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# MEDICAL POLICY – 2.04.100

# Cardiovascular Risk Panels

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| BCBSA Ref. Policy: | 2.04.100 | |
| Effective Date: | Feb. 1, 2023 | RELATED MEDICAL POLICIES: |
| Last Revised: | Jan. 23, 2023 | 2.02.16 Ultrasonographic Measurement of Carotid Intimal-Medial Thickness as an Assessment of Subclinical Atherosclerosis |
| Replaces: | 2.04.509 | |

**Select a hyperlink below to be directed to that section.**

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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## Introduction

Studies prove that certain blood tests can help predict who is at higher risk of developing heart disease. These tests include things like total cholesterol, low-density lipoproteins (LDL) and high-density lipoproteins (HDL) cholesterol, and triglycerides. There are other types of heart-risk tests that look at many other things. These are known as cardiovascular risk panels. These panels can test genes, markers that don't relate to the heart, metabolism, and inflammation. Medical studies do not show there is enough evidence that these types of heart-risk panels will bring better health results than already proven tests. For this reason, cardiovascular risk panels are not medically necessary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

| Panel | Medical Necessity |
| --- | --- |
| **Cardiovascular risk panels** | **Cardiovascular risk panels, consisting of multiple individual biomarkers intended to assess cardiac risk (other than simple lipid panels*) are considered not medically necessary.**<br>• Some examples of commercially available cardiovascular risk panels include, but are not limited to, the following (see **Evidence Review** for more details):<br>○ Applied Genetics Cardiac Panel<br>○ Atherotech® Diagnostics Lab CVD Risk Panel and VAP Lipid Panel<br>○ Boston Heart Cardiovascular Risk Markers Panels<br>○ CardioVIP/Spectracell Metabolic Characterization Panel<br>○ Genetiks Genetic Diagnosis and Research Center Cardiovascular Risk Panel<br>○ Genova Diagnostics CV Health Plus Genomics™ Panel, Cardiovascular Health Profile<br>○<br>○ Quest Diagnostics Cardio IQ® (advanced lipid panel)<br>○ Quest Diagnostics/Cleveland HeartLab® it™ inflammation testing (inflammatory biomarkers)<br>○ Singulex SMC™ Cardiac function and Inflammation testing<br>○ Veridia Diagnostics SMC™ cardiac function<br><br>***Lipid Panels:**<br>• A simple lipid panel is generally composed of the following lipid measures:<br>○ Total cholesterol<br>○ Low-density lipoprotein (LDL) cholesterol<br>○ High-density lipoprotein (HDL) cholesterol<br>○ Triglycerides<br>• Certain calculated ratios, such as the total/HDL cholesterol may also be reported as part of a simple lipid panel.<br>• Other types of lipid testing (i.e., apolipoproteins, lipid particle number or particle size, lipoprotein a, etc.) are not considered components of a simple lipid profile. |

| Panel | Medical Necessity |
|---|---|
| | **Note:** This policy does not address the use of panels of biomarkers in the diagnosis of acute myocardial infarction. |

## Coding

| Code | Description |
|---|---|
| **CPT** | |
| 83698 | Lipoprotein-associated phospholipase A2 (Lp-PLA2) |

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## Related Information

N/A

## Evidence Review

### Description

Cardiovascular risk panels refer to different combinations of cardiac markers that are intended to evaluate the risk of developing cardiovascular disease (CVD). There are numerous commercially available risk panels that include different combinations of lipids, noncardiac biomarkers, measures of inflammation, metabolic parameters, and/or genetic markers. Risk panels report the results of multiple individual tests, as distinguished from quantitative risk scores that combine the results of multiple markers into a single score.

# Background

## Cardiovascular Disease

Cardiovascular disease (CVD) remains the single largest cause of morbidity and mortality in the developed world. Mortality from CVD has accounted for 1 in 4 deaths in the United States, and there are numerous socio-economic factors that affect CVD mortality rates.[1] Lower-income, race, age, and behavioral factors all have a significant impact on health outcome disparities associated with CVD.

As a result, accurate prediction of CVD risk is a component of medical care that has the potential to focus on and direct preventive and diagnostic activities. Current methods of risk prediction in use in general clinical care are not highly accurate and, as a result, there is a potential unmet need for improved risk prediction instruments.

### Risk Assessment

Components of CVD risk include family history, cigarette smoking, hypertension, and lifestyle factors such as diet and exercise. Also, numerous laboratory tests have been associated with CVD risk, most prominently lipids such as low-density lipoprotein (LDL) and high-density lipoprotein (HDL). These clinical and lipid factors are often combined into simple risk prediction instruments, such as the Framingham Risk Score.[2] The Framingham Risk Score provides an estimate of the ten-year risk for developing cardiac disease and is currently used in clinical care to determine the aggressiveness of risk factor intervention, such as the decision to treat hyperlipidemia with statins.

Many additional biomarkers, genetic factors, and radiologic measures have been associated with increased risk of CVD. Over 100 emerging risk factors have been proposed as useful for refining estimates of CVD risk.[3-5] Some general categories of these potential risk factors are as follows:

- **Lipid markers.** In addition to LDL and HDL, other lipid markers may have predictive ability, including the apolipoproteins, lipoprotein (a) (Lp[a]), lipid subfractions, and/or other measures.
- **Inflammatory markers.** Many measures of inflammation have been linked to the likelihood of CVD. High-sensitivity C-reactive protein (hs-CRP) is an example of an inflammatory marker; others include fibrinogen, interleukins, and tumor necrosis factor.

- **Metabolic syndrome biomarkers.** Measures associated with metabolic syndrome, such as specific dyslipidemic profiles or serum insulin levels, have been associated with an increased risk of CVD.
- **Genetic markers.** A number of variants associated with increased thrombosis risk, such as the 5,10-methylene tetrahydrofolate reductase (MTHFR) variant or the prothrombin gene variants, have been associated with increased CVD risk. Also, numerous single-nucleotide variants have been associated with CVD in large genome-wide studies.

***Risk Panel Testing***

CVD risk panels may contain measures from one or all of the previous categories and may include other measures not previously listed such as radiologic markers (carotid medial thickness, coronary artery calcium score). Some CVD risk panels are relatively limited, including a few markers in addition to standard lipids. Others include a wide variety of potential risk factors from a number of different categories, often including both genetic and non-genetic risk factors. Other panels are composed entirely of genetic markers.

Some examples of commercially available CVD risk panels are as follows:

- **CV Health Plus Genomics™ Panel (Genova Diagnostics):** apolipoprotein (apo)E; prothrombin; factor V Leiden; fibrinogen; HDL; HDL size; HDL particle number; homocysteine; LDL; LDL size; LDL particle number; Lp-(a); lipoprotein-associated phospholipase A2 (Lp-PLA2); MTHFR gene; triglycerides; very low-density lipoprotein (VLDL); VLDL size; vitamin D; hs-CRP.
- **CV Health Plus™ Panel (Genova Diagnostics):** fibrinogen; HDL; HDL size; HDL particle number; homocysteine; LDL; LDL size; LDL particle number; lipid panel; Lp(a); Lp-PLA2; triglycerides; VLDL; VLDL size; vitamin D; hs-CRP.
- **CVD Inflammatory Profile (Cleveland HeartLab):** hs-CRP, urinary microalbumin, myeloperoxidase, Lp-PLA2, F2-isoprostanes.
- **Applied Genetics Cardiac Panel:** genetic variants associated with coronary artery disease: cytochrome p450 variants associated with the metabolism of clopidogrel, ticagrelor, warfarin, β-blockers, rivaroxaban, prasugrel (2C19, 2C9/VKORC1, 2D6, 3A4/3A5), factor V Leiden, prothrombin gene, MTHFR gene, APOE gene.
- **Genetiks Genetic Diagnosis and Research Center Cardiovascular Risk Panel:** factor V Leiden, factor V R2, prothrombin gene, factor XIII, fibrinogen-455, plasminogen activator

inhibitor-1( PAI-1), platelet GP IIIA variant HPA-1 (PLA1/2), MTHFR gene, angiotensin-converting enzyme insertion/deletion (ACE I/D), apo B, apo E.

In addition to panels that are specifically focused on CVD risk, a number of commercially available panels include markers associated with cardiovascular health, along with a range of other markers that have been associated with inflammation, thyroid disorders and other hormonal deficiencies, and other disorders. Examples of these panels include:

- **WellnessFX Premium (WellnessFX):** total cholesterol, HDL, LDL, triglycerides, apo A1, apo B, LP(a), Lp-PLA2, omega-3 fatty acids, free fatty acids, lipid particle numbers, lipid particle sizes, blood urea nitrogen(BUN)/creatinine, aspartate aminotransferase (AST) and alanine aminotransferase(ALT), total bilirubin, albumin, total protein, dehydroepiandrosterone (DHEA), free testosterone, total testosterone, estradiol, sex hormone binding globulin, cortisol, insulin-like growth factor (ILGF)-1, insulin, glucose, hemoglobin A1c, total T4, T3 uptake, free T4 index, thyroid-stimulating hormone(TSH), total T3, free T3, reverse T3, free T4, hs-CRP, fibrinogen, homocysteine, complete blood count (CBC) with differential, calcium, electrolytes, bicarbonate, ferritin, total iron binding capacity(TIBC), vitamin B12, red blood cell (RBC) magnesium, 25-hydroxy vitamin D, progesterone, follicle stimulating hormone (FSH), luteinizing hormone.(LH)[6]

## Summary of Evidence

For individuals who have risk factors for CVD who receive CVD risk panels, the evidence includes multiple cohort and case-control studies and systematic reviews of these studies. The relevant outcomes are test validity, other test performance measures, change in disease status, and morbid events. The available evidence from cohort and case-control studies indicates that many of the individual risk factors included in CVD risk panels are associated with an increased risk of CVD. However, it is not clear how the results of individual risk factors impact management changes, so it is also uncertain how the panels will impact management decisions. Given the lack of evidence for the clinical utility of any individual risk factor beyond simple lipid measures, it is unlikely that the use of CVD risk panels improves outcomes. Studies that have evaluated the clinical validity of panels of multiple markers have not assessed management changes that would occur as a result of testing or demonstrated improvements in outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1**.

## Table 1. Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| **Ongoing** | | | |
| NCT03599531 | A Pilot Study to Evaluate the Utility of the SomaLogic CVD Secondary Risk Panel as a Tool to Stratify Cardiovascular Risk | 244 | Oct 2020 |

NCT: national clinical trial.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## American College of Cardiology / American Heart Association

In 2013, the American College of Cardiology and the American Heart Association issued joint guidelines for the assessment of cardiovascular disease risk.[30] These guidelines recommended that age- and sex-specific pooled cohort equations, which included total cholesterol and high-density lipoprotein to predict the ten-year risk of a first hard atherosclerotic cardiovascular disease event, be used in non-Hispanic blacks and non-Hispanic whites between 40 and 79 years of age (American Heart Association/American College of Cardiology class of recommendation I, American Heart Association/American College of Cardiology level of

evidence B). Regarding newer risk markers after quantitative risk assessment, the guidelines stated the following: "If, after quantitative risk assessment, a risk-based treatment decision is uncertain, assessment of ≥1 of the following—family history, hs-CRP [high-sensitivity C-reactive protein], CAC [coronary artery calcium] score, or ABI [ankle-brachial index]—may be considered to inform treatment decision-making" (class of recommendation IIb; level of evidence B). The guidelines did not recommend other novel cardiac risk factors or panels of cardiac risk factors.

In 2019, the American College of Cardiology/American Heart Association issued a special report on the use of risk assessment tools to guide decision-making in the primary prevention of atherosclerotic CVD.[31] Although the report did not recommend specific novel cardiac risk factors or panels of cardiac risk factors, it discusses features of current US-based CV risk assessment tools including the Reynolds Risk Score, which includes hs-CRP level as one of its variables, mentions risk-enhancing factors for a clinician-patient risk discussion including elevated hs-CRP, lipoprotein(a), and apolipoprotein B levels, and the use of CAC measurement to reclassify CVD risk.

## European Society of Cardiology/European Atherosclerosis Society

In 2019, the European Society of Cardiology and European Atherosclerosis Society published a guideline for the management of dyslipidaemias: lipid modification to reduce CV risk.[32] This guideline contains updated recommendations for lipid analyses for CV disease risk estimation. Beyond traditional lipid markers (i.e., total cholesterol, HDL, LDL, and triglycerides), the guideline recommends non-HDL-C "for risk assessment, particularly in people with high triglyceride levels, diabetes mellitus, obesity, or very low LDL-C levels" [Class I recommendation: Level C evidence (consensus of opinion of the experts and/or small studies, retrospective studies, registries)]. Apolipoprotein B is recommended "for risk assessment, particularly in people with high triglyceride levels, diabetes mellitus, obesity, metabolic syndrome, or very low LDL-C levels. It can be used as an alternative to LDL-C, if available, as the primary measurement for screening, diagnosis, and management, and may be preferred over non-HDL-C in people with high triglyceride levels, diabetes mellitus, obesity, or very low LDL-C levels" [Class I recommendation: Level C evidence]. Additionally, the guideline states that lipoprotein(a) measurement "should be considered at least once in each adult person's lifetime to identify those with very high inherited lipoprotein(a) levels > 180 mg/dL who may have a lifetime risk of atherosclerotic CVD equivalent to the risk associated with heterozygous familial hypercholesterolemia" and "should be considered in selected individuals with a family history of premature CVD, and for reclassification in people who are borderline between moderate and high-risk" [Class IIa recommendation; Level C evidence].

In 2021, the European Society of Cardiology published a guideline on CVD prevention, however, the guideline did not recommend specific novel cardiac risk factors or panels of cardiac risk factors for the assessment of CVD risk.[33] The guideline states that "main causal and modifiable ASCVD [atherosclerotic cardiovascular disease] risk factors are blood apolipoprotein-B-containing lipoproteins, high BP [blood pressure], cigarette smoking, and DM [diabetes mellitus]". The guideline also states that the ankle brachial index may be considered as a risk modifier in CVD risk assessment but the "routine collection of other potential modifiers, such as genetic risk scores, circulating or urinary biomarkers, or vascular tests or imaging methods (other than CAC scoring or carotid ultrasound for plaque determination), is not recommended."

## U.S. Preventive Services Task Force Recommendations

No recommendations specific to the use of cardiovascular disease risk panels were identified. In 2018, the U.S. Preventive Services Task Force updated its recommendation on the use of nontraditional risk factors in CVD risk assessment:

> The USPSTF concludes that there are insufficient adequately powered clinical trials evaluating the incremental effect of the ankle-brachial index (ABI), high-sensitivity C-reactive protein (hsCRP) level, or coronary artery calcium (CAC) score in risk assessment and initiation of preventive therapy. Furthermore, the clinical meaning of improvements in measures of calibration, discrimination, and reclassification risk prediction studies is uncertain."[34]

## Medicare National Coverage

There is no national coverage determination.

## Regulatory Status

Multiple assay methods for cardiac risk marker components, such as lipid panels and other biochemical assays, have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process.

Other components of testing panels are laboratory-developed tests. Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed

by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the FDA has chosen not to require any regulatory review of this test.

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## History

| Date | Comments |
|---|---|
| 03/01/20 | New policy, approved February 4, 2020. This policy replaces 2.04.509 (originally effective November 2013) which is now deleted effective March 1, 2020. Policy created with literature review through October 2019. Policy statement unchanged from previous policy. |
| 03/01/21 | Annual Review, approved February 2, 2021.Policy updated with literature review through October 19, 2020; references added. Policy statement unchanged. |
| 03/01/22 | Annual Review, approved February 7, 2022. Policy updated with literature review through November 10, 2021; references added. Policy statement unchanged. |
| 02/01/23 | Annual Review, approved January 23, 2023. Policy updated with literature review through October 25, 2022; references added; DEI refinements added. Policy statement unchanged. Added examples to list of cardiovascular risk panels considered not medically necessary: Quest Diagnostics Cardio IQ®, Quest Diagnostics/Cleveland HeartLab® it™ inflammation testing, Singulex SMC™ cardiac function and inflammation testing. |



**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

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MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totogi, mo oe, Telefoni mai: 800-722-1471 (TTY: 711).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 800-722-1471 (TTY: 711).

注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。800-722-1471 （TTY:711）まで、お電話にてご連絡ください。

PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-722-1471 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 800-722-1471 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ ኣማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-722-1471 (መስማት ለተሳናቸው፡ 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-722-1471 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

**توجه**: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.