Medicare Medical Policy

Cardiac Disease Risk Screening

MEDICARE MEDICAL POLICY NUMBER: 132

Effective Date: 7/1/2025

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Next Annual Review: 6/2026

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
ApoE Genotype (CPT 81401)	**PRIOR TO 10/3/2024: For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** Local Coverage Article (LCA): Billing and Coding: MolDX: ApoE Genotype (A55095) *(For ApoE testing pertaining to cardiovascular risk assessment rendered **on or after** 10/3/2024, see row for "Biomarker Testing in Cardiovascular Risk Assessment Not Otherwise Specified".)*
Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) Testing (CPT 81439)	LCA: Billing and Coding: MolDX: Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) Testing • **For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** A54976 • **For testing performed in the states of CA or NV:** A54975 • **For testing performed in the states of NC, SC, GA, TN, AL, VA, & WV:** A53605
Corus® CAD test (CPT 81493; CardioDX, Redwood City, CA)	**PRIOR TO 2/15/2022: For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** LCD: MolDX: Corus® CAD Assay (L37673) **Note:** This LCD was retired as of February 15, 2022. This test no longer appears to be commercially available. However, between 2/10/2019 and 2/15/2022, this test was **not medically necessary**. *(Prior to 2/10/2019, the MolDX Program had determined this test was eligible for coverage [A51923 and A54428]).*
Biomarker Testing in Cardiovascular Risk Assessment Not Otherwise Specified (Includes genomic profiling, such as ApoE gene testing on/after 10/3/2024)	**For testing performed in the states of CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, or PA:** LCD: Genetic Testing for Cardiovascular Disease (L39082) **NOTE:** While this LCD does have coverage criteria, it is important to note the criteria are not for "screening" purposes, which is the

	focus of this medical policy. According to this LCD, "Medicare does not cover genetic screening for cardiovascular disease." Therefore, genetic testing of asymptomatic patients and genetic testing with family history as the only indication would be not medically necessary. In addition, based on the LCD criteria, all codes in the companion billing and coding LCA (A58795) are all not medically necessary when used to report for cardiovascular genetic testing. **For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** Local Coverage Determination (LCD): MolDX: Biomarkers in Cardiovascular Risk Assessment (~~L36362~~) ***(As of 1/22/2026, see LCD L36358 below)*** **For testing performed in the states of CA or NV:** LCD: MolDX: Biomarkers in Cardiovascular Risk Assessment (L36358) **For testing performed in the states of NC, SC, GA, TN, AL, VA, & WV:** LCD for MolDX: Biomarkers in Cardiovascular Risk Assessment (L36129) All of the above LCDs include the statement, "The policy denies coverage for all non-lipid biomarkers when used for CV risk assessment including but not limited to, biochemical, immunologic, and hematologic, and genetic biomarkers for CV risk assessment regardless of whether ordered in a panel or individually." The LCDs state "genomic profiling" is not covered for cardiovascular risk assessment. This applies to both single gene and panel tests. The following cardiovascular tests are considered **not medically necessary**, based on the above LCDs and Medicare guidelines *(See "Policy Guidelines" below)*: • VAP® Cholesterol Test, VAP Diagnostics Laboratory, Inc. (0052U) • MI–HEART Ceramides, Plasma test, Mayo Clinic (0119U) • HART CADhs®, Complete Omics, Inc. (Partnered with Prevencio) (0308U; Baltimore, MD) • HART CVE®, Complete Omics, Inc. (Partnered with Prevencio) (0309U; Baltimore, MD) • HART KD®, Complete Omics, Inc. (Partnered with Prevencio) (0310U; Baltimore, MD) • GlycA, LabCorp (0024U; Burlington, NC) (See Policy Guidelines below for more information regarding this test) • SmartHealth Vascular Dx™, Morningstar Laboratories, LLC and SmartHealth DX (0415U; Irvine, CA)

	• CARDIO inCode-Score (CICSCORE), by GEN InCode US (0401U; Irvine, CA) • HDL Reverse Cholesterol Transport Panel with pCAD Score, by Quest Diagnostics® and Cleveland HeartLab (0541U; Cleveland, OH)
Cystatin C Measurement (CPT 82610)	**For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** MolDX: Cystatin C Measurement (~~L37618~~) ***(As of 9/11/2025, use LCD L37616)***
CardioRisk+ (0466U; Gene by Gene [Texas] and Open DNA [Israel])	Billing and Coding: Genetic Testing for Cardiovascular Disease (A58795). *(According to this LCA, this service is explicitly called out as being considered **not medically necessary** based on the criteria found in the Novitas LCD L39082. This is due to no genes currently meet criteria for coverage as outlined in the LCD.)*

Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*)

- **Medicare Coverage Manuals:** Medicare Part B covers the basic **lipid** panel for cardiovascular (CV) disease screening every 5 years under Medicare preventive services, but Medicare does **not** have criteria for cardiovascular risk assessment **genetic** testing in a coverage manual. **However, broad coverage requirements exist for diagnostic laboratory testing in general.** Specifically, Medicare requires diagnostic laboratory tests be ordered by a provider who is treating the member for a specific medical problem and who will promptly use the test results in the direct management of that specific medical problem.[1,2] These coverage criteria are considered "not fully established" under CFR § 422.101(6)(i)(A) as additional criteria are needed to interpret or supplement these general coverage provisions in order to determine medical necessity consistently.
- **National Coverage Determination (NCD):** Medicare does not have an NCD for biomarker testing in cardiovascular risk assessment. The NCD 190.23 provides coverage of lipid panel testing for ***symptomatic*** patients and states routine screening and prophylactic testing for lipid disorders are not covered by Medicare, but it doesn't address genetic testing.
- **Local Coverage Determination (LCD)/Local Coverage Article (LCA):** According to Medicare guidelines, "Jurisdiction of payment requests for laboratory services furnished by an independent laboratory… lies with the A/B MAC (B) serving the area in which the laboratory test is performed."[3] The cardiovascular risk assessment or screening tests below do **not** have an available LCD or LCA for their respective service areas.
- Criteria for both asymptomatic and symptomatic members are provided in the next row, but generally speaking:
    - For ***asymptomatic*** individuals, standard Medicare regulatory coverage rules apply.
    - For ***symptomatic*** individuals, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. Medicare statutes and regulation provide general coverage criteria for diagnostic testing, but additional criteria to interpret or supplement the Medicare criteria are being used in order to determine medical necessity consistently. These additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from

delayed or decreased access to items or services **because the use of this additional criteria based on peer-reviewed evidence evaluates how testing is expected to improve diagnosis, improve patient management, change treatment decisions or improve health outcomes**. Specifically, the literature review is used to evaluate whether or not each test has established clinical utility and/or analytic validity. Review was performed to determine if this testing provides clinically important information beyond that of traditional lipid measures. In addition, genetic molecular analysis by way of larger CVD risk panels are not designed to be specific to an individual's risk, and will lack clinical utility when applied to the general population, which does not support improved individual health outcomes.

- ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*

Tests without an applicable LCD/LCA cited above: ***Examples:*** *Liposcale® Test (0377U; CIMA Sciences, LLC; Texas)* *SOMAmer® (0019M; SomaLogic; Colorado)* *Epi+Gen CHD™ and PrecisionCHD™ (0439U & 0440U; Cardio Diagnostics, Inc.; Illinois)*	***Asymptomatic*** **individuals:** General Medicare regulation and guidance applies to all services, including the Medicare requirement that every service meets "medically reasonable and necessary" requirements. For Medicare plan members, " ...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." This is based on Medicare regulation found in *Title XVIII of the Social Security Act, Section 1862(a)(1)(A)*, as well as detailed in the *Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §20 - Services Not Reasonable and Necessary*. Since the purpose of these tests is to predict the risk of developing a disease or condition, and they are not for diagnostic or therapeutic purposes, then they are considered **not medically necessary**. ***Symptomatic*** **individuals:** Clinical utility and analytical validity still need to be met in order to be considered medically reasonable and necessary under Medicare. Apply Company medical policy for Cardiac Disease Risk Screening I. These services are considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.* General Medicare regulation and guidance applies to **all** services, including the Medicare requirement that every service must meet "medically reasonable and necessary" requirements. For Medicare plan members, " ...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." (*Title XVIII of the Social Security Act, Section 1862(a)(1)(A)*, as well as detailed in the *Medicare Benefit Policy Manual, Chapter 16 - General*

	Exclusions From Coverage, §20 - Services Not Reasonable and Necessary) Since the purpose of these tests is to predict the risk of developing a disease or condition, and they are not for diagnostic or therapeutic purposes, and therefore, they are considered **not medically necessary**.

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Ther term "cardiovascular disease" can refer to a number of conditions, including but not limited to, heart disease caused by atherosclerosis, heart attack, stroke, heart failure, arrhythmia, and heart valve issues.[4] Atherosclerosis is the accumulation of plaque in the walls of arteries and may be present for many years without noticeable symptoms. As plaque builds up, the wall of the blood vessel thickens, which subsequently narrows the channel within the artery, effectively reducing blood flow. This reduced blood flow lessens the amount of oxygen and other nutrients reaching the body.[5] When this occurs in the coronary arteries, it is referred to as coronary artery disease (CAD). CAD is the most common cause of death in the United States.[6]

Testing for cardiovascular disease includes traditional biomarkers, non-traditional biomarkers, and proprietary laboratory testing. CVD risk testing is utilized to indicate the chances of having a coronary event.

The most common tests to determine cardiac risk are high-density lipoprotein (HDL) (CPT 83718), low-density lipoprotein (LDL) (CPT 83721), total cholesterol (CPT 82465) and triglycerides (CPT 84478) (often referred to as a basic or standard lipid panel; CPT 80061). The standard lipid panel test may be allowed by Medicare under some circumstances, as detailed by the Medicare NCD 190.23 (Lipid Testing). However, these traditional cardiovascular disease risk tests are **not** included within the scope of this medical policy. Instead, this policy is focused on non-traditional testing for cardiac risk assessment.

MEDICARE AND MEDICAL NECESSITY

Under Medicare, the general rule regarding jurisdiction of laboratory claims furnished by an independent laboratory is that jurisdiction lies with the A/B MAC (B) (aka, the Medicare Contractor) serving the area in which the laboratory test is performed.[3] Therefore, coverage references in this policy are assessed based on what it is anticipated the testing will be performed.

However, there may be exceptions to this rule. According to Medicare, while jurisdiction for laboratory services normally lies with the carrier serving the performing laboratory service area, there are situations where a regional or national lab chain jurisdiction (e.g., Quest Diagnostics, LabCorp, etc.) lies with a single carrier.[7] Therefore, tests performed by a national laboratory chain may have a single carrier established within the Plan medical policies for all laboratory services they perform, regardless of the individual laboratory location. This allows for consistent outcomes for all members who receive the same test by the same lab chain.

Services Areas Which Apply Guidelines by the Medicare Molecular Diagnostics (MolDX) Program

Laboratories performing tests in service areas which have adopted guidelines or coverage determinations made by the Medicare Molecular Diagnostics (MolDX) Program contractor are required to submit a technology assessment (TA) to establish analytical and clinical validity (AV/CV) and clinical utility (CU). Supporting LCDs regarding TA reviews include, but are not limited to, the following:

- Laboratories in CA & NV: LCD for MolDX: Molecular Diagnostic Tests (MDT) (L35160)
- Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, & WY: LCD for MolDX: Molecular Diagnostic Tests (MDT) (L36256)
- Laboratories in NC, SC, GA, TN, AL, VA, & WV: LCD for MolDX: Molecular Diagnostic Tests (MDT) (L35025)

Coverage or non-coverage determinations made by MolDX are maintained in the DEX™ Diagnostics Exchange registry catalog and are available for public viewing. If a test does not have a coverage determination by the MolDX Program, then AV/CV and CU have **not** been established and the test is considered not medically reasonable and necessary under *SSA §1862(a)(1)(A)* until a MolDX review is complete and coverage is indicated by MolDX or Noridian. Therefore, tests identified in this policy as not meeting this requirement are not medically reasonable or necessary for Medicare under *SSA §1862(a)(1)(A)*

Services Without an NCD or LCD

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, general Medicare regulatory guidelines still apply. This means tests with the purpose of disease risk screening are not considered medically reasonable or necessary.

Tests may be considered not medically necessary for Medicare plan members due to the intended purpose of the test. Examples include, but may not be limited to, PLA code 0024U for the GlycA test, which is used to aid in the identification and stratification of individuals at risk for future cardiovascular (CV) disease, evaluate prognosis for recurrent cardiovascular events in patients with stable coronary disease or acute coronary syndrome and aid in the assessment of disease activity and risk of CV disease in adult Rheumatoid Arthritis (RA) and psoriasis patients, when used in conjunction with standard clinical assessment and for monitoring of anti-inflammatory treatment. According to LCD L36129, "Per NCD 190.23, 'Routine screening and prophylactic testing for lipid disorders are not covered by Medicare. While lipid screening may be medically appropriate, Medicare by statue does not pay for it….' The LCD policy denies coverage for all non-lipid biomarkers when used for CV risk assessment including but not limited to, biochemical, immunologic, and hematologic, and genetic biomarkers for CV risk assessment regardless of whether ordered in a panel or individually." Therefore, when used for cardiovascular disease screening or risk assessment purposes, tests are denied as "not medically necessary."

For testing performed on symptomatic members, then clinical utility and analytical validity must still be established.

The Liposcale® test (CPT 0377U) is a proprietary advanced lipoprotein analysis based on nuclear magnetic resonance (NMR) spectroscopy that directly measures lipid content, number and size of lipoprotein particles. The Liposcale report is divided into two sections:

- Information on traditional lipid panel, concentrations of large, intermediate, and small VLDL, LDL, and HDL particles, average particle sizes of VLDL, LDL and HDL, as well as the lipidic contour.
- Information on extended lipoprotein panel -including cholesterol and triglyceride content in VLDL, IDL, LDL and HDL particles-, and patient clinical outcome.

This test includes elements which go beyond other lipoprotein particle testing using NMR spectroscopy (reported using CPT 83704). Evidence does not support that this test providers better outcomes than standard lipoprotein NMR spectroscopy testing. In addition, clinical and analytical validity, as well as clinical utility, are required to establish Medicare coverage as a medical necessity diagnostic test. Tests which evaluate proteins or other biomarkers with **no** known association to a certain indication, such as heart failure, will not have proven clinical or analytical validity or clinical utility and therefore, will not be considered medically necessary for Medicare plan members. Examples of these tests include MAAA code 0019M. In the absence of an available NCD or LCD/LCA for a relevant service area, such tests will follow Company policy criteria with regards to peer review evidence reviews.

Some tests are considered not medically necessary for Medicare plan members by nature of the test itself. For example, PLA codes 0310U and 0389U are by definition tests for "pediatric" tests. Since by definition this is a pediatric test, it isn't expected to be used for an individual of the Medicare population, and wouldn't be expected to have clinical utility or analytical validity in this population.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

The **Noridian LCD ~~L36362~~ (as of 1/22/2026, L36358)** states, "FDA approval/clearance means that a test/assay has analytical and clinical validity. The FDA does not review clinical utility (that the test/assay demonstrates improved patient outcomes). To meet Medicare's "reasonable and necessary" criteria for coverage, a test/assay must have proven clinical utility." Therefore, FDA approval or clearance of a test does not in itself establish medical necessity criteria under the Medicare Program have been met.

BILLING GUIDELINES AND CODING

GENERAL

See associated local coverage articles (LCAs) for coding and billing guidance:

- Noridian Local Coverage Article (LCA): Billing and Coding: MolDX: Biomarkers in Cardiovascular Risk Assessment (A57055) ***(As of 1/22/2026, use LCA A57037)***
- Noridian LCA: Billing and Coding: MolDX: Cystatin C Measurement (~~A57644~~) ***(As of 9/11/2025, use LCA A57643)***
- Novitas LCA: Billing and Coding: Genetic Testing for Cardiovascular Disease (A58795)

ROUTINE SCREENING AND MEDICARE

The Noridian LCD for *MolDX: Biomarkers in Cardiovascular Risk Assessment* (~~L36362~~) (as of 1/22/2026, see L36358) reads as follows:

> "NCD 190.23 covers lipid panel testing for symptomatic patients for evaluating atherosclerotic CV disease, to monitor the progress of patients on anti-lipid dietary management and pharmacologic therapy for various lipid disorders. Per NCD 190.23, "Routine screening and prophylactic testing for lipid disorders are not covered by Medicare. While lipid screening may be medically appropriate, Medicare by statue does not pay for it. Lipid testing in asymptomatic individuals is considered to be screening regardless of the presence of other risk factors such as family history, tobacco use, etc."
>
> "This policy denies coverage for all CV risk assessment panels, except the basic lipid panel, for symptomatic (with signs and symptoms) patients with suspected or documented CV disease because panel testing is not specific to a given patient's lipid abnormality or disease. The policy indicates the medical indication(s) based on published scientific articles and consensus guidelines for individual lipid biomarkers that may be covered to characterize a given lipid abnormality or disease, to determine a treatment plan or to assist with intensification of therapy. Each individual lipid biomarkers must be specifically ordered and the reason for the test order documented in the patient's medical record. The policy denies coverage for all non-lipid biomarkers when used for CV risk assessment including but not limited to, biochemical, immunologic, and hematologic, and genetic biomarkers for CV risk assessment regardless of whether ordered in a panel or individually."

In addition, the LCD L39082 for other geographical service areas also states, "Medicare does not cover genetic screening for cardiovascular disease."

While many CPT codes in the table below are not subject to routine medical necessity review, they may be subject to post-service review audit and may be denied when LCD or NCD criteria are not met.

Proprietary Codes

A number of assays addressed in this policy are to be billed with specific codes.

Assay	Code
Corus® CAD	81493
VAP® Cholesterol Test	0052U
MI–HEART Ceramides	0119U
HART CADhs®	0308U
HART CVE®	0309U
HART KD®	0310U
GlycA	0024U
SmartHealth Vascular Dx™	0415U
Liposcale®	0377U
SOMAmer®	0019M
CARDIO inCodeScore (CICSCORE)	0401U
Epi+Gen CHD™	0439U

PrecisionCHD™	0440U
CardioRisk+	0466U

CODES*		
CPT	0019M	Cardiovascular disease, plasma, analysis of protein biomarkers by aptamer-based microarray and algorithm reported as 4-year likelihood of coronary event in high-risk populations *(Used to report SOMAer® by SomaLogic)*
	0024U	Glycosylated acute phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative *(Used to report GlycA by LabCorp)*
	0052U	Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation *(Used to report VAP® Cholesterol Test by VAP Diagnostics Laboratory, Inc.)*
	0119U	Cardiology, ceramides by liquid chromatography–tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events *(Used to report MI–HEART Ceramides, Plasma test by Mayo Clinic)*
	0308U	Cardiology (coronary artery disease [CAD]), analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]) with 3 clinical parameters (age, sex, history of cardiac intervention), plasma, algorithm reported as a risk score for obstructive CAD *(Used to report HART CADhs® by Complete Omics, Inc. and Prevencio [Kennewick, WA])*
	0309U	Cardiology (cardiovascular disease), analysis of 4 proteins (NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 [TIMP-1], and kidney injury molecule-1 [KIM-1]), plasma, algorithm reported as a risk score for major adverse cardiac event *(Used to report HART CVE® by Complete Omics, Inc. and Prevencio [Kennewick, WA])*
	0310U	Pediatrics (vasculitis, Kawasaki disease [KD]), analysis of 3 biomarkers (NTproBNP, C-reactive protein, and T-uptake), plasma, algorithm reported as a risk score for KD *(Used to report HART KD® by Complete Omics, Inc. and Prevencio [Kennewick, WA])*
	0377U	Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables) *(Used to report Liposcale® by CIMA Sciences, LLC.)*
	0389U	Pediatric febrile illness (Kawasaki disease [KD]), interferon alphainducible protein 27 (IFI27) and mast cell-expressed membrane protein 1 (MCEMP1), RNA, using reverse transcription polymerase chain reaction (RT-qPCR), blood, reported as a risk score for KD *(Used to report KawasakiDx by OncoOmicsDx Laboratory)*
	0401U	Cardiology (coronary heart disease [CAD]), 9 genes (12 variants), targeted variant genotyping, blood, saliva, or buccal swab, algorithm reported as a genetic risk score for a coronary event *(Used to report CARDIO inCodeScore [CICSCORE] by GENinCode U.S. Inc.)*
	0415U	Cardiovascular disease (acute coronary syndrome [ACS]), IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN, and MCP-3 by immunoassay combined with age, sex, family history, and personal history of diabetes, blood, algorithm reported as a 5-year (deleted risk) score for ACS *(Used to report SmartHealth Vascular Dx™ by Morningstar Laboratories, LLC and SmartHealth DX)*

	0439U	Cardiology (coronary heart disease [CHD]), DNA, analysis of 5 single-nucleotide polymorphisms (SNPs) (rs11716050 [LOC105376934], rs6560711 [WDR37], rs3735222 [SCIN/LOC107986769], rs6820447 [intergenic], and rs9638144 [ESYT2]) and 3 DNA methylation markers (cg00300879 [transcription start site {TSS200} of CNKSR1], cg09552548 [intergenic], and cg14789911 [body of SPATC1L]), qPCR and digital PCR, whole blood, algorithm reported as a 4-tiered risk score for a 3-year risk of symptomatic CHD *(Used to report Epi+Gen CHD™ by Cardio Diagnostics, Inc.)*
	0440U	Cardiology (coronary heart disease [CHD]), DNA, analysis of 10 single-nucleotide polymorphisms (SNPs) (rs710987 [LINC010019], rs1333048 [CDKN2B-AS1], rs12129789 [KCND3], rs942317 [KTN1-AS1], rs1441433 [PPP3CA], rs2869675 [PREX1], rs4639796 [ZBTB41], rs4376434 [LINC00972], rs12714414 [TMEM18], and rs7585056 [TMEM18]) and 6 DNA methylation markers (cg03725309 [SARS1], cg12586707 [CXCL1, cg04988978 [MPO], cg17901584 [DHCR24-DT], cg21161138 [AHRR], and cg12655112 [EHD4]), qPCR and digital PCR, whole blood, algorithm reported as detected or not detected for CHD *(Used to report PrecisionCHD™ by Cardio Diagnostics, Inc.)*
	0466U	Cardiology (coronary artery disease [CAD]), DNA, genome-wide association studies (564856 single-nucleotide polymorphisms [SNPs], targeted variant genotyping), patient lifestyle and clinical data, buccal swab, algorithm reported as polygenic risk to acquired heart disease *(Used to report CardioRisk+ by Gene by Gene Ltd and Open DNA Ltd)*
	0541U	Cardiovascular disease (HDL reverse cholesterol transport), cholesterol efflux capacity, LC-MS/MS, quantitative measurement of 5 distinct HDL-bound apolipoproteins (apolipoproteins A1, C1, C2, C3, and C4), serum, algorithm reported as prediction of coronary artery disease (pCAD) score *(Used to report HDL Reverse Cholesterol Transport Panel with pCAD Score by Quest Diagnostics® and Cleveland HeartLab)*
	81401	Molecular Pathology Procedure Level 2
	81439	Inherited cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing of at least 5 genes, including DSG2, MYBPC3, MYH7, PKP2, and TTN
	81479	Unlisted molecular pathology procedure
	81493	Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score
	82172	Apolipoprotein, each
	82610	Cystatin C
	83090	Homocysteine
	83529	Interleukin-6 (IL-6)
	83695	Lipoprotein (a)
	83698	Lipoprotein-associated phospholipase A2 (Lp-PLA2)
	83719	Lipoprotein, direct measurement; VLDL cholesterol
	83722	Lipoprotein, direct measurement; small dense LDL cholesterol
	86141	C-reactive protein; high sensitivity (hsCRP)
HCPCS	None	

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 – Fee Schedule Administration and Coding Requirements, §30 – Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §80.1 – Clinical Laboratory Services. Last updated 11/19/2007. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf. Accessed 5/5/2025.
2. 2. 42 CFR § 410.32(a). Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests. https://www.govinfo.gov/content/pkg/CFR-2011-title42-Vol2/pdf/CFR-2011-title42-vol2-sec410-32.pdf. Accessed 5/5/2025.
3. Centers for Medicare and Medicaid Services (CMS). Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, §50.5 - Jurisdiction of Laboratory Claims. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104C16.pdf. Accessed 5/5/2025
4. American Heart Association (AHA). What is Cardiovascular Disease? https://www.heart.org/en/health-topics/consumer-healthcare/what-is-cardiovascular-disease. Accessed 5/5/2025.
5. AHA. What is Atherosclerosis? https://www.heart.org/en/health-topics/cholesterol/about-cholesterol/atherosclerosis. Accessed 5/5/2025.
6. Centers for Disease Control (CDC). About Coronary Artery Disease (CAD). https://www.cdc.gov/heart-disease/about/coronary-artery-disease.html?CDC_AAref_Val=https://www.cdc.gov/heartdisease/coronary_ad.htm. Accessed 5/5/2025.
7. CMS. Medicare Claims Processing Manual, Chapter 1 - General Billing Requirements, §10.1.5.4 - Independent Laboratories. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf. Accessed 5/5/2025.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
8/2022	Annual review (converted to new format 2/2023)
4/2023	Q2 2023 code updates

7/2023	Interim and Q3 2023 code updates; Language revision due to Company policy change from “investigational” to “not medically necessary”
9/2023	Annual review; added GlycA to the policy, with applicable coverage information
10/2023	Q4 2023 code updates
4/2024	Q2 2024 code updates
7/2024	Annual review and Q3 2024 code updates; removed retired MolDX LCAs
12/2024	Interim update; update Medicare references for ApoE testing
4/2025	Q2 2025 code updates
7/2025	Annual review; update criteria for CardioRisk+ from Company policy criteria to an LCA (9/11/2025: Replaced L37618 with L37616 due to Noridian JF consolidation with JE LCD policies) (1/26/2026: Replaced MolDX LCD L36362 with L36358 and updated companion LCA due to Noridian JF consolidation with JE LCD policies)