

## Heart Transplant SRG-008

<b>Iowa Medicaid Program:</b>	Prior Authorization	<b>Effective Date:</b>	9/11/2019
<b>Revision Number:</b>	13	<b>Last Rev Date:</b>	1/19/2024
<b>Reviewed By:</b>	Heart Transplant Consultant, MMD	<b>Next Rev Date:</b>	1/17/2025
<b>Approved By:</b>	Medicaid Clinical Advisory Committee	<b>Approved Date:</b>	3/21/2018

### Criteria

Prior authorization is required.

Heart transplant may be considered medically necessary when **ALL** the following are met:

1. Members should have psycho/social assessment prior to listing for transplantation. The evaluation should include an assessment of the member's ability to give informed consent and comply with instructions including drug therapy, as well as assessment of the support systems in place at home or in the community (*Level of Evidence: C*); **AND**
2. Dental exam and clearance must be provided; **AND**
3. Must be abstinent of all illicit drugs and not abuse any drugs or alcohol. Physician documentation must specifically address this issue. Need for laboratory testing to confirm compliance may be at the discretion of the attending physician; **AND**
4. Documentation of underlying co-morbidities must be provided; **AND**
5. Pertinent lab values must be provided; **AND**
6. Ejection fraction is less than 45 percent per ECHO or cardiac catheterization.
7. Recent cardiac catheterization results; **AND**
8. Should be 70 years of age or younger.
  - a. Carefully selected members may be considered if older than 70 years of age; **AND**
9. For obese members with body mass index greater than 35 kg<sup>2</sup>, it is reasonable to request weight loss to decrease the BMI to less than 35 prior to listing for cardiac transplantation.

### Contraindications

Transplantation is not to be approved in the presence of the following:

1. Active smoking is not necessarily considered an absolute contraindication. Smoking cessation for a minimum of 3 months is required and validated by urine nicotine tests 2-3 weeks prior to surgery; **OR**
2. In those members needing cardiac transplantation and who have a history of malignancy, collaboration with oncology specialist should occur to stratify each member as to their risk of tumor recurrence. Cardiac transplantation should be considered when tumor recurrence is low based on tumor type, response to therapy, and negative metastatic

work-up. The specific amount of time to wait to transplant after neoplasm remission will depend on the aforementioned factors and no arbitrary time period for observation should be used; **OR**

3. Untreatable advanced dysfunction of another major organ system (exception for dual-organ transplants); **OR**
4. Incurable chronic active or unresolved infection including chronic active viral hepatitis B, hepatitis C, and uncontrolled human immunodeficiency virus (HIV).
  - a. Adequately controlled HIV infection is defined by **ALL** the following:
    - 1) CD4 count greater than 200 cells/mm<sup>3</sup>, **AND**
    - 2) HIV-1 ribonucleic acid (RNA) undetectable, **AND**
    - 3) Stable combination anti-retroviral therapy for more than 3 months, **AND**
    - 4) Absence of serious complications associated with or secondary to HIV disease, such as progressive multifocal leukoencephalopathy, opportunistic infections within the past 12 months, including aspergillosis, tuberculosis, or other mycobacterial infection, coccidiomycosis, resistant fungal infections, chronic intestinal cryptosporidiosis greater than 1 month, or Kaposi's sarcoma or other neoplasm; **OR**
5. Documented non-adherence or inability to follow through with medical therapy or any aspect of follow-up care; **OR**
6. Untreatable psychiatric or psychological condition associated with the inability to cooperate or comply with medical therapy; **OR**
7. Absence of a consistent or reliable social support system; **OR**
8. Substance addiction (e.g., alcohol, tobacco, narcotics) that is either active or within the last 6 months and has not been evaluated for or entered into a structured rehabilitative program.

#### Other Coverage Issues (heart-lung transplants)

- Heart-lung transplants are covered where bilateral or unilateral lung transplantation with repair of a congenital cardiac defect is contraindicated.
- Heart and heart-lung transplants require pre-procedure review and approval.
- Covered heart and heart-lung transplants are only payable when performed in a facility that meets the requirements under IAC 441-78.3(10).
- Donor expenses incurred directly in connection with a covered transplant are payable.
- Expenses incurred for complications that arise with respect to the donor are covered only if they are directly and immediately attributed to surgery.
- Expenses of searching for a donor are not covered.

#### Other Coverage Issues (ventricular assist device [VAD])

- VAD as a temporary life-support system until a human heart becomes available for transplantation (i.e., "bridge" therapy) are covered; however, requires pre-procedure review and approval.

## Services Not Covered

- Artificial hearts and VAD as a permanent replacement for a human heart (i.e., “destination” therapy) are not covered. Coverage consideration for these devices can occur through Exception to Policy on a case-by-case basis.
- Expenses associated with organ preparation (e.g., “backbench prep”) are not separately payable and are considered paid as part of the transplant procedure.

## Coding

The following list of codes is provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

CPT	Description
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy.
33928	Removal and replacement of total replacement heart system (artificial heart).
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (list separately in addition to code for primary procedure).
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy.
33945	Heart transplant, with or without recipient cardiectomy.
33975	Insertion of ventricular assist device; extracorporeal, single ventricle.

## Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual and as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

## References

441 IAC 78.1(20)"a"(5).

Ohler, L. & Cupples, S., (2008). Core Curriculum for Transplant Nurses. Mosby Elsevier, Philadelphia, PA.

Listing Criteria for Heart Transplantation (Guidelines) (J Heart Lung Transplant 2006:25(9): (1024-1042).

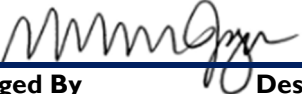

International Guidelines for the Selection of Lung Transplant Candidates: 2006 Update - A Consensus Report from the ISHLT Pulmonary Scientific Council (Consensus Document) (J Heart Lung Transplant 2006:25(7) (745-755).

A Consensus Document for the Selection of Lung Transplant Candidates: 2014 - An Update from the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation (J Heart and Lung Transplant 2014: (1-15).

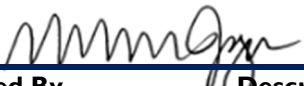
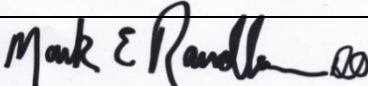
The 2016 International Society for Heart Lung Transplantation listing criteria for Heart Transplantation: A 10-year Update (J Heart and Lung Transplant 2016: (1-23).

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

## Criteria Change History

Change Date	Changed By	Description of Change	Version
<b>Signature</b>			
Change Date	Changed By	Description of Change	Version
<b>Signature</b>			
Change Date	Changed By	Description of Change	Version
1/19/2024	CAC	Annual specialist review.	13
<b>Signature</b>			
William (Bill) Jagiello, DO 			
Change Date	Changed By	Description of Change	Version
1/20/2023	CAC	Annual specialist review.	12
<b>Signature</b>			
William (Bill) Jagiello, DO 			

## Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
1/21/2022	CAC	Annual specialist criteria review with no changes needed. Formatting changes.	11
<b>Signature</b> William (Bill) Jagiello, DO 			
Change Date	Changed By	Description of Change	Version
1/6/2018	Heart Transplant Consultant	Added Criterion #9.	10
<b>Signature</b> Mark E. Randleman, DO 			
Change Date	Changed By	Description of Change	Version
4/11/2017	Policy	Other coverage issues added "bridge therapy". Services not covered added "destination therapy" and second bullet regarding associated expenses.	9
<b>Signature</b>			
Change Date	Changed By	Description of Change	Version
12/20/2016	Heart Transplant Consultant	Contraindication #2 removed "malignancy in the last 2 years with the exception of cutaneous squamous and basal cell tumors. In general, a 5-year disease free interval is prudent". Added "patients who have a history of malignancy". Contraindication #4 3) added "combination". Contraindication #4 4) added "progressive, multifocal leukoencephalopathy" "within the past 12 months" "other mycobacterial infection" and "chronic intestinal cryptosporidiosis greater than 1 month".	8
<b>Signature</b>			
Change Date	Changed By	Description of Change	Version
4/6/2016	Policy	Added VAD under other coverage issues. Added "case-by-case basis" to services not covered.	7
<b>Signature</b>			
Change Date	Changed By	Description of Change	Version
1/7/2016	Heart Transplant Consultant	Added narrative to contraindication #2. Added narrative to contraindication #8. Deleted contraindications #9 through #15. Combined other coverage issues. Added narrative to services not covered. Added last two references.	6
<b>Signature</b>			

## Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
1/16/2015	Medical Director	Added last paragraph in References.	5

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Change Date	Changed By	Description of Change	Version
7/24/2014	Medical Director	Criterion #8 added narrative after older than 70. Contraindication #4 - removed Hepatitis C and added definitions i-iv of adequately controlled HIV infection. Added other coverage issues (general) and (other related services). Services not covered removed reference to VAD. CPT Codes added for artificial heart and VAD.	4

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Change Date	Changed By	Description of Change	Version
11/27/2013	Heart Transplant Consultant	Criterion #6 - Change from "Ejection fraction is less than 45 percent per ECHO or cardiac catheterization" to "End-stage heart disease not remediable by more conservative measures". Added #9-15 under Contraindications.	3

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Change Date	Changed By	Description of Change	Version
3/22/2013	Policy	Additions to criteria to reflect details contained in 441 IAC 78.1(20)"a"(5).	2

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Change Date	Changed By	Description of Change	Version
1/18/2013	CAC	Re-ordering and new information added to Criteria #1-#8. Added Contraindications. Removed CPT Code for VAD. Added information under References.	1

Signature