KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

PATIENT REFERRAL GUIDELINES
Heart Transplantation[i]

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Heart Transplants (260.9)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, generally accepted, guidelines for Heart transplantation. These guidelines for referral for transplant evaluation and are not intended as an automatic inclusion or exclusion of a candidate for referral. As such, these should be applied together with careful clinical judgment.

1. GENERAL PRINCIPLES

1.1. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.

1.2. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.

1.3. Uncontrollable active infection is a contraindication to transplant.

1.4. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low [ii], [iii], [iv]. Exceptions may be made on a case-by- case basis.

1.5. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six
(6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines and kidney) may require abstinence from tobacco products to be actively listed.

1.6. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.

1.6.1. Patient must have a care giver or care givers who are physically and cognitively able to assist the patient with self-care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.

1.6.2. Evidence of non-adherence may be failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow

[i] Note: All patients must be continuously re-evaluated for indications and contraindications. Candidates considered for re-transplantation must be evaluated using the same indications.

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medication regimens or failure to accomplish the activities required for maintenance on the waiting list.

1.7. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.

1.8. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.

1.9. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. INDICATIONS FOR HEART TRANSPLANT

2.1. End-stage heart disease as evidenced by one or more of the following:

2.1.1. Functional class III or IV

2.1.2. Not correctable by medical or other surgical therapies

2.1.3. A low VO2 maximum: [ii]

2.1.3.1. ≤14 ml/kg/min in patients not on a beta blocker

2.1.3.2. ≤12 ml/kg/min in patients on a beta blocker [iii]

2.1.3.3. <19 ml/kg/min adjusted for lean body mass in patients with a BMI >30 kg/m^2

2.1.3.4. Less than 50% of age predicted maximum.

2.1.4. A VE/VCO2 >35 in a patient with a sub-maximal cardiopulmonary exercise test (RER <1.05)^2

2.1.5. Cardiac index < 2 L/min/m^2

2.2. Unable to wean from mechanical or inotropic support.

2.3. Amyloid Cardiomyopathy

2.3.1. TTR Amyloid

2.3.2. (AL) Amyloidosis without significant extra-cardiac involvement.

2.4. Refractory Life-Threatening Arrhythmias

3. The transplant should only be offered for conditions in which cardiac transplant has proven clinical benefits.

CONTRAINDICATIONS FOR HEART TRANSPLANT (In conjunction with the *General* Principles listed above in Section1 of these guidelines):

3.1. Significant diseases such as:

3.1.1. Severe uncontrolled or poorly controlled hypertension.

3.1.2. Clinically significant vascular disease not correctable by intervention.

3.1.3. Pulmonary hypertension not reversible by drug manipulation despite maximum tolerated medical management. [iv]

3.1.3.1. Adults: PVR > 4-6 Wood units or transpulmonary gradient > 15 mm Hg

3.1.3.2. Children: PVR > 9 Wood units

3.1.4. Severe pulmonary disease after optimal treatment of severe heart failure.[viii]

3.1.5. Severe hepatic disease after optimal treatment of severe heart failure.[viii]

[ii] Journal of Heart & Lung Transplantation, Vol.25 Number 9, pp1024 -1042. Listing Criteria for Heart Transplantation ISHLT Guidelines for the Care of Cardiac Transplant Candidates – 2006.

[iii] Patients on Beta blockers should have a cut-off of ≤12 ml/kg/min, and patients intolerant to beta blockers a VO_2 ≤14 ml/kg/min.

[iv] Circulation; 84 (3), 329 – 337. *Journal of Heart Transplantation* (1990): 526 – 537.

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3.1.6. Kidney disease with creatinine clearance <34 ml/kg/min or GFR < 30 ml/min after optimal treatment of heart failure. [v], [vi], [vii]

3.1.7. Active and/or progressive central nervous system disease excluding patients with embolic stroke who have recovered completely.

3.1.8. Evidence of cachexia or malnutrition (BMI < 19 kg/m2 or < 80% ideal body weight).x

3.1.9. Obesity (BMI>35 kg/m2 or > 140% ideal body weight) xi has been associated with poor outcomes after cardiac transplant.

3.1.10. Diabetes with complications resulting in severe end-organ damage.

3.1.11. Auto/acquired immune disease with multi-organ manifestation

3.1.12. Acute pulmonary embolus

3.1.13. Active peptic ulcer disease

3.1.14. Severe symptomatic osteoporosis

3.1.15. Age over 70 (Carefully selected patients over 70 years of age may be considered for cardiac transplantation)

3.1.16. AL Amyloidosis with significant extra-cardiac manifestations

3.1.17. Patients with viral hepatitis will require additional evaluation, including hepatology consultation.

3.1.18. Any other co-morbid condition that would limit life expectancy or quality of life.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

A heart may be irreversibly damaged by long-lasting heart disease or viral infection. When the heart can no longer adequately work, and a person is at risk of dying, a heart transplant may be appropriate.

Cardiac transplant has become increasing successful over the past several years. Adult heart transplant recipients have a one-year survival rate of eighty to ninety percent and a five-year survival rate of sixty to seventy percent. Kaiser Permanente contracts have included coverage for heart transplantation for several years. Members with coverage who meet the selection criteria are considered for transplantation.

Applicable Codes

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

CPT® Codes	Description
33940	Donor cardiectomy (including cold preservation)

[v] Selected patients for possible combined or staged heart/kidney transplant will be evaluated on a case-by-case basis.

[vi] Must have 20mg per kilogram of creatinine in a 24-hour collection period. Creatinine clearance can also be calculated by the Cockcroft-Gault formula.

[vii] The Journal of Heart & Lung Transplantation, Vol. 35, Issue 7, p893-900. Evidence Supports Severe Renal Insufficiency as a relative contraindication to heart transplantation—2016.

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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

****Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
05/1996	07/05/2011 MDCRPC, 05/01/2012 MDCRPC, 03/05/2013MDCRPC, 01/07/2014MPC, 11/04/2014MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 03/05/2019MPC, 03/03/2020MPC, 03/02/2021MPC, 03/01/2022MPC , 03/07/2023MPC	04/06/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MDCRPC Medical Policy Committee

Revision History	Description
03/05/2019	MPC approved to adopt Kaiser Permanente National Criteria for Heart Transplant
03/03/2020	MPC approved updates for Kaiser Permanente National Transplant Services patient referral guidelines
06/12/2020	Changed “criteria” to guidelines” where appropriate; updated to reflect current patient referral guidelines that were approved 03/03/2020
04/06/2021	Per National Transplant Guidelines: 1.3 added “active”

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