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| MEDICAL POLICY | Cardiac: Disease Risk Screening (Medicare Only) |
| Effective Date: 8/1/2022 | Medical Policy Number: 132 |
|  8/1/2022 | Medical Policy Committee Approved Date: 6/18; 8/18; 12/18; 9/19; 04/2020; 8/2020; 06/2021; 11/2021; 3/2022; 6/2022 |
| Medical Officer | Date |

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

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

APPLIES TO:

Medicare only

| MEDICARE POLICY CRITERIA | |
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| <p>The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.</p> | |
| Service | Medicare Guidelines |
| <i>ApoE Genotype (CPT 81401)</i> | 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: MoIDX: ApoE Genotype (A55095) |
| <i>4q25-AF Risk Genotype (CPT 81479)</i> | For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY: LCA: Billing and Coding: MoIDX: 4q25-AF Risk Genotype (A55091) |
| <i>9p21 Genotype (CPT 81479)</i> | For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY: LCA: Billing and Coding: MoIDX: 9p21 Genotype Test (A55093) |
| <i>Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) Testing (CPT 81439)</i> | For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY: LCA: Billing and Coding: MoIDX: Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) Testing (A54976) |
| <i>Corus® CAD test (CPT 81493; CardioDX, Redwood City, CA)</i> | For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY: LCD: MoIDX: Corus® CAD Assay (L37673) |

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| | 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 MoIDX Program had determined this test was eligible for coverage [A51923 and A54428]). |
| <i>LPA-Intron 25 Genotype testing (CPT 81479)</i> | For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY: LCA: Billing and Coding: MoIDX: LPA-Intron 25 Genotype (A55282) |
| <i>LPA-Aspirin Genotype testing (CPT 81479)</i> | For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY: LCA: Billing and Coding: MoIDX: LPA-Aspirin Genotype (A55280) |
| <i>Biomarker Testing in Cardiovascular Risk Assessment Not Otherwise Specified</i> | For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY: Local Coverage Determination (LCD): MoIDX: Biomarkers in Cardiovascular Risk Assessment (L36362) These cardiovascular panel tests are considered not medically necessary , based on Medicare guidelines (See “Policy Guidelines” below): <ul style="list-style-type: none"> • VAP® Cholesterol Test by VAP Diagnostics Laboratory, Inc. • MI-HEART Ceramides, Plasma test by Mayo Clinic • HART CADhs®, Prevencio, Inc. (Kennewick, WA) • HART CVE® Prevencio, Inc. (Kennewick, WA) • HART KD®, Prevencio, Inc. (Kennewick, WA) |
| <i>Cystatin C Measurement (CPT 82610)</i> | For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY: MoIDX: Cystatin C Measurement (L37618) |

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

Coverage or non-coverage determinations made by MoIDX 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 MoIDX 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 MoIDX review is complete and coverage is indicated by MoIDX 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).

BILLING GUIDELINES

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

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

Routine Screening and Medicare

The Noridian LCD for *MoIDX: 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 statute 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.

CPT/HCPCS CODES

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| Prior Authorization Required | |
| 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 |
| No Prior Authorization Required | |
| Note: Inclusion of a code in this section does not guarantee reimbursement or coverage. The following codes do not require routine review for medical necessity, but they may be subject to audit or benefit denial. | |
| 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) |
| Not Covered | |
| 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 (<i>Used to report VAP® Cholesterol Test by VAP Diagnostics Laboratory, Inc.</i>) |
| 0119U | Cardiology, ceramides by liquid chromatography–tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events (<i>Used to report MI–HEART Ceramides, Plasma test by Mayo Clinic</i>) |
| 0308U | Cardiology (coronary artery disease [CAD]), analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]), plasma, algorithm reported as a risk score for obstructive CAD (<i>Used to report HART CADhs® by Prevencio, Inc. [Kennewick, WA]</i>) |
| 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 (<i>Used to report HART CVE® by Prevencio, Inc. [Kennewick, WA]</i>) |
| 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 (<i>Used to report HART KD® by Prevencio, Inc. [Kennewick, WA]</i>) |
| 0423F | TERMED 12/31/2021 Secretory type II phospholipase A2 (sPLA2-IIA) |

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| 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 |
| Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered . | |
| 81479 | Unlisted molecular pathology procedure |

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

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.