Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting

Policy # 00287
Original Effective Date: 01/31/2005
Current Effective Date: 08/09/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure is addressed separately in medical policy 00009.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers cardiac hemodynamic monitoring for the management of heart failure utilizing thoracic bioimpedance, inert gas rebreathing, arterial pressure during the Valsalva maneuver, and implantable direct pressure monitoring of the pulmonary artery (PA) in the ambulatory care and outpatient setting to be **investigational.***

Policy Guidelines

This policy refers only to the use of stand-alone cardiac output measurement devices designed for use in ambulatory care and outpatient settings. The use of cardiac hemodynamic monitors or intrathoracic fluid monitors that are integrated into other implantable cardiac devices, including implantable cardioverter defibrillators, cardiac resynchronization therapy devices, and cardiac pacing devices, is addressed in medical policy 00009.

Background/Overview

Chronic Heart Failure

Patients with chronic heart failure are at risk of developing acute decompensated heart failure, often requiring hospital admission. Patients with a history of acute decompensation have the additional risk of future episodes of decompensation and death. Reasons for the transition from a stable, chronic state to an acute, decompensated state include disease progression, as well as acute events such as

coronary ischemia and dysrhythmias. While precipitating factors are frequently not identified, the most common preventable cause is noncompliance with medication and dietary regimens.

Management
Strategies for reducing decompensation, and thus the need for hospitalization, are aimed at early identification of patients at risk for imminent decompensation. Programs for early identification of heart failure are characterized by frequent contact with patients to review signs and symptoms with a health care provider, education, and medication adjustments as appropriate. These encounters may occur face-to-face in the office or at home, or via cellular or computed technology.

Precise measurement of cardiac hemodynamics is often employed in the intensive care setting to carefully manage fluid status in acutely decompensated heart failure. Transthoracic echocardiography, transesophageal echocardiography, and Doppler ultrasound are noninvasive methods for monitoring cardiac output on an intermittent basis for the more stable patient but are not addressed herein. A variety of biomarkers and radiologic techniques may be used for dyspnea when the diagnosis of acute decompensated heart failure is uncertain.

The criterion standard for hemodynamic monitoring is pulmonary artery catheters and central venous pressure catheters. However, they are invasive, inaccurate, and inconsistent in predicting fluid responsiveness. Several studies have demonstrated that catheters fail to improve outcomes in critically ill patients and may be associated with harm. To overcome these limitations, multiple techniques and devices have been developed that use complex imaging technology and computer algorithms to estimate fluid responsiveness, volume status, cardiac output and tissue perfusion. Many are intended for use in outpatient settings but can be used in the emergency department, intensive care unit, and operating room. Four methods are reviewed here: implantable pressure monitoring devices, thoracic bioimpedance, inert gas rebreathing, and arterial waveform during the Valsalva maneuver. Use of the last 3 is not widespread because of several limitations including use of proprietary technology making it difficult to confirm their validity and lack of large randomized controlled trials to evaluate treatment decisions guided by these hemodynamic monitors.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Noninvasive Left Ventricular End-Diastolic Pressure Measurement Devices

In 2004, the VeriCor®‡ (CVP Diagnostics), a noninvasive left ventricular end-diastolic pressure measurement device, was cleared for marketing by U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for the following indication:

> "The VeriCor is indicated for use in estimating non-invasively, left ventricular end-diastolic pressure (LVEDP). This estimate, when used along with clinical signs and symptoms and other patient test results, including weights on a daily basis, can aid the clinician in the selection of further diagnostic tests in the process of reaching a diagnosis and formulating a therapeutic plan when abnormalities of intravascular volume are suspected. The device has been clinically validated in males only. Use of the device in females has not been investigated."

FDA product code: DXN.

Thoracic Bioimpedance Devices

Multiple thoracic impedance measurement devices that do not require invasive placement have been cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices used for peripheral blood flow monitoring. Table 1 presents an inexhaustive list of representative devices (FDA product code: DSB).

Table 1. Noninvasive Thoracic Impedance Plethysmography Devices

Device	Manufacturer	Clearance Date
BioZ®‡ Thoracic Impedance Plethysmograph	SonoSite	2009
Zoe®‡ Fluid Status Monitor	Noninvasive Medical Technologies	2004
Cheetah Starling SV	Cheetah Medical	2008

Device	Manufacturer	Clearance Date
PhysioFlow®‡ Signal Morphology-based Impedance Cardiography (SM-ICG™)	Vasocom, now NeuMeDx	2008
ReDSTM Wearable System	Sensible Medical Innovations	2015

Also, several manufacturers market thoracic impedance measurement devices integrated into implantable cardiac pacemakers, cardioverter defibrillator devices, and cardiac resynchronization therapy devices. Thoracic bioimpedance devices integrated into implantable cardiac devices are addressed in medical policy 00009.

Inert Gas Rebreathing Devices
In 2006, the Innocor®‡ (Innovision), an inert gas rebreathing device, was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing inert gas rebreathing devices for use in computing blood flow. FDA product code: BZG.

Implantable Pulmonary Artery Pressure Sensor Devices
In 2014, the CardioMEMS™‡ Champion Heart Failure Monitoring System (CardioMEMS, now Abbott) was approved for marketing by the FDA through the premarket approval process. This device consists of an implantable pulmonary artery (PA) sensor, which is implanted in the distal PA, a transvenous delivery system, and an electronic sensor that processes signals from the implantable PA sensor and transmits PA pressure measurements to a secure database. The device originally underwent FDA review in 2011, at which point FDA found no reasonable assurance that the monitoring system would be effective, particularly in certain subpopulations, although the FDA agreed this monitoring system was safe for use in the indicated patient population.

Several other devices that monitor cardiac output by measuring pressure changes in the PA or right ventricular outflow tract have been investigated in the research setting but have not received the FDA approval. They include the Chronicle®‡ implantable continuous hemodynamic monitoring

device (Medtronic), which includes a sensor implanted in the right ventricular outflow tract, and the ImPressure®‡ device (Remon Medical Technologies), which includes a sensor implanted in the PA. Note: This evidence review only addresses the use of these technologies in ambulatory care and outpatient settings.

Rationale/Source

A variety of outpatient cardiac hemodynamic monitoring devices are intended to improve quality of life and reduce morbidity for patients with heart failure by decreasing episodes of acute decompensation. Monitors can identify physiologic changes that precede clinical symptoms and thus allow preventive intervention. These devices operate through various mechanisms, including implantable pressure sensors, thoracic bioimpedance measurement, inert gas rebreathing, and estimation of left ventricular end-diastolic pressure by arterial pressure during the Valsalva maneuver.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring with an implantable pulmonary artery pressure sensor device, the evidence includes randomized controlled trials. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. One implantable pressure monitor, the CardioMEMS device, has U.S. Food and Drug Administration approval. The pivotal CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA III Heart Failure Patients randomized controlled trial reported a statistically significant decrease in heart failure-related hospitalizations in patients implanted with CardioMEMS device compared with usual care. However, trial results were potentially biased in favor of the treatment group due to use of additional nurse communication to enhance protocol compliance with the device. The manufacturer conducted multiple analyses to address potential bias from the nurse interventions. Results were reviewed favorably by the Food and Drug Administration. While these analyses demonstrated the consistency of benefit from the CardioMEMS device, all such analyses have methodologic limitations. Early safety data have been suggestive of a higher rate of procedural complications, particularly related to pulmonary artery injury. Given that the intervention is invasive and intended to be used for a highly prevalent condition, in the light of limited safety data, lack of demonstrable mortality benefit, and pending questions related to its benefit in reducing hospitalizations, the net benefit remains uncertain. Many of these concerns may be clarified by an ongoing postmarketing

study that proposes to enroll 1200 patients (at least 35% women) is reported. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring by thoracic bioimpedance, the evidence includes uncontrolled prospective studies and case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. There is a lack of randomized controlled trial evidence evaluating whether the use of these technologies improves health outcomes over standard active management of heart failure patients. The case series have reported physiologic measurement-related outcomes and/or associations between monitoring information and heart failure exacerbations, but do not provide definitive evidence on device efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring with inert gas rebreathing, no studies have been identified on clinical validity or clinical utility. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring of arterial pressure during the Valsalva maneuver, a single study was identified. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. The study assessed the use of LVEDP monitoring and reported an 85% sensitivity and an 80% specificity to detect LVEDP greater than 15 mm Hg. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

American College of Cardiology et al
In 2017, the American College of Cardiology, the American Heart Association, and the Heart Failure Society of America issued joint guidelines on the management of heart failure that offered no recommendations for the use of ambulatory monitoring devices.

European Society of Cardiology
The European Society of Cardiology guidelines on the diagnosis and treatment of acute and chronic heart failure stated the following: "Monitoring of pulmonary artery pressures using a wireless implantable hemodynamic monitoring system (CardioMEMS) may be considered in symptomatic patients with HF [heart failure] with previous HF hospitalization in order to reduce the risk of recurrent HF hospitalization" (class IIb, level B recommendation.)

National Institute for Health and Care Excellence
In 2018, the National Institute for Health and Care Excellence (NICE) updated their guidelines on chronic heart failure management and did not include outpatient hemodynamic monitoring as a recommendation.

In 2013, the Institute issued guidance on the insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure. The recommendations concluded that "Current evidence on the safety and efficacy of the insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure is limited in both quality and quantity."

Heart Failure Society of America
In 2018, the Heart Failure Society of America Scientific Statements Committee (2018) published a white paper consensus statement on remote monitoring of patients with heart failure.

The committee concluded that: "Based on available evidence, routine use of external RPM devices is not recommended. Implanted devices that monitor pulmonary arterial pressure and/or other parameters may be beneficial in selected patients or when used in structured programs, but the value of these devices in routine care requires further study."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
In 2014, the Centers for Medicare & Medicaid Services updated its 2006 decision memorandum on thoracic electrical bioimpedance. Medicare's national coverage determination found thoracic bioimpedance to be reasonable and necessary for the following indications:

- Differentiation of cardiogenic from pulmonary causes of acute dyspnea;

- Optimization of atrioventricular interval for patients with atrioventricular sequential cardiac pacemakers;
- Monitoring of continuous inotropic therapy for patients with terminal heart failure;
- Evaluation for rejection in patients with a heart transplant as a predetermined alternative to myocardial biopsy; and
- Optimization of fluid management in patients with congestive heart failure.

While Medicare permits coverage of thoracic bioimpedance in these conditions, it has acknowledged that there is a "…general absence of studies evaluating the impact of using thoracic bioimpedance for managing patients with cardiac disease…." Medicare does not cover the use of thoracic bioimpedance in the management of hypertension due to inadequate evidence.

Medicare has also specified that thoracic bioimpedance is not covered for "the management of all forms of hypertension (with the exception of drug-resistant hypertension…)." Further, Medicare specified that:

> "[Contractors] have discretion to determine whether the use of TEB [thoracic bioimpedance] for the management of drug-resistant hypertension is reasonable and necessary. Drug resistant hypertension is defined as failure to achieve goal blood pressure in patients who are adhering to full doses of an appropriate 3-drug regimen that includes a diuretic."

There is no Medicare national coverage determination on implantable direct pressure monitoring, inert gas rebreathing, and arterial pressure with Valsalva.

Effective April 7, 2016, Novitas Solutions issued a noncoverage local coverage determination (ID L36419) for outpatient wireless pulmonary artery pressure monitoring for heart failure (CardioMEMS).

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02950597	Evaluation of Clinical Impact of Non-Invasive Hemodynamic Monitoring to Optimize Preventive Care of Heart Failure Patients	197	Nov 2019
NCT02693691	CardioMEMS European Monitoring Study for Heart Failure	239	Dec 2019
NCT02954341	CardioMEMS HF SystemOUS Post Market Study	800	Dec 2023
NCT03387813	Hemodynamic-GUIDEd Management of Heart Failure	3600	Apr 2023
Unpublished			
NCT01121107	Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy Study	486	Apr 2015 (updated 02/04/2019)
			Dec 2012 (unknown updated 06/03/09)

NCT: national clinical trial.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting", Policy 2.02.24, June 2020.
2. Opasich C, Rapezzi C, Lucci D, et al. Precipitating factors and decision-making processes of short-term worsening heart failure despite optimal treatment (from the IN-CHF Registry). Am J Cardiol. Aug 15 2001; 88(4): 382-7. PMID 11545758

3. McAlister FA, Stewart S, Ferrua S, et al. Multidisciplinary strategies for the management of heart failure patients at high risk for admission: a systematic review of randomized trials. J Am Coll Cardiol. Aug 18 2004; 44(4): 810-9. PMID 15312864
4. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): CardioMEMS HF System. 2014; https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100045b.pdf.
5. Loh JP, Barbash IM, Waksman R. Overview of the 2011 Food and Drug Administration Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting on the CardioMEMS Champion Heart Failure Monitoring System. J Am Coll Cardiol. Apr 16 2013; 61(15): 1571-6. PMID 23352783
6. International Consortium for Health Outcomes Measurement, Inc (ICHOM). Heart Failure version 1.1.4. Oct 2017.
7. Zannad F, Garcia AA, Anker SD, et al. Clinical outcome endpoints in heart failure trials: a European Society of Cardiology Heart Failure Association consensus document. Eur J Heart Fail. Oct 2013; 15(10): 1082-94. PMID 23787718
8. Abraham WT, Adamson PB, Bourge RC, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. Lancet. Feb 19 2011; 377(9766): 658-66. PMID 21315441
9. Abraham WT, Stevenson LW, Bourge RC, et al. Sustained efficacy of pulmonary artery pressure to guide adjustment of chronic heart failure therapy: complete follow-up results from the CHAMPION randomised trial. Lancet. Jan 30 2016; 387(10017): 453-61. PMID 26560249
10. CardioMEMS ChampionTM HF Monitoring System: FDA Review of P100045/A004FDA Presentation - CardioMEMS: Oct. 9, 2013. 2013; https://wayback.archive-it.org/7993/20170111163259/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM370955.pdf.
11. CardioMEMSChampionTM Heart Failure Monitoring System: Presentation - CardioMEMS: Oct. 9, 2013. 2013; https://wayback.archive-it.org/7993/20170111163201/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/

MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM370951.pdf.
12. Givertz MM, Stevenson LW, Costanzo MR, et al. Pulmonary Artery Pressure-Guided Management of Patients With Heart Failure and Reduced Ejection Fraction. J Am Coll Cardiol. Oct 10 2017; 70(15): 1875-1886. PMID 28982501
13. Adamson PB, Abraham WT, Bourge RC, et al. Wireless pulmonary artery pressure monitoring guides management to reduce decompensation in heart failure with preserved ejection fraction. Circ Heart Fail. Nov 2014; 7(6): 935-44. PMID 25286913
14. Adamson PB, Abraham WT, Stevenson LW, et al. Pulmonary Artery Pressure-Guided Heart Failure Management Reduces 30-Day Readmissions. Circ Heart Fail. Jun 2016; 9(6). PMID 27220593
15. Krahnke JS, Abraham WT, Adamson PB, et al. Heart failure and respiratory hospitalizations are reduced in patients with heart failure and chronic obstructive pulmonary disease with the use of an implantable pulmonary artery pressure monitoring device. J Card Fail. Mar 2015; 21(3): 240-9. PMID 25541376
16. Desai AS, Bhimaraj A, Bharmi R, et al. Ambulatory Hemodynamic Monitoring Reduces Heart Failure Hospitalizations in Real-World Clinical Practice. J Am Coll Cardiol. May 16 2017; 69(19): 2357-2365. PMID 28330751
17. Vaduganathan M, DeFilippis EM, Fonarow GC, et al. Postmarketing Adverse Events Related to the CardioMEMS HF System. JAMA Cardiol. Nov 01 2017; 2(11): 1277-1279. PMID 28975249
18. Heywood JT, Jermyn R, Shavelle D, et al. Impact of Practice-Based Management of Pulmonary Artery Pressures in 2000 Patients Implanted With the CardioMEMS Sensor. Circulation. Apr 18 2017; 135(16): 1509-1517. PMID 28219895
19. Kamath SA, Drazner MH, Tasissa G, et al. Correlation of impedance cardiography with invasive hemodynamic measurements in patients with advanced heart failure: the BioImpedance CardioGraphy (BIG) substudy of the Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE) Trial. Am Heart J. Aug 2009; 158(2): 217-23. PMID 19619697
20. Anand IS, Greenberg BH, Fogoros RN, et al. Design of the Multi-Sensor Monitoring in Congestive Heart Failure (MUSIC) study: prospective trial to assess the utility of continuous wireless physiologic monitoring in heart failure. J Card Fail. Jan 2011; 17(1): 11-6. PMID 21187259

21. Anand IS, Tang WH, Greenberg BH, et al. Design and performance of a multisensor heart failure monitoring algorithm: results from the multisensor monitoring in congestive heart failure (MUSIC) study. J Card Fail. Apr 2012; 18(4): 289-95. PMID 22464769
22. Packer M, Abraham WT, Mehra MR, et al. Utility of impedance cardiography for the identification of short-term risk of clinical decompensation in stable patients with chronic heart failure. J Am Coll Cardiol. Jun 06 2006; 47(11): 2245-52. PMID 16750691
23. Amir O, Ben-Gal T, Weinstein JM, et al. Evaluation of remote dielectric sensing (ReDS) technology-guided therapy for decreasing heart failure re-hospitalizations. Int J Cardiol. Aug 01 2017; 240: 279-284. PMID 28341372
24. Silber HA, Trost JC, Johnston PV, et al. Finger photoplethysmography during the Valsalva maneuver reflects left ventricular filling pressure. Am J Physiol Heart Circ Physiol. May 15 2012; 302(10): H2043-7. PMID 22389389
25. 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. J Am Coll Cardiol. Aug 08 2017; 70(6): 776-803. PMID 28461007
26. Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure. Rev Esp Cardiol (Engl Ed). Dec 2016; 69(12): 1167. PMID 27894487
27. National Institute for Health and Care Excellence (NICE). Chronic heart failure in adults: diagnosis and management; NICE guideline NG106. September 2018. https://www.nice.org.uk/guidance/ng106.
28. National Institute for Health and Care Excellence (NICE). Insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure [IPG463]. 2013; https://www.nice.org.uk/guidance/ipg463.
29. Dickinson MG, Allen LA, Albert NA, et al. Remote Monitoring of Patients With Heart Failure: A White Paper From the Heart Failure Society of America Scientific Statements Committee. J Card Fail. Oct 2018; 24(10): 682-694. PMID 30308242
30. Centers for Medicare & Medicaid Services (CMS). National coverage decision for cardiac output monitoring by thoracic electrical bioimpedance (TEB) (20.16). 2006; http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=267&ncdver=3&NCAId=82&NcaName=Electrical+Bioimpedance+for+Cardiac+Output+Moni toring&IsPopup=y&bc=AAAAAAAACAAAAA%3D%3D&.

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12/07/2004	Medical Director review
12/14/2004	Medical Policy Committee review
01/31/2005	Managed Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged
02/07/2007	Medical Director review
02/21/2007	Medical Policy Committee approval. Coverage eligibility unchanged. Rationale/Source and reference updated.
02/04/2009	Medical Director review
02/19/2009	Medical Policy Committee approval. No change to coverage eligibility.
02/04/2010	Medical Policy Committee approval
02/17/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/03/2011	Medical Policy Committee review
03/16/2011	Medical Policy Implementation Committee approval. This policy replaces medical policies 00116 and 00151 to create a single policy addressing cardiac hemodynamic monitoring for the management of heart failure in the outpatient setting.
03/01/2012	Medical Policy Committee review
03/21/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/16/2012	Policy Retired
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Policy returned to active status.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/05/2018	Medical Policy Committee review

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07/11/2018	Medical Policy Implementation Committee approval. Changed "arterial pressure/Valsalva" to "arterial pressure during the Valsalva maneuver". Coverage eligibility unchanged.
01/01/2019	Coding update
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/10/2019	Coding update
06/10/2020	Coding update
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/01/2021	Medical Policy Committee review
07/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2021	Coding update

Next Scheduled Review Date: 07/2022

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0607T, 0608T, 33289, 93264, 93701, 93799
HCPCS	No codes
ICD-10 Diagnosis	I20.1, I20.8, I20.9, I21.01, I21.02, I21.09, I21.11, I21.19, I21.21, I21.29, I21.3, I21.4, I21.20, I21.21, I21.22, I22.8, I22.9, I25.10, I25.110, I25.111, I25.118, I25.119, I25.5, I25.6, I25.700, I25.701. I25.708, I25.709, I25.710, I25.711, I25.718, I25.719, I25.720, I25.721, I25.728, I25.729, I25.730, I25.731, I25.738, I25.739, I25.750, I25.751, I25.758, I25.759, I25.760, I25.761, I25.768, I25.769, I25.790, I25.791, I25.798, I25.799, I25.810, I25.811, I25.812, I25.82, I25.89, I25.9, I27.0, I27.2, I27.81, I27.89, I27.9, I48.0, I48.11-I48.21, I48.3, I48.4, I48.91, I48.92, I50.1, I50.20, I50.21, I50.22, I50.23, I50.30, I50.31, I50.32, I50.33, I50.40, I50.41, I50.42, I50.43, I50.9, Z13.6 Added codes eff 10/1/2021: I5A

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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