

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

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Effective Date 4/2022

Next Review Date 4/9/2024

Coverage Policy Medical 334

Version 3

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details *.

Purpose:

This policy addresses the medical necessity of various non-invasive ways to measure vasculature for cardiovascular risk.

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 non-invasive 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 is considered **not medically necessary** for any indication, to include but not limited to:

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- 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
	None

Considered Not Medically Necessary:

Coding	Description
0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score
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
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

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2024: April2023: April

Effective Date:

April 2022

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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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. https://www.ecfr.gov/current/title-21/chapter-l/subchapter-H/part-870/subpart-C/section-870.2210

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. <a href="https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522Non-invasive%2520assessment%2520of%2520the%2520vasculature%2520for%2520Cardiovascular%2520Risk%25 22,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522sources%2522:%255B%252 2*%2522*255D,%2522sorts%2522:%255B%257B%2522field%2522:%25522_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-coverage-database/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. <a href="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.sort="https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.g=Non-invasive%20Cardiovascular&gsc.gov/manuals/provider-manuals/provider-manuals/pro

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-files-cpt-codes/#searchCPT

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

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

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#q=non-

<u>invasive%20assessment%20of%20vasculature%20for%20cardiovascular%20risk&sort=relevancy&f:@clinicaltopiccomputed=[Noninvasive%20Imaging]</u>

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

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

Special Notes: *

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. 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.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

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

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