Medicare Medical Policy

Cardiac: Disease Risk Screening

MEDICARE MEDICAL POLICY NUMBER: 132

Effective Date: 10/1/2023

Last Review Date: 8/2023

Next Annual Review: 6/2024

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)	**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)
4q25-AF Risk Genotype (CPT 81479)	**For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** LCA: Billing and Coding: MolDX: 4q25-AF Risk Genotype (A55091)
9p21 Genotype (CPT 81479)	**For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** LCA: Billing and Coding: MolDX: 9p21 Genotype Test (A55093)
Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) Testing (CPT 81439)	**For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** LCA: Billing and Coding: MolDX: Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) Testing (A54976)
Corus® CAD test (CPT 81493; CardioDX, Redwood City, CA)	**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]).*
LPA-Intron 25 Genotype testing (CPT 81479)	**For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** LCA: Billing and Coding: MolDX: LPA-Intron 25 Genotype (A55282)
LPA-Aspirin Genotype testing (CPT 81479)	**For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** LCA: Billing and Coding: MolDX: LPA-Aspirin Genotype (A55280)

Biomarker Testing in Cardiovascular Risk Assessment Not Otherwise Specified	**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) **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." Therefore, 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®, Atlas Genomics (0308U; Kennewick, WA) • HART CVE®, Atlas Genomics (0309U; Kennewick, WA) • HART KD®, Atlas Genomics (0310U; Kennewick, WA) • 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)
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)
Liposcale® Test (0377U; CIMA Sciences, LLC) *SOMAmer® (0019M; SomaLogic)*	Company medical policy for Cardiac: Disease Risk Screening I. This service is considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.*

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

MEDICARE AND MEDICAL NECESSITY

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)*.

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, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

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.

Finally, some tests are considered not medically necessary for Medicare plan members due to the intended purpose of the test. For example, PLA code 0024U is 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 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 purposes, this test is denied as "not medically necessary."

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.

BILLING GUIDELINES AND CODING

GENERAL

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

- Local Coverage Article (LCA): Billing and Coding: MolDX: Biomarkers in Cardiovascular Risk Assessment (A57055)
- LCA: Billing and Coding: MolDX: Cystatin C Measurement (A57644)

ROUTINE SCREENING AND MEDICARE

The Noridian LCD for *MolDX: Biomarkers in Cardiovascular Risk Assessment* (L36362) 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."

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.

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
	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 Atlas Genomics [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 Atlas Genomics [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 Atlas Genomics [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)*
	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

None

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