

Policy # 00251

Original Effective Date: 02/17/2010 Current Effective Date: 04/10/2023

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.

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 ultrasonographic measurement of carotid intimal-medial thickness (CIMT) as a technique of identifying subclinical atherosclerosis for use in the screening, diagnosis or management of atherosclerotic disease to be **investigational.***

Background/Overview

Coronary Heart Disease

Heart disease is the leading cause of mortality in the United States, accounting for more than half of all deaths. Coronary heart disease (CHD), also known as coronary artery disease, is the most common cause of heart disease. In a 2022 update on heart disease and stroke statistics from the American Heart Association, it was estimated that 720,000 Americans have a new coronary attack (first hospitalized myocardial infarction or CHD death) and 335,000 have a recurrent attack annually. An estimated 20.1 million Americans ≥20 years of age have CHD. The prevalence of CHD was higher for males than females ≥60 years of age. Total CHD prevalence is 7.2% in US adults ≥20 years of age; CHD prevalence is 8.3% for males and 6.2% for females. On the basis of data from the 2018 National Health Interview Survey, CHD prevalence estimates are 5.7% among White people, 5.4% among Black people, 8.6% among American Indian/Alaska Native people, and 4.4% among Asian people ≥18 years of age.

Established major risk factors for CHD have been identified by the National Cholesterol Education Program Expert Panel. These risk factors include elevated serum levels of low-density lipoprotein cholesterol and total cholesterol, and reduced levels of high-density lipoprotein cholesterol. Other

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00251

Original Effective Date: 02/17/2010 Current Effective Date: 04/10/2023

risk factors include a history of cigarette smoking, hypertension, family history of premature CHD, and age.

Diagnosis

The third report of the National Cholesterol Education Program Adult Treatment Panel established various treatment strategies to modify the risk of CHD, with emphasis on target goals of low-density lipoprotein cholesterol. Pathology studies have demonstrated that levels of traditional risk factors are associated with the extent and severity of atherosclerosis. The third report of the National Cholesterol Education Program Adult Treatment Panel recommended use of the Framingham criteria to further stratify those patients with 2 or more risk factors for more intensive lipid management. However, at every level of risk factor exposure, there is substantial variation in the amount of atherosclerosis, presumably related to genetic susceptibility and the influence of other risk factors. Thus, there has been an interest in identifying a technique that can improve the ability to diagnose those at risk of developing CHD, as well as to measure disease progression, particularly for those at intermediate risk.

The carotid arteries can be well-visualized by ultrasonography, and ultrasonographic measurement of the CIMT has been investigated as a technique to identify and monitor subclinical atherosclerosis. B-mode ultrasound is most commonly used to measure CIMT. Carotid intima-media thickness is measured and averaged over several sites in each carotid artery. Imaging the far wall of each common carotid artery yields more accurate and reproducible CIMT measurements than imaging the near wall. Two echogenic lines are produced, representing the lumen-intima interface and the media-adventitia interface. The distance between these 2 lines constitutes the CIMT.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2003, SonoCalc^{®‡} (SonoSite) was cleared for marketing by the U.S. FDA through the 510(k) process. The FDA determined that this software was substantially equivalent to existing image display products for use in the automatic measurement of the IMT of the carotid artery from images obtained from ultrasound systems. Subsequently, other devices have been cleared for marketing by the FDA through the 510(k) process.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00251

Original Effective Date: 02/17/2010 Current Effective Date: 04/10/2023

FDA product code: LLZ.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Ultrasonographic measurement of carotid intima-media (or intimal-medial) thickness (CIMT) refers to the use of B-mode ultrasound to determine the thickness of the 2 innermost layers of the carotid artery wall, the intima and the media. Detection and monitoring of intima-media thickening, which is a surrogate marker for atherosclerosis, may provide an opportunity to intervene earlier in atherogenic disease and/or monitor disease progression.

Summary of Evidence

For individuals who are undergoing cardiac risk assessment who receive ultrasonic measurement of CIMT, the evidence includes large cohort studies, case-control studies, and systematic reviews. Relevant outcomes are test accuracy and morbid events. Some studies have correlated increased CIMT with other commonly used markers for risk of CHD and with risk for future cardiovascular (CV) events. Lorenz et al (2012) found in their meta-analysis that CIMT was associated with increased CV events, although CIMT progression overtime was not associated with increased CV event risk. Peters et al (2012) found that the added predictive value of CIMT was modest, and the ability to reclassify patients into clinically relevant categories was not demonstrated. The results from these reviews and other studies have demonstrated the predictive value of CIMT is uncertain and that the predictive ability for any level of population risk cannot be determined with precision. Also, available studies do not define how the use of CIMT in clinical practice improves outcomes. There is no scientific literature that directly tests the hypothesis that measurement of CIMT results in improved patient outcomes and no specific guidance on how measurements of CIMT should be incorporated into risk assessment and risk management. The objective of 1 study, however, was to define "normal" CIMT progression in low to moderate CV risk patients. Study results showed definite patterns related to various factors that could be used as a tool to earlier identify patients at

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00251

Original Effective Date: 02/17/2010 Current Effective Date: 04/10/2023

increased CV risk, but patient outcomes were not assessed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Cardiology and American Heart Association

In 2013, the guidelines from the American College of Cardiology and the American Heart Association on the assessment of CV risk did not recommend CIMT measurement in routine risk assessment of a first atherosclerotic cardiovascular disease (CVD) event (class III: no benefit; level of evidence: B). This differs from their 2010 joint guidelines for the assessment of CV risk, which indicated that CIMT might be reasonable for assessing CV risk in intermediate-risk asymptomatic adults.

American Association of Clinical Endocrinologists

In 2017, the American Association of Clinical Endocrinologists and American College of Endocrinology published guidelines stating that CIMT could be applied as a risk stratification tool in determining the need for more aggressive preventive strategies against CVD (grade B; best evidence level 2), but not routinely.

American Society of Echocardiography

In 2008, the American Society of Echocardiography (ASE) consensus statement, endorsed by the Society for Vascular Medicine, stated that CIMT is a feature of arterial wall aging "that is not synonymous with atherosclerosis, particularly in the absence of plaque." The statement recommended measurement of both CIMT and carotid plaque by ultrasound "for refining CVD risk assessment in patients at intermediate CVD risk (Framingham Risk Score 6% to 20%) without established CHD, peripheral arterial disease, cerebrovascular disease, diabetes mellitus, or

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00251

Original Effective Date: 02/17/2010 Current Effective Date: 04/10/2023

abdominal aortic aneurysm." However, the Society acknowledged that "More research is needed to determine whether improved risk prediction observed with CIMT or carotid plaque imaging translates into improved patient outcomes." The recommendations made in the 2008 consensus statement were endorsed in ASE's 2020 guideline entitled *Recommendations for the Assessment of Carotid Arterial Plaque by Ultrasound for the Characterization of Atherosclerosis and Evaluation of Cardiovascular Risk*. Authors of the 2020 guideline also note the following: "Since the largest portion of CIMT (approximately 99% in healthy individuals and approximately 80% when diseased) consists of the medial layer, CIMT has not been shown to consistently add to CVD risk prediction."

U.S. Preventive Services Task Force Recommendations

In 2009, the U.S. Preventive Services Task Force (USPSTF) published a systematic review of CIMT within the scope of a larger recommendation on the use of nontraditional risk factors in CHD risk assessment. The USPSTF could not draw conclusions on the applicability of CIMT to the intermediate-risk population at large outside the research setting. The USPSTF summary of recommendations specific to CIMT stated that: "... the current evidence is insufficient to assess the balance of benefits and harms of using ... [CIMT] ... to screen asymptomatic men and women with no history of CHD to prevent CHD events." The USPSTF identified the following research need: "The predictive value ... of carotid IMT ... should be examined in conjunction with traditional Framingham risk factors for predicting CHD events and death."

In 2018, the USPSTF published a recommendation statement on using nontraditional risk factors to assess the risk of CVD; CIMT was not mentioned in this recommendation.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00251

Original Effective Date: 02/17/2010 Current Effective Date: 04/10/2023

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01849575	Direct Visualization of Asymptomatic Atherosclerotic Disease for Optimum Cardiovascular Prevention. A Population Based Pragmatic Randomized Controlled Trial Within Västerbotten Intervention Programme (VIP) and Ordinary Care (VIPVIZA)	3 532	Dec 2027

NCT: national clinical trial.

References

- 1. 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. PMID 35078371
- 2. Pasternak RC. Report of the Adult Treatment Panel III: the 2001 National Cholesterol Education Program guidelines on the detection, evaluation and treatment of elevated cholesterol in adults. Cardiol Clin. Aug 2003; 21(3): 393-8. PMID 14621453
- 3. Mookadam F, Moustafa SE, Lester SJ, et al. Subclinical atherosclerosis: evolving role of carotid intima-media thickness. Prev Cardiol. 2010; 13(4): 186-97. PMID 20860643
- 4. Den Ruijter HM, Peters SA, Anderson TJ, et al. Common carotid intima-media thickness measurements in cardiovascular risk prediction: a meta-analysis. JAMA. Aug 22 2012; 308(8): 796-803. PMID 22910757
- 5. Lorenz MW, Polak JF, Kavousi M, et al. Carotid intima-media thickness progression to predict cardiovascular events in the general population (the PROG-IMT collaborative project): a meta-analysis of individual participant data. Lancet. Jun 02 2012; 379(9831): 2053-62. PMID 22541275
- 6. van den Oord SC, Sijbrands EJ, ten Kate GL, et al. Carotid intima-media thickness for cardiovascular risk assessment: systematic review and meta-analysis. Atherosclerosis. May 2013; 228(1): 1-11. PMID 23395523

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00251

Original Effective Date: 02/17/2010 Current Effective Date: 04/10/2023

- 7. Bytyci I, Shenouda R, Wester P, et al. Carotid Atherosclerosis in Predicting Coronary Artery Disease: A Systematic Review and Meta-Analysis. Arterioscler Thromb Vasc Biol. Apr 2021; 41(4): e224-e237. PMID 33626907
- 8. Tschiderer L, Klingenschmid G, Seekircher L, et al. Carotid intima-media thickness predicts carotid plaque development: Meta-analysis of seven studies involving 9341 participants. Eur J Clin Invest. Apr 2020; 50(4): e13217. PMID 32112400
- 9. Plichart M, Celermajer DS, Zureik M, et al. Carotid intima-media thickness in plaque-free site, carotid plaques and coronary heart disease risk prediction in older adults. The Three-City Study. Atherosclerosis. Dec 2011; 219(2): 917-24. PMID 22005196
- 10. Keo HH, Baumgartner I, Hirsch AT, et al. Carotid plaque and intima-media thickness and the incidence of ischemic events in patients with atherosclerotic vascular disease. Vasc Med. Oct 2011; 16(5): 323-30. PMID 21908682
- 11. Nambi V, Chambless L, He M, et al. Common carotid artery intima-media thickness is as good as carotid intima-media thickness of all carotid artery segments in improving prediction of coronary heart disease risk in the Atherosclerosis Risk in Communities (ARIC) study. Eur Heart J. Jan 2012; 33(2): 183-90. PMID 21666250
- 12. Xie W, Liang L, Zhao L, et al. Combination of carotid intima-media thickness and plaque for better predicting risk of ischaemic cardiovascular events. Heart. Aug 2011; 97(16): 1326-31. PMID 21653216
- 13. Peters SA, den Ruijter HM, Bots ML, et al. Improvements in risk stratification for the occurrence of cardiovascular disease by imaging subclinical atherosclerosis: a systematic review. Heart. Feb 2012; 98(3): 177-84. PMID 22095617
- 14. Dobs AS, Nieto FJ, Szklo M, et al. Risk factors for popliteal and carotid wall thicknesses in the Atherosclerosis Risk in Communities (ARIC) Study. Am J Epidemiol. Nov 15 1999; 150(10): 1055-67. PMID 10568620
- 15. Chambless LE, Heiss G, Folsom AR, et al. Association of coronary heart disease incidence with carotid arterial wall thickness and major risk factors: the Atherosclerosis Risk in Communities (ARIC) Study, 1987-1993. Am J Epidemiol. Sep 15 1997; 146(6): 483-94. PMID 9290509
- van der Meer IM, Bots ML, Hofman A, et al. Predictive value of noninvasive measures of atherosclerosis for incident myocardial infarction: the Rotterdam Study. Circulation. Mar 09 2004; 109(9): 1089-94. PMID 14993130

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00251

Original Effective Date: 02/17/2010 Current Effective Date: 04/10/2023

- 17. O'Leary DH, Polak JF, Kronmal RA, et al. Carotid-artery intima and media thickness as a risk factor for myocardial infarction and stroke in older adults. Cardiovascular Health Study Collaborative Research Group. N Engl J Med. Jan 07 1999; 340(1): 14-22. PMID 9878640
- 18. Lorenz MW, Schaefer C, Steinmetz H, et al. Is carotid intima media thickness useful for individual prediction of cardiovascular risk? Ten-year results from the Carotid Atherosclerosis Progression Study (CAPS). Eur Heart J. Aug 2010; 31(16): 2041-8. PMID 20530503
- 19. Folsom AR, Kronmal RA, Detrano RC, et al. Coronary artery calcification compared with carotid intima-media thickness in the prediction of cardiovascular disease incidence: the Multi-Ethnic Study of Atherosclerosis (MESA). Arch Intern Med. Jun 23 2008; 168(12): 1333-9. PMID 18574091
- 20. Paramsothy P, Knopp RH, Bertoni AG, et al. Association of combinations of lipid parameters with carotid intima-media thickness and coronary artery calcium in the MESA (Multi-Ethnic Study of Atherosclerosis). J Am Coll Cardiol. Sep 21 2010; 56(13): 1034-41. PMID 20846602
- 21. Blaha MJ, Rivera JJ, Budoff MJ, et al. Association between obesity, high-sensitivity C-reactive protein 2 mg/L, and subclinical atherosclerosis: implications of JUPITER from the Multi-Ethnic Study of Atherosclerosis. Arterioscler Thromb Vasc Biol. Jun 2011; 31(6): 1430-8. PMID 21474823
- 22. Patel J, Al Rifai M, Blaha MJ, et al. Coronary Artery Calcium Improves Risk Assessment in Adults With a Family History of Premature Coronary Heart Disease: Results From Multiethnic Study of Atherosclerosis. Circ Cardiovasc Imaging. Jun 2015; 8(6): e003186. PMID 26047825
- 23. Camhi SM, Katzmarzyk PT, Broyles ST, et al. Subclinical atherosclerosis and metabolic risk: role of body mass index and waist circumference. Metab Syndr Relat Disord. Apr 2011; 9(2): 119-25. PMID 21133775
- 24. Green D, Foiles N, Chan C, et al. An association between clotting factor VII and carotid intimamedia thickness: the CARDIA study. Stroke. Jul 2010; 41(7): 1417-22. PMID 20466994
- 25. Baber U, Mehran R, Sartori S, et al. Prevalence, impact, and predictive value of detecting subclinical coronary and carotid atherosclerosis in asymptomatic adults: the BioImage study. J Am Coll Cardiol. Mar 24 2015; 65(11): 1065-74. PMID 25790876
- 26. Geisel MH, Bauer M, Hennig F, et al. Comparison of coronary artery calcification, carotid intima-media thickness and ankle-brachial index for predicting 10-year incident cardiovascular events in the general population. Eur Heart J. Jun 14 2017; 38(23): 1815-1822. PMID 28379333

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00251

Original Effective Date: 02/17/2010 Current Effective Date: 04/10/2023

- 27. Villines TC, Hsu LL, Blackshear C, et al. Relation of Carotid Intima-Media Thickness to Cardiovascular Events in Black Americans (From the Jackson Heart Study). Am J Cardiol. Nov 01 2017; 120(9): 1528-1532. PMID 28844515
- 28. Johnson HM, Turke TL, Grossklaus M, et al. Effects of an office-based carotid ultrasound screening intervention. J Am Soc Echocardiogr. Jul 2011; 24(7): 738-47. PMID 21477989
- 29. Olmastroni E, Baragetti A, Casula M, et al. Multilevel Models to Estimate Carotid Intima-Media Thickness Curves for Individual Cardiovascular Risk Evaluation. Stroke. Jul 2019; 50(7): 1758-1765. PMID 31164073
- 30. Goff DC, Lloyd-Jones DM, Bennett G, et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. Jun 24 2014; 129(25 Suppl 2): S49-73. PMID 24222018
- 31. Greenland P, Alpert JS, Beller GA, et al. 2010 ACCF/AHA guideline for assessment of cardiovascular risk in asymptomatic adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. Dec 14 2010; 56(25): e50-103. PMID 21144964
- 32. Jellinger PS, Handelsman Y, Rosenblit PD, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY GUIDELINES FOR MANAGEMENT OF DYSLIPIDEMIA AND PREVENTION OF CARDIOVASCULAR DISEASE EXECUTIVE SUMMARY Complete Appendix to Guidelines available at http://journals.aace.com. Endocr Pract. Apr 02 2017; 23(4): 479-497. PMID 28156151
- 33. Stein JH, Korcarz CE, Hurst RT, et al. Use of carotid ultrasound to identify subclinical vascular disease and evaluate cardiovascular disease risk: a consensus statement from the American Society of Echocardiography Carotid Intima-Media Thickness Task Force. Endorsed by the Society for Vascular Medicine. J Am Soc Echocardiogr. Feb 2008; 21(2): 93-111; quiz 189-90. PMID 18261694
- 34. Johri AM, Nambi V, Naqvi TZ, et al. Recommendations for the Assessment of Carotid Arterial Plaque by Ultrasound for the Characterization of Atherosclerosis and Evaluation of Cardiovascular Risk: From the American Society of Echocardiography. J Am Soc Echocardiogr. Aug 2020; 33(8): 917-933. PMID 32600741

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00251

Original Effective Date: 02/17/2010 Current Effective Date: 04/10/2023

- 35. Calonge N, Petitti DB, DeWitt TG, et al. Using nontraditional risk factors in coronary heart disease risk assessment: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. Oct 06 2009; 151(7): 474-82. PMID 19805770
- 36. Curry SJ, Krist AH, Owens DK, et al. Risk Assessment for Cardiovascular Disease With Nontraditional Risk Factors: US Preventive Services Task Force Recommendation Statement. JAMA. Jul 17 2018; 320(3): 272-280. PMID 29998297

Policy History

I Office of The	<u> </u>
Original Effecti	ive Date: 02/17/2010
Current Effective	ve Date: 04/10/2023
02/04/2010	Medical Policy Committee approval
02/17/2010	Medical Policy Implementation Committee approval. New policy.
02/03/2011	Medical Policy Committee review
02/16/2011	Medical Policy Implementation Committee approval. Coverage eligibility
	unchanged.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. Coverage eligibility
	unchanged.
02/07/2013	Medical Policy Committee review
02/20/2013	Medical Policy Implementation Committee approval. Coverage eligibility
	unchanged.
02/06/2014	Medical Policy Committee review
02/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility
	unchanged.
01/01/2015	Coding Update
02/05/2015	Medical Policy Committee approval
02/18/2015	Medical Policy Implementation Committee approval. Coverage eligibility
	unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section
	removed.
02/04/2016	Medical Policy Committee approval

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00251

Original Effective Date: 02/17/2010 Current Effective Date: 04/10/2023

02/17/2016		-	Implementation	Committee	approval.	Coverage	eligibility
01/01/2017	unchanged. Coding update: Removing ICD-9 diagnosis codes						
03/02/2017	_	•	ommittee approva	•	.5		
03/15/2017		•	Implementation		approval	Coverage	eligibility
03/13/2017	unchange	_	Implementation	Committee	арргочат.	Coverage	Cligionity
03/01/2018	_		ommittee review				
03/21/2018		•	Implementation	Committee	approval.	Coverage	eligibility
	unchange	-	1		TI		
05/16/2018	Coding u	pdate					
03/07/2019	Medical 1	Policy C	ommittee review				
03/20/2019	Medical	Policy	Implementation	Committee	approval.	Coverage	eligibility
	unchange	-	-			_	
03/05/2020	Medical 1	Policy C	ommittee review				
03/11/2020	Medical	Policy	Implementation	Committee	approval.	Coverage	eligibility
	unchange	-	-			_	
12/11/2020	Coding u	pdate					
03/04/2021	Medical 1	Policy C	ommittee review				
03/10/2021	Medical	Policy	Implementation	Committee	approval.	Coverage	eligibility
	unchange	-	-			_	
03/03/2022	Medical 1	Policy C	ommittee review				
03/09/2022	Medical	Policy	Implementation	Committee	approval.	Coverage	eligibility
	unchange		-			_	
03/02/2023	Medical 1	Policy C	ommittee review				
03/08/2023		•	Implementation	Committee	approval.	Coverage	eligibility
	unchange	-	-			J	
	_						

Coding

Next Scheduled Review Date: 03/2024

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00251

Original Effective Date: 02/17/2010 Current Effective Date: 04/10/2023

descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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

Code Type	Code
CPT	93895
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*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

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00251

Original Effective Date: 02/17/2010 Current Effective Date: 04/10/2023

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 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.