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Medicare Advantage Policy Manual **Policy ID:** M-LAB78

Biomarkers for Cardiovascular Disease

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual but they may also be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Numerous lipid and non-lipid biomarkers have been proposed as potential risk markers for cardiovascular disease, including lipoprotein subclasses and genetic testing. Some of these biomarkers have been studied as alternatives or additions to standard lipid panels for risk stratification in cardiovascular disease or as treatment targets for lipid-lowering therapy. Other tests assess genes or variants associated with developing cardiovascular disease.

MEDICARE ADVANTAGE POLICY CRITERIA

Notes: The Medicare references in this policy represent the guidance available at publication; please see the Medicare Coverage Database for the latest guidance. This policy includes links to external webpages that are not maintained by the health plan.

This policy does not address genetic testing for a specific cardiovascular disorder for the purpose of making a diagnosis in an individual who does not already have a clinical diagnosis (see Cross References).

CMS Coverage Manuals

MEDICARE BENEFIT POLICY MANUAL Chapter 16 - General Exclusions From Coverage, §20 - Services Not Reasonable and Necessary.

This is based on Title XVIII of the Social Security Act, Section 1862(a)(1)(A), which states " ...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..."

There is no Medicare benefit for cardiovascular risk assessment for asymptomatic (without signs or symptoms of disease) patients. Screening asymptomatic patients for cardiovascular risk is statutorily excluded by Medicare and considered **not medically necessary**.

National Coverage Determinations (NCDs)

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

Lipid Testing (190.23)

See also Medicare Preventive Services: Cardiovascular Disease Screening Test.

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- ✓ MolDX: Biomarkers in Cardiovascular Risk Assessment (L36362) *(Companion articles A57055 and A54976, see "Associated Documents" in the LCD)*

  These address cardiovascular risk biomarkers and panel testing, and genetic testing for arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C). For other indications, see Cross References.

LCDs and Articles for Other Jurisdictions

Note: The health plan is required to use LCDs and articles published by the contractor with jurisdiction over the service area in which the tests are performed.[1,2] See below for contractor guidance in other jurisdictions:

- ✓ *Laboratories in CA and NV:*
  MolDx: Biomarkers in Cardiovascular Risk Assessment (L36358) and associated articles
- ✓ *Laboratories in AL, GA, TN, SC, NC, VA, WV:*
  MolDx: Biomarkers in Cardiovascular Risk Assessment (L36129) and associated articles

- ✓ *Laboratories in IA, KS, MO, NE, IN, MI:*
  MolDx: Biomarkers in Cardiovascular Risk Assessment (L36523) and associated articles
- ✓ *Laboratories in KY, OH:*
  MolDx: Biomarkers in Cardiovascular Risk Assessment (L36139) and associated articles
- ✓ *Laboratories in FL, PR, and VI:*
  Genetic Testing for Cardiovascular Disease (L39084) and associated articles
- ✓ *Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA:* Genetic Testing for Cardiovascular Disease (L39082) and associated articles

CROSS REFERENCES

1. Genetic and Molecular Diagnostics – Next Generation Sequencing, Genetic Panels, and Biomarker Testing, Genetic Testing, Policy No. 64
2. Screening Laboratory Testing, Laboratory, Policy No. 80

REFERENCES

1. Medicare Claims Processing Manual, Chapter 1 - General Billing Requirements, §10.1.5.4 - Independent Laboratories
2. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §90.4.1 - MAC with Exclusive Jurisdiction over a Medicare Item or Service

CODING

NOTE: Not all policies have a coding note, but for those that do, the applicable coding note would be placed here.

Codes	Number	Description
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
	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
	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
	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
	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)

	0401U	Cardiology (coronary heart disease [CHD]), 9 genes (12 variants), targeted variant genotyping, blood, saliva, or buccal swab, algorithm reported as a genetic risk score for a coronary event
	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
	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
	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
	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
	0529U	Hematology (venous thromboembolism [VTE]), genome-wide single-nucleotide polymorphism variants, including F2 and F5 gene analysis, and Leiden variant, by microarray analysis, saliva, report as risk score for VTE
	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) scor
	81439	Hereditary cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy), genomic sequence analysis panel, must include sequencing of at least 5 cardiomyopathy-related genes (eg, DSG2, MYBPC3, MYH7, PKP2, TTN)
	81479	Unlisted molecular pathology procedure
	83722	Lipoprotein, direct measurement; small dense LDL cholesterol
HCPCS	None	