Medical Policy



Cardiovascular Disease (CVD) Risk Testing

Policy Number: PG0392 Last Review: 09/01/2024 HMO AND PPO ELITE (MEDICARE ADVANTAGE) MARKETPLACE

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each
 individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute
 a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific
 policy will supersede this general policy when group supplementary plan document or individual
 plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE

X Professional X Facility

DESCRIPTION:

Coronary artery disease (CAD), also known as atherosclerosis, is the most common cause of death among adults in the United States. Individuals with CAD have an accumulation of fat, cholesterol, and other substances (collectively referred to as plaque) in the coronary arteries. This accumulation leads to a narrowing of the arteries that can cause the heart to slow and potentially stop. There are many risk factors for CAD, including age, sex, smoking, diabetes, hypertension, high cholesterol, and a family history of the disease. The symptoms of obstructive CAD are highly variable, range in severity, and may include chest pain (angina), fatigue, shortness of breath, weakness, nausea, vomiting, indigestion, dizziness, palpitations, and pain or discomfort in the back, shoulders, arms, or jaw. At this time, invasive coronary angiography (ICA) is considered the reference standard for establishing a diagnosis of obstructive CAD, although patients may also be evaluated using a variety of noninvasive imaging techniques, electrocardiography, and exercise stress tests. Because of the challenges posed by patients presenting with symptoms of CAD, which can be highly variable, often vague, and sometimes atypical, recent studies have focused on developing a genomic test that may facilitate the diagnosis of obstructive CAD in a noninvasive manner.

Cardiovascular disease (CVD) describes the category of diseases caused by atherosclerosis, the accumulation of plaque in the walls of arteries. Atherosclerosis may be present for many years without noticeable symptoms. Plaques impede blood flow as they grow in size and 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 developed countries.

Cardiovascular risk panels refer to different combinations of cardiac markers that are intended to evaluate risk of cardiovascular (CV) disease. Testing for CVD 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) (83718), low-density lipoprotein (LDL) (83721), total cholesterol (82465) and triglycerides (84478) (often referred to as a basic or standard lipid panel (80061)).
- Non-traditional testing for cardiac risk includes, not all-inclusive: apolipoprotein(82172), C-reactive protein; high sensitivity(hsCRP)(86141), column chromatography, includes mass spectrometry if performed, non-drug analyte not elsewhere specified, qualitative or quantitative(82542), C-peptide (84681), Cystatin C(82610), Fatty acids, nonesterified (82725), Galectin-3(82777), Glycosylated acute

phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative(0024U), Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)(83006), Homocysteine(83090), Insulin, Total(83525), Insulin, Free(83527), Proinsulin(84206), Lipoprotein (a)(83695), Lipoprotein-associated phospholipase A2 (Lp-PLA2)(83698), Lipoprotein, blood; electrophoretic separation and quantitation(83701), Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (e.g., electrophoresis, ultracentrifugation)(83701), Lipoprotein, blood; quantitation of lipoprotein particle numbers and lipoprotein particle subclasses, e.g., by nuclear magnetic resonance (NMR) spectroscopy, includes lipoprotein particle subclass(es) when performed(83704), 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(0052U), MI-HEART Ceramides, Plasma(0119U), Myeloperoxidase (MPO)(83876), Natriuretic peptide(83880), Organic acid, total, quantitative(83918), Organic acid, qualitative(83919), Organic acid, single(83921), Thromboxane metabolite(s), including thromboxane if performed, urine(84431), Troponin, quantitative(84484), Unlisted chemistry procedure(84999), VLDL cholesterol Lipoprotein, direct measurement(83719), and Very long chain fatty acids(82726).

Risk factors other than LDL cholesterol include a variety of tests such as serum inflammatory markers, comprehensive lipoprotein testing, angiotensin gene testing, prothrombotic factors and other types of gene testing.

Given the lack of evidence for clinical utility of any individual risk factor beyond simple lipid measures, it is unlikely that the use of CV risk panels improves outcome. Several clinical trials are underway to evaluate methods aimed at cardiovascular risk reduction, however evidence in the form of randomized controlled trials supporting that treating to target levels of emerging risk factors lowers risk is lacking. Furthermore, no study has provided high-quality evidence that measurement of markers leads to changes in management that improve health outcomes.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

- The following Cardiovascular Disease (CVD) Risk Tests procedure codes are noncovered: 0019M, 0024U, 0052U, 0119U, 0308U, 0309U, 0377U, 0415U, 83700, 83701, 83704, 83719, 83722, 83876, and 84431.
- The following procedure codes are noncovered when performed as part of a Cardiovascular Disease (CVD) Risk Testing, not an all-inclusive list: 0055U, 81493, 82542, 82610, 82725, 82726, 82777, 83006, 83090, 83519, 83520, 83525, 83527, 83698, 83880, 83918, 83919, 83921, 84206, 84484, 84681, 85246, 85384, 85415, 93050, 93895, 93922, 93923.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Paramount covers simple lipid panel testing for cardiovascular risk assessment, includes: High-density lipoprotein (HDL) (83718), low-density lipoprotein (LDL) (83721), total cholesterol (82465) and triglycerides (84478) (often referred to as a basic or standard lipid panel (80061)) and are indicated for the following:

- CVD Risk Testing in all children, regardless of general health or the presence or absence of CVD risk factors, between 9 and 11 years of age, with repeat lipid screening every five years thereafter if normal.
- CVD Risk Testing in children 2–18 years of age who have the following cardiovascular risk factors:
 - One or both biological parents are known to have hypercholesterolemia or are receiving lipidlowering medications.
 - Have a family history of premature CVD in an expanded first-degree pedigree in men <55 or women <65 years of age.
 - Have an unknown family history of CVD (e.g., children who were adopted).
- CVD Risk Testing in asymptomatic individuals 18-79 years who do not have CVD up to once every four to six years.

- CVD Risk Testing in individuals who have one or more of the following CVD risk factors but who do not have CVD once per year:
 - o risk for familial hypercholesterolemia, or related inherited disorders predisposing to CVD
 - o major CVD risk factors including any of the following:
 - diabetes
 - hypertension
 - cigarette smoking
 - chronic kidney disease
 - o additional CVD risk factors such as:
 - obesity or metabolic syndrome
 - pregnancy associated conditions
 - hypothyroidism or Hyperthyroidism
 - HIV infection
 - pancreatitis
 - cushing's syndrome
 - autoimmune inflammatory disorders
 - obstructive liver disease
 - use of prescription drugs associated with cardiotoxicity (e.g., anabolic steroids, cyclosporine, amiodarone)
 - Diagnostic evaluation or monitoring up to six times per year in individuals with a history of at least one
 of the following:
 - o stable or unstable angina
 - o myocardial infarction
 - o non-hemorrhagic stroke
 - o transient ischemic attacks
 - o aortic aneurysm
 - o peripheral vascular disease effecting limbs, kidneys, skin, or other organs
 - Risk assessment, diagnostic evaluation, or monitoring of patients with a history of dyslipidemia including increased Total-C, increased Non-HDL-C; or increased LDL-C

High-Sensitivity C-Reactive Protein (hs-CRP)

Paramount considers high-sensitivity C-Reactive Protein (hs-CRP) (86141) testing medically necessary when ALL of the following criteria are met:

- Member has 2 or more coronary heart disease (CHD) major risk factors
 - Age (men aged 45 years or older; women aged 55 years or older)
 - Current cigarette smoking
 - Family history of premature CHD (CHD in male first-degree relative less than 55 years of age;
 CHD in female first-degree relative less than 65 years of age)
 - Hypertension (blood pressure [BP] of 140 mm Hg or higher, or on anti-hypertensive medication)
 - Low high-density lipoprotein (HDL) cholesterol (less than 40 mg/dL).
 - Member has low-density lipoprotein (LDL) cholesterol levels between 100 to 130 mg/dL; and
- Member has been judged to be at an intermediate risk of cardiovascular disease by global risk assessment (i.e., 10 to 20 % risk of CHD per 10 years using Framingham point scoring).

Paramount considers hs-CRP testing experimental, investigational, or unproven for all other indications, including use as a screening test for the general population and for monitoring response to therapy, because its clinical value for these uses has not been established.

Apolipoprotein B (apo B)

Paramount considers measurement of apolipoprotein B (apoB) (82172) medically necessary for use in high-risk persons with hypercholesterolemia to assess whether additional intense interventions are necessary when LDL cholesterol goals are reached (LDL cholesterol less than 70 mg/dL and non-HDL cholesterol less than 100 mg/dL in persons with known cardio-vascular disease (CVD) or diabetes mellitus, or LDL-C less than 100 mg/dL PG0392-09/01/2024

and non-HDL cholesterol less than 130 mg/dL in persons with other risk factors). High-risk persons are those with one or more of the following criteria:

- Diabetes mellitus; or
- Known CVD; or
- Obesity or metabolic syndrome
- Hypertriglyceridemia or other dyslipidemias
- Two or more of the following CVD risk factors:
 - o Current cigarette smoking; or
 - Family history of premature CVD (CHD in male first-degree relative less than 55 years of age;
 CHD in female first-degree relative less than 65 years of age); or
 - o Hypertension (BP of 140 mm Hg or higher, or on anti-hypertensive medication).

Paramount considers measurement of apolipoprotein B (apoB) experimental, investigational, or unproven for all other indications because its clinical value for other indications has not been established.

Lipoprotein(a) (Lp[a])

Paramount considers measurement of Lipoprotein(a) (Lpa) (83695) medically necessary for members 18 years of age or older, <u>once per lifetime</u> when coverage criteria are met.

- Family history of premature atherosclerotic cardiovascular disease (ASCVD) and/or increased Lp(a)
- Personal or family history of aortic valve stenosis
- Personal history of ASCVD (premature or recurrent) despite LDL- lowering
- Members of South Asian or African ancestry
- Members with a 10-year ASCVD risk ≥ 10%

There is insufficient evidence to conclude that the following tests are effective as expanded CVD risk screening tools for the early detection of cardiovascular disease, individually or as part of a CVD risk panel, therefore are considered not medically necessary and non-covered, experimental/investigation, because their clinical value has not been established (this list may not be all-inclusive):

- 4q25-AF Risk Genotype Test (rs2200733 allele)(81479)
- 9p21 Genotype Test (rs10757278 and rs1333049 alleles)(81479)
- Activated factor VII
- Adiponectin
- Anti-thrombin III
- Apelin
- Apolipoprotein E (apo E)(81401)
- Apolipopritein E genotyping
- ASCVD risk testing (individual or panel) (e.g., c-peptide(84681), glycated protein(0024U), islet cell antibodies, nonesterified fatty acids (free fatty acids)(82725), proinsulin(84206) and total insulin(83525))
- Brain natriuretic peptide (BNP)(83880) or N-terminal pro-BNP (NT-proBNP) to predict CVD risk
- CADence System
- Carotid intima media thickness testing
- Cathepsin S
- Cholesterol production and absorption biomarkers (Boston Heart Diagnostics)
- Chromosome 9 polymorphism 9p21
- Circulating microRNAs (e.g., miR-1, miR-16, miR-26a, miR-27a, and miR-29a, miR-133a, and miR-199a-5p; not an all-inclusive list)
- Coenzyme Q10 (CoQ10)
- Comprehensive lipid panel (e.g., Cardio IQ Advanced Lipid Panel, NMR LipoProfile)
- Cortisol
- Corus CAD Gene Expression Profile (Exception: coverage for Elite (Medicare Advantage) Plan only
 coverage criteria as indicated below)

- Cystatin-C (82610)
- Extended fatty acid profiles (Boston Heart Diagnostics; Framingham, MA)
- Fibrinogen (85384)
- Galectin-3 (82777)
- Glycosylated acute phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative (0024U)
- Growth stimulation expressed gene 2 (ST2)
- HDL subclass
- HDL subpopulation analysis (Boston Heart Diagnostics)
- Homocysteine (83090)
- Insulin, Total (83525)
- Insulin, Free (83527)
- Interleukin 6 (IL-6)
- Interleukin 6 -174 g/c promoter polymorphism
- Interleukin 17 gene polymorphism
- Interleukin 18 (IL-18)
- Iron studies (e.g., ferritin, serum iron)
- KIF6 Genotype Test (81479)
- LDL subclasses (e.g., NMR)
- Leptin
- LPA-Aspirin Genotype Test (4399Met allele)(81479)
- LPA-Intron 25 Genotype Test (81479)
- Lipoprotein, blood; electrophoretic separation and quantitation (83700)
- Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (e.g., electrophoresis, ultracentrifugation)(83701)
- Lipoprotein, blood; quantitation of lipoprotein particle numbers and lipoprotein particle subclasses (e.g., by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es) when performed (83704)
- 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 (0052U)
- Lipoprotein, direct measurement; small dense LDL cholesterol (83722)
- Lipoprotein-associated phospholipase A2 (Lp-PLA2 or PLAC)(83698)
- Lipoprotein remnants (intermediate density lipoproteins [IDL] and small density lipoproteins [sdLDL])
- Long-chain omega-3 fatty acids
- LPA Intron-25 genotype testing (e.g., Cardio IQ Intron-25 Genotype Test, LPA Intron-25 Genotype Test)
- MaxPulse testing
- MI-HEART Ceramides, Plasma (0119U)
- MIRISK VP test
- Myeloperoxidase (MPO)(83876)
- myTAIHEART (0055U)
- NMR lipoprotein particle counting (LipoScience, Inc.; Raleigh, NC), Lipoprotein Particle Profile (SpectraCell Laboratories; Houston, TX)
- Non-invasive measurements of arterial elasticity by means of blood pressure waveforms (e.g., CardioVision MS-2000, CVProfilor, Digital Pulse Analyzer (DPA), DSI Pulse Wave Velocity analysis, Max Pulse and HD/PulseWave CR-2000) and noninvasive calculation and analysis of central arterial pressure waveforms (SphygmoCor))
- Non-invasive calculation and analysis of central arterial pressure waveforms (SphygmoCor)
- OmegaCheck Panel
- Organic acid, total, quantitative (83918)

- Organic acid, qualitative (83919)
- Organic acid, single (83921)
- Osteoprotegerin
- Oxidized phospholipids
- PAI-1 Testing for Cardiovascular Disease Risk Assessment (81400, 85415)
- Peroxisome proliferator-activated receptor
- Plasma ceramide
- Plasma levels of trimethylamine-N-oxide (TMAO) BG. Plasminogen activator inhibitor (PAI–1)
- Proinsulin (84206)
- Prothrombin gene mutation testing
- Receptor for advanced glycosylation end products (RAGE) gene Gly82Ser polymorphism testing
- Resisting
- Retinol binding protein 4 (RBP4)
- Secretory type II phospholipase A2 (sPLA2-11A)(84999)
- Serum sterols (e.g., Boston Heart Cholesterol Balance Test)
- Singulex SMC testing for risk of cardiac dysfunction and vascular inflammation (e.g., SMC Endothelin, SMC IL-6, SMC IL 17A, SMC c TnI and SMC TNF-α)
- Skin cholesterol (e.g., PREVU)
- SNP-based testing (e.g., Cardiac Healthy Weight DNA Insight, Healthy Woman DNA Insight Test, Heart Health Genetic Test)
- Soluble cell adhesion molecules (e.g., intercellular adhesion molecule-1 [ICAM-1], vascular cell adhesion molecule-1 [VCAM 1], E-selectin, and P-selectin)
- Statin Induced Myopathy Genotype (SLCO1B1)(81328)
- Thromboxane metabolite(s) testing (84431)
- Tissue plasminogen activator (tPA)
- Toll-likereceptor 4(TLR4) Asp299Gly (rs4986790) polymorphism
- Troponin I (e.g., PATHFAST cTnI-II)(84484)
- Tumor necrosis factor-alpha (TNF-a)
- Vertical Auto Profile (VAP) with or without vertical lipoprotein particle (VLP) technology
- Visfatin
- Vitamin D
- VLDL cholesterol Lipoprotein, direct measurement (83719)
- von Willebrand factor antigen level
- > Testing for hsCRP (86141), Lp(a) (83695), and/or Lp-PLA2 (83698) should only be performed when medically necessary, as supported with the lipid panel testing indicating an intermediate CVD risk.
- Apo B (82172) or ApoB:ApoA (82172) ratio is indicated to monitor individuals being treated for either CVD or high CVD risk, and who are not being monitored by a lipid panel. Apo B or ApoB:ApoA ratio is not indicated in screening for CVD in asymptomatic individuals.
- ➤ B-Natriuretic Peptide (83880) or N-Terminal B-Natriuretic peptide (83880) are not indicated in ASCVD risk testing and are not coverable for indications other than assessment of heart failure.
- Organic Acids, (83918, 83919 83921), or Column chromatography/Mass Specnon-drug analyte (82542) are not indicated in CVD risk testing and are not coverable for indications other than inborn errors of metabolism.
- ➤ Galectin-3 (82777), ST2 (83006) are not indicated in CVD risk testing and are not coverable for indications other than risk stratification in individuals with heart failure.
- > Troponin, quantitative (84484) is not indicated in CVD risk testing and is not coverable for indications other than assessment of myocardial injury.
- Non-esterified fatty acids (82725), Very long chain fatty acids (82726), and column chromatography/ with mass spectrometry (82542) are not indicated in CVD risk testing and is not coverable for indications other than malabsorption and other diseases of the digestive system, reduced intake of fats and cystic fibrosis.

- > Cystatin C (82610) is not indicated in CVD risk testing and is not coverable for indications other than assessment of renal failure.
- ➤ Homocysteine (83090) has no role in CVD risk testing and is not coverable for indications other than diagnosis and management of homocystinuria, Vitamin B12 deficiency, or folate deficiency.
- Insulin, Total (83525), Insulin, Free (83527), Proinsulin (84206), and Cpeptide (84681) are not indicated in screening for CVD risk testing and are not coverable for indications other than diagnosis and management of insulimomas, insulin antibodies suspected of interfering with the assay for total insulin and inefficacy of treatment due to insulin antibodies.
- The following tests for CVD risk testing have no additional coverable indications and are considered investigational and experimental and are therefore not eligible for reimbursement for any clinical indication, may not be an all-inclusive listing: Glycosylated acute phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative (0024U), Lipoprotein, blood; electrophoretic separation and quantitation (83700), Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (e.g., electrophoresis, ultracentrifugation)(83701), Lipoprotein, blood; quantitation of lipoprotein particle numbers and lipoprotein particle subclasses (e.g., by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es) when performed(83704), 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(0052U), Lipoprotein, direct measurement; small dense LDL cholesterol(83722), MI-HEART Ceramides, Plasma(0119U), Myeloperoxidase (MPO)(83876), Secretory type II phospholipase A2 (sPLA2-IIA)(84999), Thromboxane metabolite(s), including thromboxane if performed, urine(84431), VLDL cholesterol Lipoprotein, direct measurement(83719).
- The following proprietary tests for CVD risk testing assessment or management are specifically noted to be investigational and experimental, regardless of the procedure codes used to bill them:

 CardioMetabolic Risk Assessment; SpectraCell Laboratories, Boston Heart HDL Map; Boston Heart Diagnostics, Boston Heart Fatty Acid Balance Test; Boston Heart Diagnostics, Boston Heart Cholesterol Balance Test; Boston Heart Diagnostics, Cardio IQ Lipid Subfractionation by Ion Mobility; Quest Diagnostics, True Health Diagnostics: Comprehensive Cardiovascular Disease Testing, NMR LipoProfile: Cleveland HeartLab, Cardiovascular Risk Marker Panel; Mayo Clinic.

Elite (Medicare Advantage) Plans

The Corus® CAD (coronary artery disease) (81493) examines the expression of 23 genes in peripheral blood cells and uses this information to estimate the likelihood of obstructive CAD in nondiabetic individuals with clinical signs of this disease. A complex algorithm that includes gene expression data, patient sex, and patient age yields a gene expression score (GES) that ranges from 1 to 40, with a higher number reflecting a higher probability of obstructive CAD. It is suggested that a combination of Corus CAD and other noninvasive tests or evaluations may help physicians identify patients who are unlikely to have obstructive CAD, thus avoiding invasive diagnostic testing.

While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of Corus® CAD, gene expression testing to predict coronary artery disease, per CMS guidelines it may be covered with prior authorization for Elite members.

COVERAGE CRITERIA:

The Corus® CAD (coronary artery disease) test is considered reasonable and necessary for the evaluation of members with stable symptoms that have a history of chest pain, suspected anginal equivalent to chest pain, or a high risk of CAD, but no known prior myocardial infarction or revascularization procedures. Supporting ICD-10 codes include:

Corus® CAD – Procedure 81493

ICD-10 CODES

I. Typical Symptoms

Identifying	appropriate patients for Corus CAD:
I20.1	Angina pectoris with documented spasm [prinzmetal angina; variant angina pectoris]
120.8	Other forms of angina pectoris
120.9	Angina pectoris, unspecified
R06.02	Shortness of breath
R07.2	Precordial pain
R07.82	Intercostal pain
R07.89	Other chest pain
R07.9	Chest pain, unspecified
	Anginal Equivalent Symptoms ng diagnoses require at least one CAD risk factor from III:
M54.9	Dorsalgia, unspecified
M79.602	Pain in left arm
M79.622	Pain in left upper arm
R00.2	Palpitations
R10.9	Unspecified abdominal pain
R11.0	Nausea
R11.10	Vomiting, unspecified
R11.2	Nausea with vomiting, unspecified
R12	Heartburn
R42	Dizziness and giddiness
R53.81	Other malaise
R68.84	Jaw pain
	on CAD Risk Factors Patient must have at least one atypical symptom listed in II in at least one risk factor in list III:
E66.9	Obesity, unspecified
E78.00	Pure hypercholesterolemia, unspecified
E78.01	Familial hypercholesterolemia
E78.1	Pure hyperglyceridemia
E78.2	Mixed hyperlipidemia
E78.4	Other hyperlipidemia
E78.5	Hyperlipidemia, unspecified

E88.81	Metabolic syndrome
F17.200	Nicotine dependence, unspecified, uncomplicated
F17.201	Nicotine dependence, unspecified, in remission
F17.210	Nicotine dependence, cigarettes, uncomplicated
F17.211	Nicotine dependence, cigarettes, in remission
F17.220	Nicotine dependence, chewing tobacco, uncomplicated
F17.221	Nicotine dependence, chewing tobacco, in remission
F17.290	Nicotine dependence, other tobacco product, uncomplicated
F17.291	Nicotine dependence, other tobacco product, in remission
I10	Essential (primary) hypertension
I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm
I25.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris
165.21	Occlusion and stenosis of right carotid artery
165.22	Occlusion and stenosis of left carotid artery
165.23	Occlusion and stenosis of bilateral carotid arteries
167.2	Cerebral atherosclerosis
I70.1	Atherosclerosis of renal artery
170.201	Unspecified atherosclerosis of native arteries of extremities, right leg
170.202	Unspecified atherosclerosis of native arteries of extremities, left leg
170.203	Unspecified atherosclerosis of native arteries of extremities, bilateral legs
170.208	Unspecified atherosclerosis of native arteries of extremities, other extremity
170.209	Unspecified atherosclerosis of native arteries of extremities, unspecified extremity
Z82.41	Family history of sudden cardiac death
Z82.49	Family history of ischemic heart disease and other diseases of the circulatory system
Z87.891	Personal history of nicotine dependence

LIMITATIONS:

- The Corus® CAD test is considered not reasonable and necessary for members who are currently taking steroids, immunosuppressive agents, or chemotherapeutic agents or for members with:

 o acute or previous myocardial infarction;

 - o high-risk unstable angina;

- a history of obstructive CAD;
- o a previous revascularization procedure:
- o a history of a previous invasive procedure to open a blocked or narrow artery;
- o systemic infectious or systemic inflammatory conditions; or
- diabetes.
- The Corus® CAD test is considered not reasonable and necessary when used for any of the following:
 - to be used to screen for stenosis among members who are asymptomatic and not considered at high-risk for CAD;
 - o to predict or detect response to therapy, or
 - o to help select the optimal therapy for members.

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
80061	Lipid panel
81229	Cytogenomicconstitutional(genome-wide)microarrayanalysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities [not covered for cardiovascular disease risk]
81240	F2 (prothrombin, coagulation factor II) (e.g., hereditary hypercoagulability)geneanalysis,20210G>Avariant
81241	F5 (coagulation Factor V) (e.g., hereditary hypercoagulability) gene analysis, Leiden variant
81291	F2 (prothrombin, coagulation factor II) (e.g., hereditary hypercoagulability)geneanalysis,20210G>Avariant
81328	SLCO1B1 (SOLUTE CARRIER ORGANIC ANION TRANSPORTER FAMILY, MEMBER 1BA)(e.g., adverse drug reaction), gene analysis, common variant(s)(e.g., #5)
81400	Molecular pathology procedure, Level 1 (e.g., identification of single germline variant [e.g., SNP] by techniques such as restriction enzyme digestion or melt curve analysis)
81401	Molecular pathology procedure, Level 2 (er, 2-10 SNPs, 1 methylate variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)
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
82163	Angiotensin II
82172	Apolipoprotein, each
82465	Cholesterol, serum or whole blood, total
82542	Column chromatography, includes mass spectrometry if performed, non-drug analyte not elsewhere specified, qualitative or quantitative
82553	Creatinine kinase (CK), (CPK); MB fraction only
82610	Cystatin C
82725	Fatty acids, nonesterified
82726	Very long chain fatty acids
82777	Galectin-3
83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)
83090	Homocysteine
83519	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, by radioimmunoassay (e.g., RIA)
83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen
83525	Insulin; total
83527	Insulin, Free

 83695 Lipoprotein (a) 83698 Lipoprotein-associated phospholipase A2 (Lp-PLA2) 83700 Lipoprotein, blood; electrophoretic separation and quantitation 	
Lipoprotein, blood: high resolution fractionation and quantitation of lipoproteins including	
lipoprotein subclasses when performed (e.g., electrophoresis, ultracentrifugation)	
Lipoprotein blood: quantitation of lipoprotein particle numbers and lipoprotein particle	
83704 subclasses (e.g., by nuclear magnetic resonance spectroscopy)	
83718 Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)	
83719 Lipoprotein, direct measurement; VLDL cholesterol	
83721 Lipoprotein, direct measurement; LDL cholesterol	
83722 Lipoprotein, direct measurement; small dense LDL cholesterol	
83876 Myeloperoxidase (MPO)	
83880 Natriuretic peptide	
83918 Organic acid, total, quantitative	
83919 Organic acid, qualitative	
83921 Organic acid, quantitative	
84206 Proinsulin	
84431 Thromboxane metabolite(s), including thromboxane if performed, urine	
84478 Triglycerides	
84484 Troponin, quantitative	
84681 C-peptide	
85246 Factor VIII, VW factor antigen	
85384 Fibrinogen; activity	
86141 C-reactive protein; high sensitivity (hsCRP)	
Arterial pressure waveform analysis for assessment of central arterial pressures, include	.C
93050 obtaining waveform(s), digitization, and application of nonlinear mathematical transformation of the state of the st	
determine central arterial pressures and augmentation index, with interpretation and rep	ort,
upper extremity artery, non-hypheninvasive	
93895 Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral	
Limited bilateral noninvasive physiologic of upper or lower extremity arteries, (e.g., for lo	
extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis	arteries
plus bidirectional, Doppler waveform recording and analysis at 1-hyphen2 levels, or	
93922 ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries pl	
volume plethysmography at 1-hyphen2 levels, or ankle/brachial indices at distal posterio	
and anterior tibial/dorsalis pedis arteries with transcutaneous oxygen tension measurem	ents at
1-hyphen2 levels)	
Complete bilateral noninvasive physiologic studies of upper or lower extremity arteries,	
more levels (e.g., for lower extremity: ankle/brachial indices at distal posterior tibial and a tibial/dorsalis pedis arteries plus segmental blood pressure measurements with bidirection	
Doppler waveform recording and analysis, at 3 or more levels, or ankle/brachial indices a posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental volume	al uistai
plethysmography at 3 or more levels, or ankle/brachial indices at distal posterior tibial ar	nd
anterior tibial/dorsalis pedis arteries plus segmental transcutaneous oxygen tension	u
measurements at 3 or more level(s), or single level study with provocative functional ma	neuvers
(e.g., measurements with postural provocative tests, or measurements with reactive hyp	
Cardiovascular disease, plasma, analysis of protein biomarkers by aptamer-based micro	
0019M and algorithm reported as 4-year likelihood of coronary event in high-risk populations N	
10/01/2023	
Glycosylated acute phase proteins (GlycA), puclear magnetic resonance spectroscopy	
quantitative	
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	
major ipoprotein classes and subclasses of TIDE, EDE, and VEDE by Vertical auto profile	

0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control target(s), plasma
0119U	MI-HEART Ceramides, Plasma
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 New 04/01/2022
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 New 04/01/2022
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) New 04/01/2023
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 New 10/01/2023

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 1/27/2017

	STORT EXPLANATION. ORIGINAL EFFECTIVE DATE. 1/2/1/2017
Date	Explanation & Changes
01/27/17	 Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
08/25/17	 Added codes 82610, 82725, 83090, 83525, 83721, 83880, 83921, 85384 & 86141 as non-covered Cardiovascular Disease (CVD) Risk Tests for all product lines Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
01/25/18	 Added codes 93050, 93922, & 93923 as non-covered Cardiovascular Disease (CVD) Risk Tests for all product lines Added ICD-10 diagnosis codes E75.21-E75.6, E78.0-E78.9, F17.200-F17.201, F17.210-F17.211, F17.220-F17.221, F17.290-F17.291, I10-I15.9, I25.10-I25.119, I25.700-I25.9, Z13.6, Z82.49, Z87.891 as non-covered for assessing cardiovascular disease risk Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
12/28/2020	Medical policy placed on the new Paramount Medical policy format
12/08/2021	 Policy reviewed and updated to reflect most current clinical evidence Added additional procedure codes, 80061, 81229, 81240, 81241, 81291, 81328, 81400, 81401, 81493, 82163, 82465, 82542, 82553, 83006, 83519, 83520, 83527, 83718, 83722, 83876, 83918, 83919, 84206, 84478, 84484, 84681, 85246, 0024U, 0052U, 0055U Deleted end-dated procedure codes 0111T, 0126T, 0423T Documented covered coverage r/t simple lipid panel testing for cardiovascular risk assessment Extended the documentation r/t to the noncoverage of expanded CVD risk screening procedures
12/01/2022	 Paramount added the Elite/ProMedica Medicare Plan covered coverage criteria for Corus® CAD (coronary artery disease) (81493), from archived medical policy PG0363 CORUS CAD (Coronary Artery Disease) Policy updated to reflect most current clinical evidence
03/01/2023	 Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
09/01/2024	 Medical policy reviewed and updated to reflect the most current clinical evidence Added coverage for Apolipoprotein B (apo B) (82172), Lipoprotein a (Lp(a)) (83695) and High-sensitivity C-Reactive Protein (hs-CRP) (86141)

Add noncovered codes 0019M, 0308U, 0309U, 0377U, and 0415U

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to

https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Manuals-Index https://www.cms.gov/Regulations-and-Guidance/Manuals-Index https://www.cms.gov/Regulations-and-Guidance/Manuals-Index https://www.cms.gov/Regulations-and-Guidance/Manuals-Index https://www.cms.gov/Regulations-and-Index https://www.cms.gov/Regulations-and-Index https://www.cms.gov/Regulations-and-Index https://www.cms.gov/Regulations-and-Index <a href="https://www.

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American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/ Industry Standard Review

Hayes, Inc., Lansdale, PA: Author. Health Technology Assessments. https://www.hayesinc.com/

Industry Standard Review