



MEDICAL COVERAGE GUIDELINES
SECTION: LABORATORY

ORIGINAL EFFECTIVE DATE: 04/22/14
LAST REVIEW DATE: 01/22/19
LAST CRITERIA REVISION DATE: 05/24/16
ARCHIVE DATE:

CARDIOVASCULAR RISK PANELS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Cardiovascular risk panels are comprised of different combinations of cardiac and noncardiac markers that are intended to evaluate risk of cardiovascular (CV) disease. The panels 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. Components of cardiovascular risk may include family history, cigarette smoking, hypertension and lifestyle factors such as diet and exercise.



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CARDIOVASCULAR RISK PANELS (cont.)

Description: (cont.)

Cardiovascular risk panels have been investigated as an aid to focus and direct preventive and diagnostic activities.

Over 100 emerging risk factors have been proposed as useful for refining estimates of cardiovascular risk. Some general categories of these potential risk factors include:

- **Lipid markers:** A simple lipid panel is generally composed of total cholesterol, low-density lipoproteins (LDL), high-density lipoproteins (HDL) and triglycerides. In addition, certain calculated ratios, such as the total/HDL cholesterol may be reported as part of a simple lipid panel. In addition to LDL and HDL, other lipid markers may have predictive ability, including the apolipoproteins, lipoprotein (a), lipid subfractions and/or other measures.
- **Inflammatory markers:** Many measures of inflammation have been linked to the likelihood of CV disease. High-sensitivity c-reactive protein (CRP) is one 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 increased risk of CV disease.
- **Genetic markers:** A number of mutations associated with increased thrombosis risk, such as the MTHFR mutation or the prothrombin gene mutations, have been associated with increased CV risk. In addition, numerous single nucleotide polymorphisms (SNPs) have been associated with CV disease.

CV risk panels may contain measures from one or all of the above categories, and may include additional measures not listed above such as radiologic markers (carotid CMT, calcium score). Some cardiovascular 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 nongenetic risk factors. Other panels are composed entirely of genetic markers.

Commercially available cardiovascular risk panels, include, but are not limited to:

- Applied Genetics Cardiac Panel
- VAP Cholesterol Test VAP Diagnostics Laboratory
- Boston Heart Diagnostics® Advanced Risk Markers Panel
- Cleveland HeartLab® CVD Inflammatory Biomarker Testing
- Genetiks® Genetic Diagnosis and Research Center Cardiovascular Risk Panel
- GenovaSM Diagnostics CV Health Plus Genomics™ Panel
- GenovaSM Diagnostics CV Health Plus™ Panel
- Health Diagnostics Laboratory, Inc. Advanced Cardio Vascular Panel
- Metamatrix Cardiovascular Health Profile
- Singulex® Cardiac-Related Test Panels



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CARDIOVASCULAR RISK PANELS (cont.)

Description: (cont.)

In addition to panels that are specifically focused on cardiovascular risk, a number of commercially-available panels include makers 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.

Commercially available panels as described above, include, but are not limited to:

- Singulex Cardiometabolic Panel
- Wellness FX Premium

Definitions:

Genetic Testing:

Analysis of DNA, RNA, chromosomes, proteins and certain metabolites in order to detect alterations related to an inherited disorder.

Gene:

A hereditary unit consisting of segments of DNA that occupies a specific location on chromosomes. Genes undergo mutation when their DNA sequence changes.

Genetic Counseling:

Instruction that provides interpretation of genetic tests and information about courses of action that are available for the care of an individual with a genetic disorder or for future family planning.

Affected Individual:

An individual displaying signs or symptoms characteristic of a suspected or specific inherited disorder.

Unaffected Individual:

An individual who displays no signs or symptoms characteristic of a suspected or specific inherited disorder.

Screening:

Genetic screening is the testing of an individual with no symptoms for a specific inherited disorder to determine if the individual carries an abnormal gene. Screening can be used to predict risk or potential risk for the individual or their offspring.

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CARDIOVASCULAR RISK PANELS (cont.)

Criteria:

- Cardiovascular genetic testing and/or counseling of an **unaffected** individual, regardless of risk factors is considered **screening** and **not eligible for coverage**.
- Cardiovascular genetic testing and/or counseling of an **affected** individual to confirm a disease when confirmation of the diagnosis would not impact the care and/or management is considered **not medically necessary** and **not eligible for coverage**.
- Cardiovascular risk panels (e.g., lipids, noncardiac biomarkers, measures of inflammation, metabolic parameters, and/or genetic testing and/or counseling) for the assessment of cardiovascular disease is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 01/30/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 2.04.100 BCBS Association Medical Policy Reference Manual. Cardiovascular Risk Panels. Re-issue date 12/14/2017, issue date 11/14/2013.



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CARDIOVASCULAR RISK PANELS (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilínigíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

