



MEDICAL COVERAGE GUIDELINES
SECTION: LABORATORY

ORIGINAL EFFECTIVE DATE: 06/20/17
LAST REVIEW DATE: 06/19/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

MOLECULAR TESTING IN THE MANAGEMENT OF PULMONARY NODULES

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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MOLECULAR TESTING IN THE MANAGEMENT OF PULMONARY NODULES (cont.)

Description:

Plasma-based proteomic screening and gene expression profiling of bronchial brushing are molecular diagnostic tests used in the diagnostic workup of pulmonary nodules. Pulmonary nodules are common and may be found as an incidental finding on a chest x-ray or CT scan or in lung cancer screening studies of smokers. Molecular diagnostic tests have been investigated to aid in risk-stratifying individuals to eliminate the need for subsequent invasive diagnostic procedures.

Proteomics is the study of the structure and function of proteins. The study of the concentration, structure and other characteristics of proteins in various bodily tissues, fluids and other materials have been investigated as a method of identifying and managing various diseases , including cancers.

Plasma-based proteomic screening is a molecular test that measures the relative abundance of proteins from multiple disease pathways associated with lung cancer using an analytic technique called multiple reaction monitoring mass spectroscopy (MRM-mass spec). The role of the test is to aid physicians in differentiating likely benign versus malignant nodules. The test is only used to rule-in or rule-out for invasive diagnostic procedures and does not provide a diagnosis of lung cancer. Xpresys® Lung (Indi®) is a laboratory developed test and is available under the auspices of Clinical Laboratory Improvement Amendments (CLIA).

Gene expression profiling is the measurement of the activity of genes with cells. Gene expression profiling in molecular diagnostics is used to detect cancer-associated gene expression of clinical samples to assess the risk of malignancy. The Percepta® Bronchial Genomic Classifier is a 23-gene gene expression profiling test that analyzes genomic changes in the airways of current and former smokers with cancer to assess a patient's risk of having lung cancer, without the direct testing of a pulmonary nodule. The test is only indicated for current and former smokers following an indeterminate bronchoscopy result to determine subsequent management of pulmonary nodules, e.g., active surveillance or invasive diagnostic procedures and does not provide a diagnosis of lung cancer. Percepta® Bronchial Genomic Classifier (Veracyte) is a laboratory developed test and is available under the auspices of CLIA.

MOLECULAR TESTING IN THE MANAGEMENT OF PULMONARY NODULES (cont.)

Criteria:

- Plasma-based proteomic screening to evaluate individuals for the treatment of undiagnosed pulmonary nodules detected by computed tomography 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.

These tests include, *but are not limited to*:

- Xpresys Lung (Indi®)

- Gene expression profiling on bronchial brushings in individuals with indeterminate bronchoscopy results from undiagnosed pulmonary nodules 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.

These tests include, *but are not limited to*:

- Percepta Bronchial Genomic Classifier (Veracyte)

Resources:

Literature reviewed 06/19/18. 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. 2.04.142 BCBS Association Medical Policy Reference Manual. Molecular Testing in the Management of Pulmonary Nodules. Re-issue date 05/04/2018, issue date 05/08/2017.



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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 hólo díí t'áa hazaadk'ehjí háká a'doowolgo bee haz'á doo baqah ilínigóó. 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.

