I. POLICY/CRITERIA

A. In addition to traditional risk assessment, the following cardiovascular disease (CVD) risk markers are a covered benefit:

1. Lipoprotein-associated phospholipase A2 (Lp-PLA2) (PLAC), limited to one test per year.

2. High-sensitivity C-reactive protein (hs-CRP) if both of the following:
   a. Using the 10-year risk assessment tool recommended by the NCEP, the patient is at intermediate risk of developing CHD (i.e. 10-year risk of 10–20%).
   b. The patient is metabolically stable without obvious inflammatory or infectious conditions.

B. The medical literature does not support the utility of the following tests for screening, diagnosis, or management of CVD and they are not a covered benefit:

1. Apolipoprotein A-I (apo AI)
2. Apolipoprotein B (apo B)
3. Apolipoprotein E (apo E)
4. Homocysteine testing
5. LDL gradient gel electrophoresis
6. Lipoprotein(a) enzyme immunoassay
7. Angiotensin gene (CardiaRisk™ AGT)
8. Measurement of long chain omega-3 fatty acids
9. Interleukin 6 -174 g/c promoter polymorphism
10. Carotid intimal-media thickness
11. LipiScan IVUS Coronary Imaging System (fat composition of plaque)
12. Prothrombotic factors (e.g., plasminogen activator inhibitor [PAI–1], activated factor VII, tissue plasminogen activator [tPA], von Willebrand factor, factor V Leiden, protein C, antithrombin III, fibrinogen)
13. Skin cholesterol test (PREVU Point of Care (POC) Skin Sterol Test, PreMD Inc.)
14. Lipoprotein particle size and concentration/density measurement (e.g., NMR LipoProfile® test)  
15. Natriuretic peptides  
16. Peripheral arterial tonometry, endothelial function test (e.g. EndoPAT™)  
17. Gene expression analysis (e.g. Corus® CAD)  
18. Secretory type II phospholipase A2 (sPLA2-IIA)  
19. Singulex SMCT™ 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)

II. MEDICAL NECESSITY REVIEW

☐ Required  ☒ Not Required  ☐ Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

- HMO/EPO: This policy applies to insured HMO/EPO plans.
- POS: This policy applies to insured POS plans.
- PPO: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- ASO: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- INDIVIDUAL: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- MEDICARE: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- MEDICAID/HEALTHY MICHIGAN PLAN: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945-42542-42543-42546-42551-159815--00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945-5100-87572--00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IV. DESCRIPTION

Determination of cardiovascular disease (CVD) risk is based on standard, accepted risk-stratification approaches. These approaches are based on global
assessment and traditional risk factor assessment including cholesterol/low density lipoprotein levels (LDL), diet, smoking, diabetes and family and personal medical history. The National Cholesterol Education Program (NCEP) utilizes the Framingham risk scoring calculation, endorsed by the National Heart Lung and Blood Institute (NHLBI) and the AHA for determining 10-year coronary heart disease (CHD) risk.

Newer generation cardiovascular risk markers are developed and proposed to enhance the prediction of cardiovascular disease. Evaluation of the potential clinical utility of these emerging tests includes the following:

- Does the test better identify those at higher risk than the current risk scores (Framingham risk score)?
- Does treatment differ for those at highest risk?
- Does treatment improve clinical outcomes?

V. CODING INFORMATION

ICD-10 Codes that may support medical necessity:

- E71.30 Disorder of fatty-acid metabolism, unspecified
- E75.21 Fabry (-Anderson) disease
- E75.22 Gaucher disease
- E75.240 Niemann-Pick disease type A
- E75.241 Niemann-Pick disease type B
- E75.242 Niemann-Pick disease type C
- E75.243 Niemann-Pick disease type D
- E75.248 Other Niemann-Pick disease
- E75.249 Niemann-Pick disease, unspecified
- E75.3 Sphingolipidosis, unspecified
- E75.5 Other lipid storage disorders
- E75.6 Lipid storage disorder, unspecified
- E77.0–E77.9 Disorders of glycoprotein metabolism
- E78.00–E78.9 Disorders of lipoprotein metabolism and other lipidemias
- E88.1 Lipodystrophy, not elsewhere classified
- E88.2 Lipomatosis, not elsewhere classified
- E88.89 Other specified metabolic disorders
- F17.200–F17.299 Nicotine dependence
- I10 Essential (primary) hypertension
- I11.0–I11.9 Hypertensive heart disease
- I12.0–I12.9 Hypertensive chronic kidney disease
- I16.0 – I16.9 Hypertensive crisis
- Z82.49 Family history of ischemic heart disease and other diseases of the circulatory system
May be preventive:
Z00.00-Z00.01  Encounter for general adult medical examination
Z00.121-Z00.129  Encounter for routine child health examination
Z13.220  Encounter for screening for lipid disorders
Z01.411-Z01.419  Encounter for gynecological examination
Z13.6  Encounter for screening for cardiovascular disorders

CPT/HCPCS Codes:
See criteria above for coverage information.

83698  Lipoprotein-associated phospholipase A2 (Lp-PLA2)
83719  Lipoprotein, direct measurement; VLDL cholesterol
86141  C-reactive protein; high sensitivity (hsCRP)
84999  Unlisted chemistry procedure
(Explanatory notes must accompany claims billed with unlisted codes.)

May be preventive
80061  Lipid panel
82465  Cholesterol, serum or whole blood, total
83718  Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)
83721  Lipoprotein, direct measurement; LDL cholesterol
84478  Triglycerides

Not covered for screening
See also Policy# 91540 Genetics: Counseling, Testing and Screening
81240  F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant
81241  F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant
82615  Cystine and homocystine, urine, qualitative
83090  Homocysteine
85300  Clotting inhibitors or anticoagulants; antithrombin III, activity
85303  Clotting inhibitors or anticoagulants; protein C, activity
85384  Fibrinogen; activity
85385  Fibrinogen; antigen
85415  Fibrinolytic factors and inhibitors; plasminogen activator
85420  Fibrinolytic factors and inhibitors; plasminogen, except antigenic assay
85421  Fibrinolytic factors and inhibitors; plasminogen, antigenic assay
83700  Lipoprotein, blood; electrophoretic separation and quantitation
83701  Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (eg, electrophoresis, ultracentrifugation)
83704  Lipoprotein, blood; quantitation of lipoprotein particle numbers and lipoprotein particle subclasses (eg, by nuclear magnetic resonance spectroscopy)
83695  Lipoprotein (a)
83880  Natriuretic peptide
### Not Covered for any dx

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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0111T</td>
<td>Long-chain (C20-22) omega-3 fatty acids in red blood cell (RBC) membranes</td>
</tr>
<tr>
<td>0126T</td>
<td>Common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment</td>
</tr>
<tr>
<td>0205T</td>
<td>Intravascular catheter-based coronary vessel or graft spectroscopy (eg, infrared) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation, and report, each vessel (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>0337T</td>
<td>Endothelial function assessment, using peripheral vascular response to reactive hyperemia, non-invasive (eg, brachial artery ultrasound, peripheral artery tonometry), unilateral or bilateral</td>
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<tr>
<td>0423T</td>
<td>Secretory type II phospholipase A2 (sPLA2-IIA)</td>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>81401</td>
<td>Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat) <em>(billed for evaluation of angiotensin gene)</em></td>
</tr>
<tr>
<td>81479</td>
<td>Unlisted molecular pathology procedure – when billed for any test not described as covered. <em>(Explanatory notes must accompany claim)</em></td>
</tr>
<tr>
<td>81493</td>
<td>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 Corus® CAD <em>(Covered for PH Medicare only)</em></td>
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<thead>
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<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>82172</td>
<td>Apolipoprotein, each</td>
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<tr>
<td>82777</td>
<td>Galectin-3</td>
</tr>
<tr>
<td>83006</td>
<td>Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)</td>
</tr>
</tbody>
</table>

### VI. REFERENCES


Lipoprotein-Associated Phospholipase A2 (Lp-PLA2) Test (PLAC Test; diaDexus) for Prediction of Coronary Heart Disease, Hayes, Inc. Search & Summary, January 2007.

Lipoprotein Subclass Quantification Using NMR LipoProfile® Test for Atherosclerosis/Coronary Heart disease (CHD), Hayes, Inc. Brief, April 7, 2007.


Hayes, Inc. Skin Cholesterol Test Using the PREVU* Point of Care (POC) Skin Sterol Test (PreMD Inc.) for Prediction of Coronary Artery Disease Risk, Health Technology Brief. October 30, 2008.


Hayes, Inc. Noninvasive Peripheral Arterial Tonometry, December 11, 2014

Cardiovascular Disease (CVD) Risk Testing, Humana Medical Coverage Policy HGO-0401-014; Effective Date: October 27, 2016.

Advanced Lipoprotein Testing, Anthem Medical Policy LAB.00031; Effective Date: January 1, 2017

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