CareSource

# MEDICAL POLICY STATEMENT
# OHIO MEDICAID

| Original Issue Date | Next Annual Review | Effective Date |
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| 11/14/2015 | 11/01/2019 | 11/01/2018 |
| **Policy Name** | | **Policy Number** |
| Lipid Testing in Assessing Cardiovascular (CV) Risk | | MM-0012 |
| **Policy Type** | | |
| **MEDICAL** | Administrative / Pharmacy | Reimbursement |

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.



## Contents of Policy

## A. SUBJECT

**Lipid Testing in Assessing Cardiovascular (CV) Risk**

## B. BACKGROUND

Cardiovascular disease (CVD) is one of the leading causes of morbidity and mortality in the United States, approximately 630,000 people die from heart disease each year. Vascular disease is the major contributor to CVD events. Risk factors include: age, race, gender, family history of heart disease, high blood pressure, diabetes and prediabetes, elevated LDL, decreased HDL, chronic kidney disease, overweight and obesity, smoking, substance abuse, lack of physical activity, unhealthy diet, and stress. Heart disease risks increase with age, men having a higher risk than pre-menopausal women. However, the risk for women increases post menopause and becomes closer to the risk for men. Additionally, specific racial groups are at a higher risk including African Americans, Mexican Americans, American Indians, Hawaiians, and some Asian Americans.

High levels of cholesterol in the blood, increase a person's risk of developing CVD. Total cholesterol levels include all the cholesterol found in various lipoproteins. Lipoproteins vary in size and density and include cholesterol esters and free cholesterol, triglycerides, phospholipids and A, C, and E apoproteins. Blood levels of total cholesterol and various fractions of cholesterol, especially low density lipoproteins (LDL) and high density lipoproteins (HDL), are useful in assessing and monitoring treatment for that risk in patients with cardiovascular and related diseases. Lipid testing is used to indicate the chances of having cardiovascular disease (CVD) and/or of having a coronary event. The most common blood tests (often referred to as a basic or standard lipid panel) to determine cardiac risk are high-density lipoprotein (HDL), low-density lipoprotein (LDL), total cholesterol, and triglycerides Apo-B testing is indicated for persons at an elevated risk and is recommended by the American College of Cardiology (ACC) and the American Diabetes Association (ADA).

There have been rapid developments in the understanding of appropriate cardiac screening tests. For example the American College of Preventive Medicine (ACPM) in a publication dated 2011 recommends the use of a CHD risk assessment tool such as the Framingham Risk Score, while the most recent guidelines from the ACC/AHA (2013) recommend a more robust risk calculator.

Professional Societies

The following professional society's recommendations are derived from the latest guidelines and scientific based literature available.

American College of Cardiology, American Diabetes Association, American Association of Clinical Chemistry, National Lipid Association, and American Association of Clinical Endocrinologists:

Recommend screening and treating LDL particle number targets (NMR LDL-P or measured Apo B) as well as LDL-C and non HDL-C in order to improve the management of high and moderate risk patients. This is due to the limitations in only monitoring individual's LDLC levels in order to lower LDL levels. Studies have demonstrated the differences found between cholesterol and particle numbers of LDL and increased risk when LDL particle numbers are not tracked accordingly.

National Heart, Lung and Blood Institute (NHLBI), American Academy of Pediatrics (AAP):

The NHLBI endorses the AAP guidelines recommending selective cholesterol screening in pediatric patients ages 2-21 years with risk factors associated with obesity, diabetes, metabolic syndrome or other risk factors and a positive family history of heart disease. Treatment should be started if LDL-cholesterol levels are higher than 190 mg/dL. Recent evidence has shown an

association between dyslipidemia and atherosclerosis in childhood. Evidence supports early detection and control of dyslipidemia throughout youth and into adulthood reduces CVD risk.

## C. DEFINITIONS

- **Medically necessary** – health products, supplies or services that are necessary for the diagnosis or treatment of disease, illness, or injury and meet accepted guidelines of medical practice
- **Cholesterol** - White, crystalline substance found in animal tissues and various foods that is normally synthesized by the liver and is important as a constituent of cell membrane and a precursor to steroid hormones; its level in the bloodstream can influence the pathogenesis of certain conditions, such as the development of atherosclerotic plaque and coronary artery disease
- **Coronary Heart Disease (CHD) -** Any heart disorder caused by disease of the coronary arteries
- **High Density Lipoprotein (HDL)** - A lipoprotein that transports cholesterol in the blood; composed of a high proportion of protein and relatively little cholesterol. High levels are thought to be associated with decreased risk of CHD and atherosclerosis
- **Low Density Lipoprotein (LDL)** - A lipoprotein that transports cholesterol in the blood; composed of a moderate amount of protein and a large amount of cholesterol. High levels are thought to be associated with increased risk of CHD and atherosclerosis
- **High-sensitivity C-reactive protein (hs-CRP)**- A protein produced in the liver that is a marker of inflammation
- **Apolipoprotein B (apo B)** - The primary apolipoprotein of LDL, important in the transport of cholesterol in the body and the regulation of cholesterol levels in the blood and cells
- **Immunoassay** - Any laboratory method for detecting a substance by using an antibody reactive with it
- **Framingham Risk Scoring**- a gender specific algorithm used to estimate cardiovascular risk
- **Lipid** - Oily organic compound insoluble in water but soluble in organic solvents; essential structural component of living cells (along with proteins and carbohydrates)
- **Peripheral Arterial Disease (PAD)** - A narrowing of the vessels that carry blood to the legs, arms, abdomen or kidneys; also known as peripheral vascular disease (PVD).
- **Plaque** - Deposit of fatty material on the inner lining of an arterial wall; characteristic of atherosclerosis
- **Triglyceride** – Naturally occurring ester (compound) of three fatty acids and glycerol that is the chief constituent of fats and oils
- **Unsaturated** - Capable of taking up, or of uniting with, certain other elements or compounds, without the elimination of any side

## D. POLICY

I. CareSource members may be eligible for standard lipid testing without prior authorization for evaluating atherosclerotic cardiovascular disease, testing includes:
   A. HDL (High Density Lipoprotein)
   B. LDL (Low Density Lipoprotein)
   C. Total Cholesterol
   D. Triglycerides

II. Apo-B (Apolipoprotein) measurement is considered medically necessary for patients considered high risk with 1 or more of the following criteria:
   A. Diabetes Mellitus
   B. Known CVD
   C. Two or more CVD risk factors, including:
      1. Cigarette smoking
      2. Positive family history of early onset CVD
      3. Hypertension

III. Conditions in which lipid testing may be indicated include:
- A. Assessment of patients with atherosclerotic cardiovascular disease.
- B. Evaluation of primary dyslipidemia.
- C. Any form of atherosclerotic disease, or any disease leading to the formation of atherosclerotic disease.
- D. Diagnostic evaluation of diseases associated with altered lipid metabolism, such as: nephrotic syndrome, pancreatitis, hepatic disease, and hypo and hyperthyroidism.
- E. Secondary dyslipidemia, including diabetes mellitus, disorders of gastrointestinal absorption, chronic renal failure.
- F. Signs or symptoms of dyslipidemias, such as skin lesions.
- G. As follow-up to the initial screen for coronary heart disease (total cholesterol + HDL cholesterol) when total cholesterol is determined to be high (>240 mg/dL), or borderline-high (200-240 mg/dL) plus two or more coronary heart disease risk factors, or an HDL cholesterol, <35 mg/dl.
- H. Antipsychotic Drug Monitoring every 6 months

IV. Electrophoretic or other quantitation of lipoproteins may be indicated if the patient has a primary disorder of lipoid metabolism.

V. Lipid panel and hepatic panel testing may be used for patients with severe psoriasis which has not responded to conventional therapy and for which the retinoid etretinate has been prescribed and who have developed hyperlipidemia or hepatic toxicity. Specific examples include erythrodermia and generalized pustular type and psoriasis associated with arthritis.

VI. Monitoring
- A. Monitoring patients on anti-lipid dietary management and pharmacologic therapy for the treatment of elevated blood lipid disorders, total cholesterol, HDL cholesterol and LDL cholesterol may be used. Triglycerides may be obtained if this lipid fraction is also elevated or if the patient is put on drugs (for example, thiazide diuretics, beta blockers, estrogens, glucocorticoids, and tamoxifen) which may raise the triglyceride level.
- B. When monitoring long term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels, it may be reasonable to perform the lipid panel annually. A lipid panel at a yearly interval will usually be adequate while measurement of the serum total cholesterol or a measured LDL should suffice for interim visits if the patient does not have hypertriglyceridemia.
- C. Any one component of the panel or a measured LDL may be reasonable and necessary up to six times the first year for monitoring dietary or pharmacologic therapy. More frequent total cholesterol HDL cholesterol, LDL cholesterol and triglyceride testing may be indicated for marked elevations or for changes to anti-lipid therapy due to inadequate initial patient response to dietary or pharmacologic therapy. The LDL cholesterol or total cholesterol may be measured three times yearly after treatment goals have been achieved.

VII. Statin Medication
- A. The new ACC/AHA guidelines cited above identify four separate groups of patients who may benefit from the use of a statin medication to reduce cardiovascular risk:
  1. Individuals with clinical atherosclerotic cardiovascular disease (ASCVD)
  2. Individuals with primary elevation of low-density lipoprotein cholesterol (LDL-C) higher than 190 mg/dL,
  3. Individuals aged 40-75 years with diabetes with an LDL-C between 70 and 189 mg/dL,
  4. Individuals without clinical ASCVD or diabetes aged 40-75 years with an LDL-C from 70-189 mg/dL and an estimated 10-year atherosclerotic cardiovascular risk (as identified by a risk calculator) of 7.5% or greater.

VIII. Non-Covered Services

A. CareSource members may NOT be eligible under the Plan for CVD lipid testing listed below or for any other testing or indications other than those listed above. These technologies are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

1. Note: Non-covered tests related to this policy include, but may not be limited to, the following:
   - 1.1. Apolipoprotein A-1 (apo A-1)
   - 1.2. Apolipoprotein E (apo E)
   - 1.3. Comprehensive lipid panel (e.g., VAP)
   - 1.4. Fibrinogen
   - 1.5. Galectin-3
   - 1.6. HDL subclass
   - 1.7. Homocysteine
   - 1.8. LDL subclasses (e.g., NMR)
   - 1.9. Lipoprotein(a) (Lp[a])
   - 1.10. Lipoprotein-associated phospholipase A2 (Lp-PLA2 or PLAC
   - 1.11. Lipoprotein remnants - intermediate density lipoproteins (IDL) and small densitylipoproteins)
   - 1.12. Long-chain omega-3 fatty acids
   - 1.13. Skin cholesterol (e.g., PREVU)

## E. CONDITIONS OF COVERAGE

**HCPCS**
**CPT**

**AUTHORIZATION PERIOD**

## F. RELATED POLICIES/RULES

N/A

## G. REVIEW/REVISION HISTORY

| | DATE | ACTION |
|---|---|---|
| **Date Issued** | 11/17/2015 | New Policy. |
| **Date Revised** | | |
| **Date Effective** | 11/01/2018 | |

## H. REFERENCES

1. National Coverage Determination (NCD) for Lipid Testing (190.23). (2005, March 1).
2. Division for Heart Disease and Stroke Prevention. (2017, August 23).
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7. Stone, N. J., Robinson, J. G., Lichtenstein, A. H., Merz, C. N., Blum, C. B., Eckel, R. H., . . . Wilson, P. W. (2014, June 24). 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults.
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**The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.**