MedStar Health, Inc. POLICY AND PROCEDURE MANUAL

Policy Number: PA.003.MH Last Review Date: 05/11/2017 Effective Date: 07/01/2017

PA.003.MH – Transplant: Heart-Lung

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar MA DSNP CSNP
- ✓ MedStar CareFirst PPO

MedStar Health considers **Heart-Lung Transplant** medically necessary for the following indications:

Recipient Criteria

 The member has no medical, cognitive, or other psychiatric condition that is likely to interfere with their ability to manage the sequelae of the transplant, including complex medication regimens

General Criteria for Heart-Lung Transplant

• The member meets the institution's selection criteria for heart-lung transplantation.

Specific Criteria for Heart-Lung Transplant- Heart-lung transplantation may be medically necessary for members with irreversible, progressively disabling, end-stage cardiopulmonary disease including any one of the conditions listed below:

- Refractory NYHA Class III or IV heart failure associated with:
 - End-stage chronic obstructive pulmonary disease
 - Severe pulmonary fibrosis
 - Cystic Fibrosis
 - Severe primary pulmonary hypertension
- Irreversible, uncontrollable pulmonary hypertension associated with:
 - Refractory NYHA Class III or IV heart failure
 - Pulmonary fibrosis
 - Cardiomyopathy and/or severe coronary heart disease
 - Congenital heart disease with complications that cannot be repaired with conventional surgical approaches to the heart and lungs
- Eisenmenger's complex with irreversible pulmonary hypertension and refractory NYHA Class III or IV heart failure
- End-stage lung disease with malignant ventricular arrhythmias that is uncontrollable despite optimal pharmacologic or electrophysiologic treatments (including implantable cardioverter-defibrillator).
- Subsequent operation for failure of original graft



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Specific Criteria for Heart-Lung Transplant in HIV+ Members

Heart-lung transplantation in HIV+ members is considered medically necessary when all of the following conditions are met:

- 1. The member has a life expectancy of at least five years
- 2. CD4 count ≥200 cells/mL for at least six months
- 3. Undetectable HIV viremia (<50 copies/mL) for six months
- 4. Demonstrated adherence to highly active antiretroviral therapy (HAART) regiment for ≥ six months
- 5. Available antiretroviral treatment options post-transplant

Limitations

- All other medical and surgical therapies that might be expected to yield both short-and long-term survival comparable to that of transplantation must have been tried or considered.
- Members must first undergo stringent physical and psychological evaluation to determine eligibility for transplant. Members should have no other serious medical problems, and they should be psychologically willing to undergo the stressful surgery and postoperative care necessary.
- 3. Heart Xeno-transplantation for any cardiac condition is considered experimental-investigational and is **not** covered.

Background

Heart-lung transplantation, also known as cardiopulmonary transplantation, is the simultaneous surgical replacement of the heart and lungs in patients with end-stage cardiac and pulmonary disease. Eisenmenger syndrome, pulmonary artery hypertension and cystic fibrosis account for the top three conditions for heart-lung transplant recipients. In 2014, there were 24 heart-lung transplantations according to OPTN data from UNOS.

It is a complex, expensive, and resource-intensive procedure. It is performed more often where there is coexistence of end-stage pulmonary disease with advanced cardiac disease that is not secondary to pulmonary hypertension (e. g., some forms of congenital heart disease, some situations with Eisenmenger's syndrome, and possibly the coexistence of end-stage heart and end-stage lung disease).

New York Heart Association (NYHA) Functional Classification:

I. No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).



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- II. Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
- III. Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
- IV. Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Codes:

CPT/HCPCS Codes	
Code	Description
33933	Backbench preparation for cadaver donor heart/lung
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy

References

- American Heart Association Classes of Heart Failure. Updated April 23, 2015. http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Classes-of-Heart-Failure_UCM_306328_Article.jsp
- 2. Bando K. Armitage JM, Paradis H. et al. Indications for and results of single, bilateral and heart-lung transplantation for pulmonary hypertension. J Thorac Cardiovasc Surg. 1994; 108:1056-1065. http://www.ncbi.nlm.nih.gov/pubmed/7983875
- 3. Bhagani S, Sweny P, Brook G. Guidelines for kidney transplantation in patients with HIV disease.. HIV Med. 2006 Apr. 7(3):133-139. https://www.ncbi.nlm.nih.gov/pubmed/16494626
- 4. Centers for Disease Control and Prevention (CDC). About HIV/AIDS. Last modified: Jan. 16, 2015 . http://www.cdc.gov/hiv/basics/whatishiv.html
- Centers for Medicare and Medicaid Services, Coverage Issues Manual, Transmittal 165, Section 35-87 Heart Transplants, effective date 4/1/2003. http://www.cms.gov/Regulations-and-guidance/Guidance/Transmittals/downloads/r165cim.pdf
- 7. Centers for Medicare and Medicaid Services: Medicare National Coverage Determinations Manual Ch.1, Part 4 (Sections 200-310.1), Revised), Last Revised: 03/27/2015. Section 260.9 Heart Transplants (Effective Date:



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- 05/01/2008). http://www.cms.gov/Regulations-and-guidance/Guidance/Manuals/downloads/ncd103c1_part4.pdf
- 8. Green, I.: Institutional & Patient Criteria for Heart Lung Transplantation. Health Technology Assessment No.1. AHCPR Pub. 94-0042, Rockville MD. May 1994. http://www.ncbi.nlm.nih.gov/books/NBK63984/?report=reader
- Halpern SD, Ubel PA, Caplan AL. Solid organ transplantation in HIV infected patients. N Engl J. Med. 2002 July; 347(4):284-287. http://www.nejm.org/doi/pdf/10.1056/NEJMsb020632
- 10. Hosenpud JD, Bennett LE, Keck BM, et al. The registry for the International Society for Heart and Lung Transplantation: Eighteenth Official Report 2001. J Heart Lung Transplant. 2001; 20(8):805-815. https://www.ncbi.nlm.nih.gov/pubmed/11044685
- 11. Heart Failure Society of America. New York Heart Association [NYHA] Stages of Heart Failure.. Accessed: 04/25/2017. Available at: http://www.hfsa.org/patient/learn-heart-failure/heart-failure-facts-information/
- 12. Kaiser Family Foundation. Global Health Reporting. AIDS 2010: The double-edged sword: Long-term complications of ART and HIV. July 19, 2010. [video conference presentation]. http://kff.org/global-health-policy/event/aids-2010-the-double-edged-sword-long-term-complications-of-art-and-hiv/
- 13. Nador RG, Lien D. Heart-Lung transplantation. UpToDate®. Last updated: May 2, 2014. Topic 3525 Version 7.0. http://www.uptodate.com/contents/heart-lung-transplantation?topicKey=CARD%2F3525&elapsedTimeMs=0&source=search_result&searchTerm=Heart-Lung+Transplantation&selectedTitle=1%7E46&view=print&displayedView=full#">https://www.uptodate.com/contents/heart-lung-transplantation?topicKey=CARD%2F3525&elapsedTimeMs=0&source=search_result&searchTerm=Heart-Lung+Transplantation&selectedTitle=1%7E46&view=print&displayedView=full#">https://www.uptodate.com/contents/heart-lung-transplantation?topicKey=CARD%2F3525&elapsedTimeMs=0&source=search_result&searchTerm=Heart-Lung+Transplantation&selectedTitle=1%7E46&view=print&displayedView=full#">https://www.uptodate.com/contents/heart-lung-transplantation&selectedTitle=1%7E46&view=print&displayedView=full#">https://www.uptodate.com/contents/heart-lung-transplantation?topicKey=CARD%2F3525&elapsedTimeMs=0&source=search_result&searchTerm=Heart-lung+Transplantation&selectedTitle=1%7E46&view=print&displayedView=full#"
- 14. Orens JB, Estenne M, Arcasoy S, et al. International guidelies for the selection of lung transplant candidates: 2006 update a consensus report from the Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation. J Heart Lung Transplant, 2006 Jul; 25(7); 745-55. http://www.jhltonline.org/article/S1053-2498(06)00251-8/fulltext
- 15. Organ Procurement and Transplantation Network (OPTN). Policy 6: Allocation of Hearts and Hearts-Lungs. Effective: 03/31/2015. http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf
- 16. Roland ME, Stock, PG: Solid organ transplantation is a reality for patients with HIV infection. Curr HIV/AIDS Rep. 2006 Sep; 3(3):132-138. http://ejournals.ebsco.com/Direct.asp?AccessToken=3P1P1XD81N2Z21EXEN2D2SSLT2LS8X%2D1P&Show=Object&msid=201404960
- 17. Stock, PG, Roland ME. Evolving clinical strategies for transplantation in the HIV-positive recipient. Transplantation. 2007; 84: 563-571. . http://www.ncbi.nlm.nih.gov/pubmed/17876267



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- Steinman TI, Becker BN, Frost AE, et al. Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplantation. 2001 May; 71(9):1189-1204. http://www.ncbi.nlm.nih.gov/pubmed/11397947
- 19. United Network for Organ Sharing (UNOS) Transplant trends. Last updated September 4, 2015. https://www.unos.org/data/transplant-trends/#transplants-by-organ_type+year+2014
- 20.U.S. Preventive Services Task Force: Recommendations for adults. Current as of April 2015. Accessed: 04/25/2017. http://www.uspreventiveservicestaskforce.org/BrowseRec/Index

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