <18 years of age should be listed when they are in the EPPVDN high risk category and on optimal therapy without improvement

LUNG RE-TRANSPLANTATION

- The timing of re-transplant is a complex issue and requires consideration of the rate of deterioration, time since initial transplant, the need for supportive therapies and donor lung availability, which may be limiting in some cases.
- Survival after re-transplant is inferior to that seen with the primary operation and should only be undertaken in carefully selected candidates.
- In the evaluation of patients being considered for lung re-transplant, particular emphasis should be focused on understanding the possible reasons for the graft failure, such as alloimmunization, poor adherence, gastroesophageal reflux, or repeated infections.

MULTI-ORGAN TRANSPLANTATION

- Heart-lung and other multi-organ transplantation should be limited to centers with experience in such procedures and where specialists are available to manage each of the transplanted organs.
- Candidates should meet the criteria for lung transplant listing and have significant dysfunction of one or more additional organs or meet the listing criteria for a non-pulmonary organ transplant and have significant pulmonary dysfunction.
- Waiting times are likely to be longer and the likelihood of receiving a transplant is reduced when an individual requires more than one organ. Thus, referral should occur earlier in the disease course if multi-organ transplantation may be considered.

DISEASE SPECIFIC CANDIDATE RECOMMENDATIONS

Additionally, there are disease specific considerations for which transplantation may be indicated. These include:

Chronic Obstructive Airway Disease:

- BODE index (i.e., body mass index [B], degree of obstruction [O], dyspnea [D], exercise capacity [E]), score of 7-10
- FEV1 (i.e., forced expiratory volume in the first second) < 20% predicted
- history of severe exacerbations
- moderate to severe pulmonary hypertension
- chronic hypercapnia

Interstitial Lung Disease (ILD):

- a 10% or greater decrease in FVC (i.e., forced vital capacity) or FVC > 5% with radiographic progression during six months of follow-up
- a decline in diffusion capacity of carbon monoxide (DLCO) > 10% during 6 months of follow-up
- decrease in pulse oximetry <88% during a six-minute walk test
- confirmed pulmonary hypertension
- hospitalization for decline in respiratory status, pneumothorax or acute exacerbation

Cystic Fibrosis:

- FEV1 < 25% predicted
- chronic respiratory failure with hypoxemia or hypercapnia
- any exacerbation requiring mechanical ventilation
- nutritional status declining particularly with BMI < 18 kg/m^2
- pulmonary hypertension
- frequent hospitalization
- rapid decline in lung function or progressive symptoms
- recurrent massive hemoptysis despite bronchial artery embolization
- World Health Organization Functional Class IV

Non-CF Bronchiectasis:

- For individuals with non-CF bronchiectasis, similar criteria as with CF for referral and listing for lung transplantation is reasonable, though providers should recognize that prognosis is highly variable with many patients experiencing a more stable course.

Pulmonary Arterial Hypertension (PAH):

- European Society of Cardiology (ESC)/European Respiratory Society (ERS) high risk or REVEAL risk score > 10 on appropriate PAH therapy, including IV or SC prostacyclin analogues
- Progressive hypoxemia
- Progressive liver or kidney dysfunction due to PAH (not end-stage)
- Life-threatening hemoptysis

Lymphangioleiomyomatosis (LAM):

- despite mammalian target of rapamycin (mTOR) inhibitor therapy there is:
  - disease progression
  - severely abnormal lung function (e.g. FEV1 < 30% predicted)
  - NYHA class III or IV exertional dyspnea
  - hypoxemia at rest
  - pulmonary hyptertension
  - pneumothorax refractory to treatment

Thoracic Malignancy:

- Lung transplant should be limited to very select cases of lung-limited adenocarcinoma in situ, minimally invasive adenocarcinoma, or lepidic predominant adenocarcinoma for patients in whom:
  - surgical resection is not feasible either because of multifocal disease or significant underlying pulmonary disease;
  - multifocal disease has resulted in significant lung restriction and respiratory compromise;
  - medical oncology therapies have failed or are contraindicated; and
  - lung transplant is expected to be curative.

Acute Respiratory Distress Syndrome (ARDS):

- continuous requirement for mechanical ventilator support and/or extracorporeal life support (ECLS)
- no expectation of clinical recovery
- irreversible lung damage

ABSOLUTE CONTRAINDICATIONS

Candidates with these conditions are considered too high risk to achieve successful outcomes post lung transplantation. Factor or condition that significantly increases the risk of an adverse outcome post-transplant and /or would make transplant most likely harmful for a recipient. Most lung transplant programs should not transplant patients with these risk factors except under very exceptional or extenuating circumstances:

- Lack of patient willingness or acceptance of transplant
- Malignancy with high risk of recurrence or death related to cancer
- Glomerular filtration rate < 40 mL/min/1.73m2 unless being considered for multi-organ transplant
- Acute coronary syndrome or myocardial infarction within 30 days (excluding demand ischemia)
- Stroke within 30 days

- Liver cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multi-organ transplant
- Acute liver failure
- Acute renal failure with rising creatinine or on dialysis and low likelihood of recovery
- Septic shock
- Active extrapulmonary or disseminated infection
- Active tuberculosis infection
- HIV infection with detectable viral load
- Limited functional status (e.g. non-ambulatory) with poor potential for post-transplant rehabilitation
- Progressive cognitive impairment
- Repeated episodes of non-adherence without evidence of improvement (Note: For pediatric patients this is not an absolute contraindication and ongoing assessment of non-adherence should occur as they progress through different developmental stages.)
- Active substance use or dependence including current tobacco use, vaping, marijuana smoking, or IV drug use
- Other severe uncontrolled medical condition expected to limit survival after transplant

(ISHLT / Leard, et al., 2021).

International Society for Heart and Lung Transplantation (ISHLT)

The International Society for Heart and Lung Transplantation/Heart Failure Society of America Guideline on Acute Mechanical Circulatory Support (Bernhardt, et al., 2023) states that primary indications for venovenous extracorporeal membrane oxygenation (VV-ECMO) in acute pulmonary failure may include but are not limited to:

- Respiratory failure while awaiting lung transplantation

Heart-Lung Transplantation

Heart-lung transplantation is the procedure of choice for selected patients with concomitant end-stage heart failure and end-stage lung disease. Combined heart and lung transplantation is limited to patients in whom it offers the only surgical option for their end-stage cardiac and pulmonary disease. The procedure of choice for pulmonary parenchymal and vascular diseases in the absence of left heart dysfunction is single or double lung transplantation.

Where possible, isolated lung or heart transplantation is preferred to heart-lung transplantation because of several major disadvantages with the combined procedure. The need to procure a heart–lung block can lead to increased waiting time and increased mortality among patients awaiting combined heart-lung transplantation compared with those waiting for isolated heart or lung transplants. Other disadvantages include exposure of the recipient to risks of both graft coronary artery vasculopathy and chronic lung allograft dysfunction. In addition, heart-lung recipients may be disadvantaged by the obligate requirement for cardiopulmonary bypass during surgery and the physiological effects of a denervated heart.

Indications — Adult patients with concomitant refractory end-stage heart disease and chronic end-stage lung disease should undergo evaluation to determine if they are candidates for heart-lung transplantation. The most common indication for adult heart-lung transplantation is complex congenital heart disease with Eisenmenger syndrome (systemic-to-pulmonary communication, pulmonary arterial disease causing severe pulmonary hypertension, and cyanosis). Heart-lung transplant is also infrequently indicated in patients with concomitant end-stage pulmonary disease (eg, idiopathic pulmonary arterial hypertension [IPAH] or cystic fibrosis) and either right ventricular failure with objective evidence of right ventricular fibrosis or infarction or refractory left ventricular failure (UpToDate/Singer, et al., 2025).

The International Society for Heart and Lung Transplantation (ISHLT) 2021 consensus document for the selection of lung transplant candidates (Leard, et al., 2021) indicated that:

- Heart-lung and other multi-organ transplantation should be limited to centers with experience in such procedures and where specialists are available to manage each of the transplanted organs.
- Candidates should meet the criteria for lung transplant listing and have significant dysfunction of one or more additional organs or meet the listing criteria for a non-pulmonary organ transplant and have significant pulmonary dysfunction.
- Waiting times are likely to be longer and the likelihood of receiving a transplant is reduced when an individual requires more than one organ. Thus, referral should occur earlier in the disease course if multi-organ transplantation may be considered (ISHLT/Leard, et al., 2021).

The International Thoracic Organ Transplant Registry of the International Society for Heart and Lung Transplantation (Chambers, et al., 2019) reported number of adult heart-lung transplants remains static with 59 procedures reported in 2017. There were no significant changes in indication for heart-lung transplantation, with pulmonary hypertension accounting for the majority of procedures. The trend for a small but increasing number of heart-lung transplants performed for idiopathic interstitial pneumonia (IIP) and other diagnoses continued unabated in the past year. This increased activity has occurred at the expense of heart-lung transplantation for CF, which has become a rare indication compared with the 1990s. As has been the case for the past few years, an increasing proportion of heart-lung transplant recipients are older than 50 years at the time of transplant. The trend for older, non-CF recipients is particularly strong in North America, where 34% of recipients are now 50 years or older, and 8% 60 years or older.

Renal dysfunction, diabetes mellitus, malignancy, and chronic allograft rejection (allograft vasculopathy and BOS) are unfortunately common complications of heart-lung transplantation. The median survival for heart-lung transplant recipients has increased over the past few decades to 6.5 years in the most recent era; much of this mortality occurs early after transplantation, with median survival, conditional on survival to 1 year after transplant, almost double that at 12.8 years. Recipients transplanted for IIP have particularly poor outcomes, with median survival of only 1.9 years, significantly lower than median survival for CF recipients (ISHLT/Chambers, et al., 2019).

The International Thoracic Organ Transplant Registry of the International Society for Heart and Lung Transplantation (Hayes, et al., 2019) reported pediatric heart-lung transplantation is a rare procedure for children with cardiopulmonary failure, with most transplantations performed in the 11- to 17-year age group. From January 2010 to June 2018, significant differences were seen with respect to indication for pediatric heart-lung transplantation between Europe, North America, and other Regions. In Europe, CF is a more common indication, whereas idiopathic pulmonary arterial hypertension (IPAH) and pulmonary hypertension (PH)-not IPAH are more common in North America and other Regions. Survival in pediatric heart-lung recipients across the 3 major indications (CF, IPAH, and PH-not IPAH) was not statistically different (ISHLT/Hayes, et al., 2019).

Re-transplantation

Re-transplantation remains a controversial procedure, in part due to ethical concerns over the limited supply of organs. The recipient of the re-transplantation procedure often suffers from the systemic sequelae of short-or long-term immunosuppression, infection, and technical issues attributable to the initial transplantation surgery.

The International Society for Heart and Lung Transplantation (ISHLT) 2016 Listing Criteria for Heart Transplantation (Mehra, et al., 2016) notes that heart retransplantation remains a small portion of overall adult transplants performed, accounting for approximately 3% of all transplants. Although outcomes have improved in recent eras, retransplantation remains in the highest 1-year mortality group and is also a significant predictor of long-term mortality. More striking is the finding that the mortality for retransplantation in registry data is 18% at 30 days and 22% at 90 days. Even in pediatric patients, retransplantation confers a worse long-term mortality compared with that of primary HTs (63%, 46%, and 26% vs 72%, 60%, and 42% for 5, 10, and 20 years, respectively; $p<0.001$)

- Retransplantation is indicated for those patients who develop significant CAV with refractory cardiac allograft dysfunction, without evidence of ongoing acute rejection (ISHLT/Mehra, et al., 2016).

The International Society for Heart and Lung Transplantation (ISHLT) 2021 consensus document for the selection of lung transplant candidates (Leard, et al., 2021) notes that approximately 5% of all lung transplants performed are re-transplants. The outcomes after re-transplants are inferior compared to first lung transplants, particularly if the re-transplant is done within the first year after the original transplant or for patients with restrictive allograft syndrome (RAS).

- The timing of re-transplant is a complex issue and requires consideration of the rate of deterioration, time since initial transplant, the need for supportive therapies and donor lung availability, which may be limiting in some cases.
- Survival after re-transplant is inferior to that seen with the primary operation and should only be undertaken in carefully selected candidates.
- In the evaluation of patients being considered for lung re-transplant, particular emphasis should be focused on understanding the possible reasons for the graft failure, such as alloimmunization, poor adherence, gastroesophageal reflux, or repeated infections (ISHLT /Leard, et al., 2021).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Heart Transplants (260.9)	5/1/2008
LCD		No Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Appendix

See next page

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.

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
32850	Donor pneumonectomy(s) (including cold preservation), from cadaver donor
32851	Lung transplant, single; without cardiopulmonary bypass
32852	Lung transplant, single; with cardiopulmonary bypass
32853	Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass
32854	Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass
32855	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral
32856	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; bilateral
33930	Donor cardiectomy-pneumonectomy (including cold preservation)
33933	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy
33940	Donor cardiectomy (including cold preservation)
33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation
33945	Heart transplant, with or without recipient cardiectomy

HCPCS Codes	Description
S2060	Lobar lung transplantation
S2061	Donor lobectomy (lung) for transplantation, living donor
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

References

1. Acuna SA, Huang JW, Daly C, Shah PS, Kim SJ, Baxter NN. Outcomes of Solid Organ Transplant Recipients With Preexisting Malignancies in Remission: A Systematic Review and Meta-Analysis. Transplantation. 2017 Mar;101(3):471-481.

2. Ahmad U, Wang Z, Bryant AS, Kim AW, Kukreja J, Mason DP, Bermudez CA, Detterbeck FC, Boffa DJ. Outcomes for lung transplantation for lung cancer in the United Network for Organ Sharing Registry. Ann Thorac Surg. 2012 Sep;94(3):935-40; discussion 940-1.

3. Al-Adra DP, Hammel L, Roberts J, Woodle ES, Levine D, Mandelbrot D, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant. 2021a Feb;21(2):460-474. (Appendix)

4. Al-Adra DP, Hammel L, Roberts J, Woodle ES, Levine D, Mandelbrot D, et al. Preexisting melanoma and hematological malignancies, prognosis, and timing to solid organ transplantation: A consensus expert opinion statement. Am J Transplant. 2021b Feb;21(2):475-483. (Appendix)

5. Amdani S, American Heart Association Council on Lifelong Congenital Heart Disease and Heart Health in the Young; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular Surgery and Anesthesia; and Council on Cardiovascular and Stroke Nursing, et al. Evaluation and Management of Chronic Heart Failure in Children and Adolescents With Congenital Heart Disease: A Scientific Statement From the American Heart Association. Circulation. 2024 Jul 9;150(2):e33-e50.

6. American Society of Transplantation. Accessed July 2025. Available at URL address:
Guidelines and Opinions: https://www.myast.org/education/guidelines-and-opinions
Key Position Statements: https://www.myast.org/public-policy/key-position-statements/key-position-statements

7. Bernhardt AM, Copeland H, Deswal A, Gluck J, Givertz MM. The International Society for Heart and Lung Transplantation/Heart Failure Society of America Guideline on Acute Mechanical Circulatory Support. J Heart Lung Transplant. 2023 Apr;42(4):e1-e64. doi: 10.1016/j.healun.2022.10.028. Epub 2023 Feb 6. Erratum in: J Heart Lung Transplant. 2023 Dec;42(12):1770.

8. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) Heart Transplants (260.9). 12/01/2008. Accessed July 2025. Available at URL address https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=112&ncdver=3&NCAId=126&NcaName=Autologous+Stem+Cell+Transplantation+(AuSCT)+for+Amyloidosis&ExpandComments=n&CommentPeriod=0&bc=ACAAAAAACAAA&

9. Chambers DC, Cherikh WS, Harhay MO, Hayes D Jr, International Society for Heart and Lung Transplantation, et al. The International Thoracic Organ Transplant Registry of the International Society for Heart and Lung Transplantation: Thirty-sixth adult lung and heart-lung transplantation Report-2019; Focus theme: Donor and recipient size match. J Heart Lung Transplant. 2019 Oct;38(10):1042-1055.

10. Colvin MM, Smith JM, Ahn YS, Lindblad KA, Handarova D, Israni AK, Snyder JJ. OPTN/SRTR 2023 Annual Data Report: Heart. Am J Transplant. 2025 Feb;25(2S1):S329-S421. Accessed July 2025. Available at URL address: https://srtr.transplant.hrsa.gov/

11. Copeland H, Knezevic I, Baran DA, Rao V, Pham M, et al. Donor heart selection: Evidence-based guidelines for providers. J Heart Lung Transplant. 2023 Jan;42(1):7-29.

12. DREAM (Double lung transplant REgistry Aimed for lung-limited Malignancies) Program. NCT05671887. Accessed May 2025. Available at URL address: https://clinicaltrials.gov/study/NCT05671887#study-plan

13. Glanville AR, Wilson BE. Lung transplantation for non-small cell lung cancer and multifocal bronchioalveolar cell carcinoma. Lancet Oncol. 2018 Jul;19(7):e351-e358.

14. Hachem RR. Lung transplantation: General guidelines for recipient selection. In: UpToDate, Kotloff RM (Ed). Literature review current through July 2025. Topic last updated August 30, 2024. Accessed August 2025. Available at URL address: https://www.uptodate.com/contents/lung-transplantation-general-guidelines-for-recipient-selection?search=Malignancy%20and%20Organ%20Transplant%20Candidacy%3A%20A%20Consensus%20Expert%20Opinion%20Statement&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4 (Appendix)

15. Hayes D Jr, Cherikh WS, Chambers DC, Harhay MO, International Society for Heart and Lung Transplantation, et al. The International Thoracic Organ Transplant Registry of the International Society for Heart and Lung Transplantation: Twenty-second pediatric lung and heart-lung transplantation report-2019; Focus theme: Donor and recipient size match. J Heart Lung Transplant. 2019 Oct;38(10):1015-1027.

16. Heidenreich PA, Bozkurt B, Aguilar D, Allen LA, Byun JJ, Colvin MM, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022 May 3;145(18):e895-e1032.

17. International Society for Heart & Lung Transplantation. Standards & Guidelines. Accessed July 2025. Available at URL address: https://www.ishlt.org/education-and-publications/standards-guidelines

18. Leard LE, Holm AM, Valapour M, Glanville AR, Attawar S, Aversa M, et al. Consensus document for the selection of lung transplant candidates: An update from the International Society for Heart and Lung Transplantation. J Heart Lung Transplant. 2021 Nov;40(11):1349-1379.

19. Lee J, Aguilera Chuchuca MJ, Yu J, Chung LI, Bharat A, Chae YK. Survival Outcomes After Double-Lung Transplantation for Refractory Lung-Limited Cancers and Incidence of Post-Transplant Lung Cancer. Ann Transplant. 2023 Dec 5;28:e941301.

20. Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2023 Annual Data Report. U.S. Department of Health and Human Services, Health Resources and Services Administration; 2024. Accessed July 2025. Available at URL address: https://www.srtr.org/reports/optnsrtr-annual-data-report/ https://srtr.transplant.hrsa.gov/ (See Colvin, et al., 2025; Valapour, et al., 2025)

21. Organ Procurement and Transplant Network (OPTN). Data & Calculations. View Data Reports, National data. Accessed July 2025. https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/

22. Organ Procurement and Transplant Network (OPTN). Metrics. Survival. Accessed July 2025. Available at URL address: https://insights.unos.org/OPTN-metrics/

23. Organ Procurement and Transplant Network (OPTN). News. Accessed July 2025. Available at URL address: https://optn.transplant.hrsa.gov/news/

24. Organ Procurement and Transplant Network (OPTN). News. March 20, 2023. New lung allocation policy in effect. Accessed July 2025. Available at URL address: https://optn.transplant.hrsa.gov/news/new-lung-allocation-policy-in-effect/#:~:text=Effective%20March%209%2C%202023%2C%20the,the%20most%20medically%20urgent%20candidates https://optn.transplant.hrsa.gov/news/new-lung-allocation-policy-in-effect/

25. Organ Procurement and Transplant Network (OPTN). Policies and Bylaws. Policies. OPTN Policy. Updated 6.26.25. Accessed July 2025. Available at URL address: https://optn.transplant.hrsa.gov/policies-bylaws/policies/

26. Peled Y, Ducharme A, Kittleson M, Bansal N, Stehlik J, Amdani S, et al. International Society for Heart and Lung Transplantation Guidelines for the Evaluation and Care of Cardiac Transplant Candidates-2024. J Heart Lung Transplant. 2024 Oct;43(10):1529-1628.e54.

27. Saeed D, Feldman D, Banayosy AE, Birks E, Blume E, et al. The 2023 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support: A 10-Year Update. J Heart Lung Transplant. 2023 Jul;42(7):e1-e222.

28. Singer LG, Mooney J. Heart-lung transplantation in adults. In: UpToDate, Hunt SA (Ed). UpToDate, Waltham, MA. Literature review current through June 2025. Topic last updated March 28, 2024.

29. Stout KK, Daniels CJ, Aboulhosn JA, Bozkurt B, Broberg CS, Colman J, et al. 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019 Apr 2;139(14):e637-e697. Accessed July 2025. Available at URL address: https://www.acc.org/Guidelines

30. Stout KK, Broberg CS, Book WM, Cecchin F, Chen JM, Dimopoulos K, et al. Chronic Heart Failure in Congenital Heart Disease A Scientific Statement From the American Heart Association. Circulation. 2016 Feb 23;133(8):770-801. Accessed July 2025. Available at URL address: https://www.ahajournals.org/doi/10.1161/cir.0000000000000352 (See Amdani, et al., 2024).

31. United Network for Organ Sharing (UNOS). Equity in Access to Transplant. Accessed July 2025. Available at URL address: https://insights.unos.org/equity-in-access//

32. United Network for Organ Sharing (UNOS). Data. Transplant trends. Accessed July 2025. Available at URL address: https://unos.org/data/transplant-trends/

33. United Network for Organ Sharing (UNOS). Press releases. Policy. Accessed July 2025. Available at URL address: https://unos.org/media-resources/releases/ (search by 'policy')

34. United Network for Organ Sharing (UNOS). News. Mar 17, 2023. Heart/lung, News, Policy changes. Accessed July 2025. Available at URL address: https://unos.org/news/pediatric-1a-1b-heart-lung-expanded-access-to-intended-incompatible-blood-type-offers/#:~:text=On%20March%2016%2C%202023%2C%20the,lung%20transplant%20candidates%20who%20are

35. Valapour M, Lehr CJ, Schladt DP, Swanner K, Poff K, Handarova D, Weiss S, Hawkins CJ, Israni AK, Snyder JJ. OPTN/SRTR 2023 Annual Data Report: Lung. Am J Transplant. 2025 Feb;25(2S1):S422-S489. Accessed July 2025. Available at URL address: https://srtr.transplant.hrsa.gov/

36. Woo W, Kim HS, Bharat A, Chae YK. The association between pretransplant malignancy and post-transplant survival and cancer recurrence in bilateral lung transplantation: An analysis of 23,291 recipients. JHLT Open. 2024 Oct 9;7:100161.

37. Writing Committee; Kittleson MM, Ruberg FL, Ambardekar AV, Brannagan TH, et al. 2023 ACC Expert Consensus Decision Pathway on Comprehensive Multidisciplinary Care for the Patient With Cardiac Amyloidosis: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2023 Mar 21;81(11):1076-1126. doi: 10.1016/j.jacc.2022.11.022. Epub 2023 Jan 23. Erratum in: J Am Coll Cardiol. 2023 Mar 21;81(11):1135. doi: 10.1016/j.jacc.2023.02.013. PMID: 36697326.

38. Writing Committee Members; Ommen SR, Ho CY, Asif IM, Balaji S, et al. 2024 AHA/ACC/AMSSM/HRS/PACES/SCMR Guideline for the Management of Hypertrophic Cardiomyopathy: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2024 Jun 11;83(23):2324-2405.

39. Zwald F, Leitenberger J, Zeitouni N, Soon S, Brewer J, 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 Feb;16(2):407-13. (Appendix)

Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• Added policy statements regarding history of malignancy	9/15/2025
Focused review	• Revised policy statement on lung transplantation. • Revised policy statement addressing contraindications.	7/15/2025
Focused review	• Revised policy statement on lung transplantation.	12/15/2024
Annual review	• No clinical policy statement changes.	9/15/2024

Type of Revision	Summary of Changes	Date
Annual review	• Updated to new template and formatting standards.	9/15/2023