

Non-Invasive Assessment of the Vasculature for Cardiovascular Risk, Medical 334

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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.<u>*</u>.

Purpose:

This policy addresses the medical necessity of Non-Invasive Assessment of the Vasculature for Cardiovascular Risk testing.

Description & Definitions:

Non-invasive assessment of the Vasculature for Cardiovascular Risk are diagnostic tests (non-lab related)

Carotid Intima-Media Thickness (CIMT) is a noninvasive diagnostic ultrasound that measures the thickness in the inner layers of the carotid artery.

Peripheral arterial tonometry (e.g., the Endo-PAT2000 device) and Endothelial monitoring Device (EndoPAT) are noninvasive devices connected to a computer and software attached by a thimble-shaped, finger probe to aid in the detection and prediction of the Coronary Artery Endothelial Dysfunction.

CardioVision MS-2000, CVProfilor, and HDI PulseWave is noninvasive diagnostic screening device by applying a blood pressure cuff on the upper arm and a sensor on the skin over radial artery. The device measures blood pressure, pulse, and arterial and brachial artery elasticity called the Arterial Stiffness Index (ASI) by producing electrocardiograph (ECG) waveforms.

QuantaFlo System is a noninvasive device connected to a computer and software with transducers placed on bilateral lower and upper extremities to aid in the detection and measurement of blood volume distribution in peripheral arteries.

Criteria:

Non-Invasive Assessment of the Vasculature for Cardiovascular Risk testing is considered **not medically necessary** for any indication, to include but not limited to:

- Carotid intima-media thickness (CIMT) assessment
- Cardiac acoustic waveform recording with automated analysis
- Non-invasive endothelial monitoring Device (EndoPAT)
- Non-invasive measurements of arterial elasticity by means of blood pressure waveforms (e.g., CardioVision MS-2000, CVProfilor, and HDI PulseWave)
- Peripheral arterial tonometry (e.g., the Endo-PAT2000 device)

Coding:

Medically necessary with criteria:

Coding	Description
93050	Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, non-invasive

Considered Not Medically Necessary:			
Coding	Description		
0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score		
93799	Unlisted cardiovascular service or procedure		
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral		
93998	Unlisted noninvasive vascular diagnostic study		

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

• 2022: July

Reviewed Dates:

- 2024: April
- 2023: April

Effective Date:

• April 2022

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

Code of Federal Regulations. National Archives and Records Administration. Title 21 Chapter I Subchapter H Part 870 Subpart C § 870.2210. 3.21.2024. Retrieved 3.25.2024. <u>https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-870/subpart-C/section-870.2210</u>

U.S. Food and Drug Administration. Electrocardiograph. Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A). 3-105 IEC 60601-2-25 Edition 2.0 2011-10. 3.25.2024. Retrieved 3.26.2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=763

Hayes. A symplr Company. Evidence Analysis. 2024. Retrieved 3.26.24. <u>https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522Non-</u> invasive%2520assessment%2520of%2520the%2520vasculature%2520for%2520Cardiovascular%2520Risk%25

22,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522pa ge%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522sources%2522:%255B%252 2*%2522%255D,%2522sorts%2522:%255B%257B%2522field%2522:%2522 score%2522,%2522direction%252 2:%2522desc%2522%257D%255D,%2522filters%2522:%255B%255D%257D

Centers for Medicare and Medicaid Services, CMS.gov, Cardiac Event Detection, L34573, 03/07/2024, Retrieved 3.26.24. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34573&ver=28&

Centers for Medicare and Medicaid Services. CMS.gov Obsolete or Unreliable Diagnostic Tests. 300.1. 6.19.2006. Retrieved 3.26.24. https://www.cms.gov/medicare-coveragedatabase/view/ncd.aspx?NCDId=204&NCDver=2

Centers for Medicare and Medicaid Services. CMS.gov. Displacement Cardiography. NCD 20.24. 10.12.1988. Retrieved 3.26.24. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=262&ncdver=1&bc=0

Commonwealth of Virginia. Department of Medical Assistance Services. Provider Manuals Library. 2024 DMAS. Retrieved 3.26.24. https://vamedicaid.dmas.virginia.gov/manuals/provider-manualslibrary#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.sort=

Commonwealth of Virginia. Department of Medical Assistance Services. Procedure Fee Files & CPT Codes. 2024. Retrieved 3.26.2024. https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-filescpt-codes/#searchCPT

National Comprehensive Cancer Network. Search result. 2024. Retrieved 3.26.24 https://www.nccn.org/searchresult?indexCatalogue=nccn-search-index&searchQuery=non-invasive%20vasculature%20cardiovascular

NIA. Now Evolent. Cardiac Solutions. 2024. Retrieved 3.26.24. https://www1.radmd.com/solutions/cardiacsolution

MCG Informed Care Solutions. 27th Edition. Retrieved 3.26.24. https://careweb.careguidelines.com/ed27/index.html

American College of Cardiology, Clinical Topics. Noninvasive Imaging. 2024. Retrieved 3.26.24. https://www.acc.org/search#g=noninvasive%20assessment%20of%20vasculature%20for%20cardiovascular%20risk&sort=relevancy&f:@clinicaltopi ccomputed=[Noninvasive%20Imaging]

American Heart Association. Circulation. Carotid Intima-Media Thickness Progression as Surrogate Marker for Cardiovascular Risk. Meta-Analysis of 119 Clinical Trials Involving 100 667 Patients. Circulation. 2020;142:621-642. Originally published17 June 2020 https://doi.org/10.1161/CIRCULATIONAHA.120.046361

Carelon Insights. Guideline search. Retrieved 3.26.24. https://www.careloninsights.com/searchresults?q=noninvasive%20cardiovascular%20risks

Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Medical 334

Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Keywords:

SHP Non-Invasive Assessment of the Vasculature for Cardiovascular Risk, SHP Medical 334, Carotid intimamedia thickness assessment, Non-invasive endothelial monitoring Device, EndoPAT, Non-invasive measurements of arterial elasticity by means of blood pressure waveforms, CardioVision MS-2000, CVProfilor, HDI PulseWave, Peripheral arterial tonometry, Endo-PAT2000 device, CADScor®System, Acarix A/S