



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:

Total Artificial Hearts and Related Devices

Policy #: 033

Latest Review Date: September 2023

Category: Surgery

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after December 1, 2020:

Blue Advantage will treat **total artificial hearts with FDA-approved devices** as a **covered benefit** when performed in a Medicare-approved heart transplant facility as a bridge to heart transplantation when ALL of the following criteria are met:

- Biventricular failure AND,
- No other reasonable medical or surgical treatment options; AND
- Are ineligible for other univentricular or biventricular support devices; AND
- Are currently listed as heart transplantation candidates

OR

- Are undergoing evaluation to determine candidacy for heart transplantation; AND
- Are not expected to survive until a donor heart can be obtained.

Blue Advantage will treat **total artificial hearts** as a **non-covered benefit** and **investigational** for all other indications, including, but not limited to, the use of total artificial hearts as destination therapy.

Blue Advantage will treat **implantable aortic counterpulsation ventricular assist devices** (e.g., the NuPulseCV iVAS and the Symphony Heart Assist System) as a **non-covered benefit** and **investigational** for all indications.

For dates of service February 26, 2018 through November 30, 2020:

For artificial hearts and related devices refer to NCD 20.9.

For percutaneous ventricular assist devices, refer to Articles A53986 & A53988.

For ventricular assist devices refer to NCD 20.9.1.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

According to a 2022 report from the American Heart Association and based on data collected from 2015 to 2018, roughly 6 million Americans ages 20 years or older had heart failure during that time frame. Prevalence of heart failure is projected to affect more than 8 million people 18 years of age and older by the year 2030. Between 2015 and 2018, the prevalence of heart failure was highest in non-Hispanic Black males. Based on data from the Multi-Ethnic Study of Atherosclerosis (MESA), in those without baseline cardiovascular disease, Black individuals had the highest risk of developing heart failure (4.6 per 1000 person-years), followed by Hispanic (3.5 per 1000 person-years), White (2.4 per 1000 person-years), and Chinese individuals (1.0 per 1000 person-years). Similar findings were demonstrated in the Atherosclerosis Risk in Communities (ARIC) Community Surveillance data, in which Black men and women had the highest burden of new-onset heart failure cases and the highest-age adjusted 30-day case fatality rate in comparison to White men and women. Higher risk reflected differential prevalence of hypertension, diabetes, and low socio-economic status.

Mechanical devices to assist or replace a failing heart have been developed over many decades of research. A ventricular assist device (VAD) is a mechanical support, attached to the native heart and vessels to augment cardiac output. The total artificial heart (TAH) replaces the native ventricles and is attached to the pulmonary artery and aorta; the native heart is typically removed. Both the VAD and TAH may be used as a bridge to heart transplantation or as destination therapy in those who are not candidates for transplantation. The VAD has also been used as a bridge to recovery in individuals with reversible conditions affecting cardiac output.

Heart Failure

Heart failure may be the consequence of a number of differing etiologies, including ischemic heart disease, cardiomyopathy, congenital heart defects, or rejection of a heart transplant. The reduction of cardiac output is considered to be severe when systemic circulation cannot meet the body's needs under minimal exertion. Heart transplantation improves quality of life and has survival rates at 1-, 3-, and 5-years of 91%, 85%, and 78%, respectively. The number of candidates for transplants exceeds the supply of donor organs; thus the interest in the development of mechanical devices.

Treatment

Total Artificial Heart (TAH)

Initial research into mechanical assistance for the heart focused on the total artificial heart, a biventricular device that completely replaces the function of the diseased heart. An internal battery required frequent recharging from an external power source. Many systems utilize a percutaneous power line, but a transcutaneous power-transfer coil allows for a system without lines traversing the skin, possibly reducing the risk of infection. Because the native heart must be removed, failure of the device is synonymous with cardiac death.

A fully bioprosthetic TAH, which is fully implanted in the pericardial sac and is electrohydraulically actuated, has been developed and tested in 2 individuals, but is currently experimental.

KEY POINTS:

The most recent literature search was performed for the period through June 20, 2023.

Summary of Evidence

Total Artificial Heart

For individuals who have end-stage heart failure who receive a total artificial heart (TAH) as a bridge to transplant, the evidence includes case series. Relevant outcomes are OS, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. Compared with VADs, the evidence for TAHs in these settings is less robust. However, given the lack of medical or surgical options for these patients and the evidence case series provide, TAH is likely to improve outcomes for a carefully selected population with end-stage biventricular heart failure awaiting transplant who are not appropriate candidates for a left VAD. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have end-stage heart failure who receive a TAH as destination therapy, the evidence includes 2 case series. Relevant outcomes are OS, symptoms, functional outcomes, QOL, and treatment-related mortality and morbidity. The body of evidence for TAHs as destination therapy is too limited to draw conclusions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Ventricular assist device, biventricular support, BIVAD, cardiac support, heart transplantation (transplant), LVAD, VAD, destination therapy, HeartWare®, Impella LV®, Impella 2.5, Impella 2.5 circulatory assist device, DeBakey, percutaneous ventricular assist device, pVAD, TandemHeart®, Berlin Heart EXCOR®, Impella RP, Carmat, bioprosthetic artificial heart, HeartMate III™, Total Artificial Heart, TAH, CardioWest™ Total Artificial Heart, HeartMate II®, SynCardia artificial heart, Right Ventricular Assist Device, RVAD, PediMag®, short-term continuous flow ventricular assist devices, STCF-VADs, intraluminal axial support, HeartAssist 5 Pediatric Ventricular Assist Device; NuPulseCV iVAS; Symphony Heart Assist System; CentriMag® Blood Pump; Implantable Aortic Counterpulsation Ventricular Assist Devices; Intravascular Ventricular Assist Systems; iVAS); C-Pulse, CardioVAD

APPROVED BY GOVERNING BODIES:

Total Artificial Heart

The total artificial heart (TAH) is a biventricular device that completely replaces the function of the diseased heart. An internal battery needs frequent recharging from an external power source. Several systems use a percutaneous power line, but a transcutaneous power-transfer coil allows for a system without lines traversing the skin, possibly reducing the risk of infection. Because the native heart must be removed, failure of the device is synonymous with cardiac death.

Currently, the Syncardia Temporary Total Artificial Heart (Syncardia Systems) is the only Total Artificial Heart available in the US (Table 6). The AbioCor Total Artificial Heart was FDA approved under the Humanitarian Device Exemption program in 2006, but is no longer being marketed or in development.

Table 6. Available Total Artificial Heart

Device	Manufacturer	Approval Date	FDA Clearance	PMA No.	Indication
SynCardia Temporary Total Artificial Heart (Formerly CardioWest Total Artificial Heart and Jarvik Total Artificial Heart)	SynCardia Systems	2004	510(k)	P030011	Bridge to transplant in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure.

FDA: U.S. Food and Drug Administration; PMA: premarket approval.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

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)

As of 1/1/22, aortic counterpulsation ventricular assist devices should be reported using the unlisted code below.

33999	Unlisted procedure, cardiac surgery
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HCPCS Codes:

L8698	Miscellaneous component, supply or accessory for use with total artificial heart system
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REFERENCES:

1. Aaronson KD, Eppinger MJ, Dyke DB et al. Left ventricular assist device therapy improves utilization of donor hearts. J Am Coll Cardiol 2002; 39(8):1247-54.
2. Aissaoui N, Morshuis M, Maoulida H, et al. Management of end-stage heart failure patients with or without ventricular assist device: an observational comparison of clinical and economic outcomes. Eur J Cardiothorac Surg. 2018 53(1).
3. Alba AC, McDonald M, Rao V et al. The effect of ventricular assist devices on long-term post-transplant outcomes: a systematic review of observational studies. Eur J Heart Fail 2011; 13(7):785-95.
4. Almond CS, Morales DL, Blackstone EH, et al. Berlin Heart EXCOR pediatric ventricular assist device for bridge to heart transplantation in US children. Circulation. Apr 23 2013; 127(16):1702-1711.
5. 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.
6. Ait Ichou J, Larivée N, Eisenberg MJ, Suissa K, Filion KB. The effectiveness and safety of the Impella ventricular assist device for high-risk percutaneous coronary interventions: A systematic review. Catheter Cardiovasc Interv. 2018 Jun; 91(7):1250-1260.
7. Arnold SV, Jones PG, Allen LA, et al. Frequency of poor outcome (death or poor quality of life) after left ventricular assist device for destination therapy: results from the INTERMACS Registry. Circ Heart Fail. Aug 2016; 9(8).
8. Aryana A, Gearoid O'Neill P, Gregory D, et al. Procedural and clinical outcomes after catheter ablation of unstable ventricular tachycardia supported by a percutaneous left ventricular assist device. Heart Rhythm. Jul 2014; 11(7):1122-1130.
9. Bank AJ, Mir SH, Nguyen DQ et al. Effects of left ventricular assist devices on outcomes in patients undergoing heart transplantation. Ann Thorac Surg 2000; 69(5):1369-74; discussion 75.
10. Bernhardt AM, Copeland H, Deswal A, et al. The International Society for Heart and Lung Transplantation/Heart Failure Society of America Guideline on Acute Mechanical Circulatory Support. J Heart Lung Transplant. Apr 2023; 42(4): e1-e64.
11. 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. May 2016; 35(5):578-584.

12. Briasoulis A, Telila T, Palla M, et al. Meta-analysis of usefulness of percutaneous left ventricular assist devices for high-risk percutaneous coronary interventions. *Am J Cardiol.* Aug 1 2016;118(3):369-375.
13. 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.* Aug 2017; 36(8):890-896.
14. Burkhoff D, Cohen H, Brunckhorst C, et al. A randomized multicenter clinical study to evaluate the safety and efficacy of the TandemHeart percutaneous ventricular assist device versus conventional therapy with intra-aortic balloon pumping for treatment of cardiogenic shock. *Am Heart J.* Sep 2006; 152(3):469 e461-468.
15. Chen S, Lin A, Liu E, et al. Outpatient outcomes of pediatric patients with left ventricular assist devices. *ASAIO J.* Mar-Apr 2016; 62(2):163-168.
16. Colombo PC, Mehra MR, Goldstein DJ, et al. Comprehensive Analysis of Stroke in the Long-Term Cohort of the MOMENTUM 3 Study. *Circulation.* Jan 08 2019;139(2): 155-168.
17. Conway J, Al-Aklabi M, Granoski D, et al. Supporting pediatric patients with short-term continuous-flow devices. *J Heart Lung Transplant.* May 2016; 35(5):603-609.
18. Copeland JG, Copeland H, Gustafson M et al. Experience with more than 100 total artificial heart implants. *J Thorac Cardiovasc Surg* 2012; 143(3):727-34.
19. Copeland JG, Smith RG, Arabia FA et al. Cardiac replacement with a total artificial heart as a bridge to transplantation. *N Engl J Med* 2004; 351(9):859-67.
20. Cowger JA, Naka Y, Aaronson KD, et al. Quality of life and functional capacity outcomes in the MOMENTUM 3 trial at 6 months: A call for new metrics for left ventricular assist device patients. *J Heart Lung Transplant.* Jan 2018; 37(1): 15-24.
21. Davies RR, Russo MJ, Hong KN et al. The use of mechanical circulatory support as a bridge to transplantation in pediatric patients: an analysis of the United Network for Organ Sharing database. *J Thorac Cardiovasc Surg* 2008; 135(2):421-427, 427 e421.
22. Deo SV, Sung K, Daly RC, et al. Cardiac transplantation after bridged therapy with continuous flow left ventricular assist devices. *Heart Lung Circ.* Mar 2014; 23(3):224-228.
23. Dickstein K, Cohen-Solal A, Filippatos G, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008: the Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2008 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association of the ESC (HFA) and endorsed by the European Society of Intensive Care Medicine (ESICM). *Eur Heart J.* Oct 2008; 29(19):2388-2442.
24. Dowling RD, Gray LA, Etoch SW, et al. Initial experience with the AbioCor implantable replacement heart system. *J Thorac Cardiovasc Surg.* Jan 2004; 127(1): 131-41.
25. Estep JD, Starling RC, Horstmannshof DA, et al. Risk assessment and comparative effectiveness of left ventricular assist device and medical management in ambulatory heart failure patients: results from the ROADMAP study. *J Am Coll Cardiol.* Oct 20 2015; 66(16):1747-1761.

26. 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.
27. Fraser CD, Jr., Jaquiss RD, Rosenthal DN, et al. Prospective trial of a pediatric ventricular assist device. *N Engl J Med*. Aug 9 2012; 367(6):532-541.
28. Frazier OH, Gemmato C, Myers TJ et al. Initial clinical experience with the HeartMate II axial-flow left ventricular assist device. *Tex Heart Inst J* 2007; 34(3):275-81.
29. Frazier OH, Rose EA, McCarthy P et al. Improved mortality and rehabilitation of transplant candidates treated with a long-term implantable left ventricular assist system. *Ann Surg* 1995; 222(3):327-336; discussion 336-338.
30. Griffith BP, Anderson MB, Samuels LE et al. The RECOVER I: A multicenter prospective study of Impella 5.0/LD for postcardiotomy circulatory support. *J Thorac Cardiovasc Surg*. 2013 Feb; 145(2):548-54
31. 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*. Jul 2016; 102(1):102-108.
32. Goldstein DJ, Naka Y, Horstmanshof D, et al. Association of Clinical Outcomes With Left Ventricular Assist Device Use by Bridge to Transplant or Destination Therapy Intent: The Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy With HeartMate 3 (MOMENTUM 3) Randomized Clinical Trial. *JAMA Cardiol*. Apr 01 2020; 5(4): 411-419.
33. Goldstein DJ, Ox MC, and Rose EA. Implantable left ventricular assist devices. *N England J Med* 1998; 339(21):1522-1533.
34. Gustafsson F, Shaw S, Lavee J, et al. Six-month outcomes after treatment of advanced heart failure with a full magnetically levitated continuous flow left ventricular assist device: report from the ELEVATE registry. *Eur Heart J*. Oct 01 2018; 39(37): 3454-3460.
35. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. May 03 2022; 145(18): e876-e894.
36. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
37. John R, Kamdar F, Liao K et al. Improved survival and decreasing incidence of adverse events with the HeartMate II left ventricular assist device as bridge-to-transplant therapy. *Ann Thorac Surg* 2008; 86(4):1227-34; discussion 34-5.
38. Jordan LC, Ichord RN, Reinhartz O, et al. Neurological complications and outcomes in the Berlin Heart EXCOR(R) pediatric investigational device exemption trial. *J Am Heart Assoc*. Jan 2015; 4(1):e001429.
39. Jorde UP, Kushwaha SS, Tatroles AJ, et al. Results of the destination therapy post-food and drug administration approval study with a continuous flow left ventricular assist device: a prospective study using the INTERMACS registry (Interagency Registry for

Mechanically Assisted Circulatory Support). J Am Coll Cardiol. May 6 2014; 63(17):1751-1757.

40. Kar B, Gregoric ID, Basra SS et al. The percutaneous ventricular assist device in severe refractory cardiogenic shock. J Am Coll Cardiol 2011; 57(6):688-96.
41. Karami M, Eriksen E, Ouweneel DM, et al. Long-term 5-year outcome of the randomized IMPRESS in severe shock trial: percutaneous mechanical circulatory support vs. intra-aortic balloon pump in cardiogenic shock after acute myocardial infarction. Eur Heart J Acute Cardiovasc Care. Dec 06 2021; 10(9): 1009-1015.
42. Kirklin JK, Naftel DC, Stevenson LW et al. INTERMACS database for durable devices for circulatory support: first annual report. J Heart Lung Transplant 2008; 27(10):1065-72.
43. 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. Mar 2020; 39(3): 187-219.
44. Lauten A, Engstrom AE, Jung C, et al. Percutaneous left-ventricular support with the Impella-2.5-assist device in acute cardiogenic shock: results of the Impella-EUROSHOCK-registry. Circ Heart Fail. Jan 2013; 6(1):23-30.
45. Lemaire A, Anderson MB, Lee LY, et al. The Impella device for acute mechanical circulatory support in patients in cardiogenic shock. Ann Thorac Surg. Jan 2014; 97(1):133-138.
46. Lewsey SC, Breathett K. Racial and ethnic disparities in heart failure: current state and future directions. Curr Opin Cardiol. May 01 2021; 36(3): 320-328.
47. Long JW, Kfoury AG, Slaughter MS et al. Long-term destination therapy with the HeartMate XVE left ventricular assist device: improved outcomes since the REMATCH study. Congest Heart Fail 2005; 11(3):133-8.
48. Maybaum S, Mancini D, Xydas S, et al. Cardiac improvement during mechanical circulatory support: a prospective multicenter study of the LVAD Working Group. Circulation. May 15 2007;115(19):2497-2505.
49. Mehra MR, Goldstein DJ, Cleveland JC, et al. Five-Year Outcomes in Patients With Fully Magnetically Levitated vs Axial-Flow Left Ventricular Assist Devices in the MOMENTUM 3 Randomized Trial. JAMA. Sep 27 2022; 328(12): 1233-1242.
50. Mehra MR, Uriel N, Naka Y, et al. A Fully Magnetically Levitated Left Ventricular Assist Device - Final Report. N Engl J Med. Apr 25 2019; 380(17): 1618-1627.
51. Mehra MR, Cleveland JC, Uriel N, et al. Primary results of long-term outcomes in the MOMENTUM 3 pivotal trial and continued access protocol study phase: a study of 2200 HeartMate 3 left ventricular assist device implants. Eur J Heart Fail. Aug 2021; 23(8): 1392-1400.
52. Miller LW, Pagani FD, Russell SD et al. Use of a continuous-flow device in patients awaiting heart transplantation. N Engl J Med 2007; 357(9):885-896.
53. O'Neill WW, Kleiman NS, Moses J, et al. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients

undergoing high-risk percutaneous coronary intervention: the PROTECT II study. *Circulation*. Oct 02 2012; 126(14): 1717-27.

54. Organ Procurement and Transplantation Network. Heart Kaplan-Meier Patient Survival Rates For Transplants Performed : 2008 - 2015. 2018;
<https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#>
55. 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*. Jun 2019; 8(4): 338-349.
56. Ouweneel DM, Eriksen E, Sjaauw KD, et al. Percutaneous mechanical circulatory support versus intra-aortic balloon pump in cardiogenic shock after acute myocardial infarction. *J Am Coll Cardiol*. Jan 24 2017; 69(3):278-287.
57. Pagani FD, Mehra MR, Cowger JA, et al. Clinical outcomes and healthcare expenditures in the real world with left ventricular assist devices - The CLEAR-LVAD study. *J Heart Lung Transplant*. May 2021; 40(5): 323-333.
58. Park SJ, Tector A, Piccioni W et al. Left ventricular assist devices as destination therapy: a new look at survival. *J Thorac Cardiovasc Surg* 2005; 129(1):9-17.
59. Patel ND, Weiss ES, Schaffer J et al. Right heart dysfunction after left ventricular assist device implantation: a comparison of the pulsatile HeartMate I and axial-flow HeartMate II devices. *Ann Thorac Surg* 2008; 86(3):832-40; discussion 32-40.
60. Peura JL, Colvin-Adams M, Francis GS, et al. Recommendations for the use of mechanical circulatory support: device strategies and patient selection: a scientific statement from the American Heart Association. *Circulation*. Nov 27 2012;126(22):2648-2667.
61. Reddy YM, Chinitz L, Mansour M, et al. Percutaneous left ventricular assist devices in ventricular tachycardia ablation: multicenter experience. *Circ Arrhythm Electrophysiol*. Apr 2014;7(2):244-250.
62. Rihal CS, Naidu SS, Givertz MM, et al. 2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care: Endorsed by the American Heart Association, the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencion; Affirmation of Value by the Canadian Association of Interventional Cardiology-Association Canadienne de Cardiologie d'intervention. *J Am Coll Cardiol*. May 19 2015; 65(19):e7-e26.
63. Rogers JG, Butler J, Lansman SL, et al. Chronic mechanical circulatory support for Inotrope-dependent heart failure patients who are not transplant candidates- Results of the INTREPID Trial. *J Am Coll Cardiol*. 2007; 50(8):741-747.
64. Rogers JG, Pagani FD, Tatroles AJ, et al. Intrapericardial left ventricular assist device for advanced heart failure. *N Engl J Med*. Feb 02 2017; 376(5):451-460.
65. Romeo F, Acconcia MC, Sergi D, et al. Percutaneous assist devices in acute myocardial infarction with cardiogenic shock: Review, meta-analysis. *World J Cardiol*. Jan 26 2016; 8(1):98-111.

66. Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term use of a left ventricular assist device for end-state heart failure. The New England Journal of Medicine, November 2001, Vol. 345, No. 20: 1435-43.
67. 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.
68. Schmitto JD, Pya Y, Zimpfer D, et al. Long-term evaluation of a fully magnetically levitated circulatory support device for advanced heart failure-two-year results from the HeartMate 3 CE Mark Study. Eur J Heart Fail. Jan 2019; 21(1): 90-97.
69. Schrage B, Ibrahim K, Loehn T, et al. Impella Support for Acute Myocardial Infarction Complicated by Cardiogenic Shock. Circulation. Mar 05 2019; 139(10): 1249-1258.
70. Seyfarth M, Sibbing D, Bauer I, et al. A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction. J Am Coll Cardiol. Nov 4 2008; 52(19):1584-1588.
71. Shuhaiber JH, Hur K, Gibbons R. The influence of preoperative use of ventricular assist devices on survival after heart transplantation: propensity score matched analysis. BMJ 2010; 340:c392.
72. 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. Mar 2020; 9(2): 138-148.
73. Slaughter MS, Pagani FD, McGee EC, et al. HeartWare ventricular assist system for bridge to transplant: combined results of the bridge to transplant and continued access protocol trial. J Heart Lung Transplant. Jul 2013; 32(7):675-683.
74. Starling RC, Estep JD, Horstmannshof 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. Jul 2017; 5(7):518-527.
75. Struber M, Sander K, Lahpor J et al. HeartMate II left ventricular assist device; early European experience. Eur J Cardiothorac Surg 2008; 34(2):289-94.
76. Strueber M, O'Driscoll G, Jansz P et al. Multicenter evaluation of an intrapericardial left ventricular assist system. J Am Coll Cardiol 2011; 57(12):1375-82.
77. TEC Assessment Program. Left ventricular assist devices as destination therapy for end-stage heart failure. 2002;Volume 17; Tab 19.
78. TEC Assessment Program. Ventricular assist devices in bridging to heart transplantation. 1996;Volume 11; Tab 26.
79. Thiele H, Sick P, Boudriot E, et al. Randomized comparison of intra-aortic balloon support with a percutaneous left ventricular assist device in patients with revascularized acute myocardial infarction complicated by cardiogenic shock. Eur Heart J. Jul 2005; 26(13):1276-1283.
80. Topkara VK, Garan AR, Fine B, et al. Myocardial recovery in patients receiving contemporary left ventricular assist devices: results from the Interagency Registry for

Mechanically Assisted Circulatory Support (INTERMACS). *Circ Heart Fail*. Jul 2016;9(7).

81. Torregrossa G, Morshuis M, Varghese R, et al. Results with SynCardia total artificial heart beyond 1 year. *ASAIO J*. Nov-Dec 2014; 60(6):626-634.
82. Tsao CW, Aday AW, Almarzooq ZI, et al. Heart Disease and Stroke Statistics-2022 Update: A Report From the American Heart Association. *Circulation*. Feb 22 2022; 145(8): e153-e639.
83. Wehman B, Stafford KA, Bittle GJ, et al. Modern outcomes of mechanical circulatory support as a bridge to pediatric heart transplantation. *Ann Thorac Surg*. Jun 2016; 101(6):2321-2327.
84. Wever-Pinzon O, Drakos SG, McKellar SH, et al. Cardiac recovery during long-term left ventricular assist device support. *J Am Coll Cardiol*. Oct 04 2016; 68(14):1540-1553.
85. 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. *Circulation*. Aug 08 2017; 136(6): e137-e161.
86. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure-A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2013; 62(16):e147-e239.

POLICY HISTORY:

Adopted for Blue Advantage, February 2016

Available for comment February 15 through March 30, 2016

Medical Policy Group, August 2016

Medical Policy Group, September 2017

Medical Policy Group, February 2018

Medical Policy Group, September 2020

Medical Policy Group, November 2020: Annual Coding Update. Added new CPT codes 33995 and 33997. Revised CPT codes 33990-33993 to clarify left or right heart.

Medical Policy Group, April 2021

Medical Policy Group, August 2021

Medical Policy Group, December 2021: 2022 Annual Coding Update. Moved CPT codes from Current coding section. Updated Previous Coding section to include codes 0451T, 0452T, 0453T, 0454T, 0455T, 0456T, 0457T, 0458T, 0459T, 0460T, 0461T, and 0462T. Added unlisted CPT Code 33999 to Current Coding section. CPT Code 33999 will be used to report permanently implantable aortic counterpulsation ventricular assist devices after 1/1/2022.

Medical Policy Group, September 2022

Medical Policy Group, September 2023

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date

services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.