

References

S-60

1. CMS Online Manual Pub.100-3, National Coverage Determination (NCD) for Artificial Hearts and Related Devices. Section 20.9.
2. PROTECT II: A prospective, multi-center, randomized controlled trial of the Impella Recover LP System versus intra-aortic balloon pump (IABP) in patients undergoing non emergent high risk PCI. Clinical trials.gov.
3. Acharya D. Ventricular assist device in acute myocardial infarction. *J Am Coll Cardiol.* 2016;67(16):1781- 1880.
4. Chen S. Outpatient outcomes of pediatric patients with left ventricular assist devices. *ASAIO J.* 2016;163- 168.
5. Muthiah K. Longitudinal structural, functional, and cellular myocardial alterations with chronic centrifugal continuous-flow left ventricular assist device support. *J Heart Transplant.* 2017;36(7):722-731.
6. Acharya D, Loyaga-Rendon RY, Pamboukian SV, et al. Ventricular assist device in acute myocardial infarction. *J Am Coll Cardiol.* 2016;67(16):1871-1880.
7. Wehman B, Stafford KA, Bittle GJ, et al. Modern outcomes of mechanical circulatory support as a bridge to pediatric heart transplantation. *Ann Thorac Surg.* 2016;101(6):2321-2327.
8. Hayes, Inc. Health Technology Assessment. *Total Artificial Heart, Temporary or Permanent, Biventricular Mechanical Circulatory Support Device.* Lansdale, Pa: Hayes, Inc; June, 2019.
9. Stehlik J, Estep JD, Selzman CH. Patient-reported health-related quality of life is a predictor of outcomes in ambulatory heart failure patients treated with left ventricular assist device compared with medical management: Results from the ROADMAP study (Risk Assessment and comparative effectiveness of left ventricular assist device and medical management). *Circ Heart Fail.* 2017;10(6):e003910.
10. Cook JL, Colvin M, Francis GS, et al Recommendations for the use of mechanical circulatory support: ambulatory and community patient care: a

scientific statement from the American Heart Association. *Circulation*. 2017;135(25):e1145-58.

11. Ergle K, Parto P, Krim SR. Percutaneous ventricular assist devices: a novel approach in the management of patients with acute cardiogenic shock. *Ochsner J*. 2016;16(3):243-9.
12. Blume ED, Rosenthal DN, Rossano JW, et al. Outcomes of children implanted with ventricular assist devices in the United States: First analysis of the pediatric interagency registry for mechanical circulatory support (PediMACS). *J Heart Lung Transplant*. 2016;35(5):578-84.
13. Nelson McMillan K, Hibino N, Brown EE, et al. HeartWare ventricular assist device implantation for pediatric heart failure—A single center approach. *Artif Organs*. 2019;43(1):21-9.
14. Bulic A, Maeda K, Zhang Y, et al. Functional status of United States children supported with a left ventricular assist device at heart transplantation. *J Heart Lung Transplant*. 2017;36(8):890-6.
15. Villa CR, Moore RA, Lorts A. The total artificial heart in pediatrics: outcomes in an evolving field. *Ann Cardiothorac Surg*. 2020;9(2):104-109.
16. Mehra MR, Naka Y, Uriel N, et al. A fully magnetically levitated circulatory pump for advanced heart failure. *N Engl J Med*. 2017;376(5):440-450.
17. Rogers JG, Pagani FD, Tatroles AJ, et al. Intrapericardial left ventricular assist device for advanced heart failure. *N Engl J Med*. 2017;376(5):451-460.
18. Mehra MR, Uriel N, Naka Y, et al. A fully magnetically levitated left ventricular assist device - final report. *N Engl J Med*. 2019;380(17):1618-1627.
19. Colombo PC, Mehra MR, Goldstein DJ, et al. Comprehensive analysis of stroke in the long-term cohort of the Momentum 3 study. 2019;139(2):155-168.
20. Al-Sarie M, Rauf A, Kfoury AG, et al. Myocardial structural and functional response after long-term mechanical unloading with continuous flow left ventricular assist device: axial versus centrifugal flow. *JACC Heart Fail*. 2016;4(7):570-576

21. Agrawal S, Garg L, Shah M, et al. Thirty-day readmissions after left ventricular assist device implantation in the united states: insights from the nationwide readmissions database. *Circ Heart Fail*. 2018;11(3):e004628.
22. Conway J, Al-Aklabi M, Granoski D, et al. Supporting pediatric patients with short-term continuous-flow devices. *J Heart Lung Transplant*. 2016;35(5):603-9.
23. Grimm JC, Sciortino CM, Magruder JT, et al. Outcomes in patients bridged with univentricular and biventricular devices in the modern era of heart transplantation. *Ann Thorac Surg*. 2016;102(1):102-8.
24. Starling RC, Estep JD, Horstmanshof DA, et al. Risk assessment and comparative effectiveness of left ventricular assist device and medical management in ambulatory heart failure patients: the roadmap study 2-year results. *JACC Heart Fail*. 2017;5(7):518-527.
25. Food and Drug Administration. Summary of Safety and Probable Benefit - H040006: AbioCor implantable replacement heart. 2006; https://www.accessdata.fda.gov/cdrh_docs/pdf4/H040006b.pdf. Accessed April 2020.
26. Romeo F, Acconcia MC, Sergi D, et al. Percutaneous assist devices in acute myocardial infarction with cardiogenic shock: Review, meta-analysis. *World J Cardiol*. 2016;8(1):98-111.
27. Ouweneel DM, Eriksen E, Sjauw KD, et al. Percutaneous mechanical circulatory support versus intra-aortic balloon pump in cardiogenic shock after acute myocardial infarction. *J Am Coll Cardiol*. 2017;69(3):278-287.
28. Schrage B, Ibrahim K, Loehn T, et al. Impella support for acute myocardial infarction complicated by cardiogenic shock. 2019;139(10):1249-1258.
29. Sieweke JT, Berliner D, Tongers J, et al. Mortality in patients with cardiogenic shock treated with the Impella CP microaxial pump for isolated left ventricular failure. *Eur Heart J Acute Cardiovasc Care*. 2020;9(2):138-148.
30. Schafer A, Werner N, Burkhoff D, et al. Influence of timing and predicted risk on mortality in impella-treated infarct-related cardiogenic shock patients. *Front Cardiovasc Med*. 2020;7:74.

31. Ouweneel DM, de Brabander J, Karami M, et al. Real-life use of left ventricular circulatory support with Impella in cardiogenic shock after acute myocardial infarction: 12 years AMC experience. *Eur Heart J Acute Cardiovasc Care*. 2019;8(4):338-349.
32. Ait Ichou J, Larivee N, Eisenberg MJ, et al. The effectiveness and safety of the Impella ventricular assist device for high-risk percutaneous coronary interventions: A systematic review. *Catheter Cardiovasc Interv*. 2018;91(7):1250-1260.
33. Kirklin JK, Pagani FD, Goldstein DJ, et al. American association for thoracic surgery/international society for heart and lung transplantation guidelines on selected topics in mechanical circulatory support. *J Heart Lung Transplant*. 2020;39(3):187-219.
34. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of cardiology/American heart association task force on clinical practice guidelines and the heart failure Society of America. 2017;136(6):e137-e161.
35. Hayes, Inc. Hayes Health Technology Assessment. *FDA Safety Alert: Medtronic HVAD Pump Implant Kits*. Lansdale, PA. Hayes, Inc.; 03/20/2021.
36. InterQual® Level of Care Criteria 2019. Acute Care Adult. Change Healthcare, LLC.