BlueCross BlueShield Arizona

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EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 09/19/22**
SECTION: LABORATORY	**LAST REVIEW DATE: 07/24/24**
	CURRENT EFFECTIVE DATE: 07/24/24
	LAST CRITERIA REVISION DATE: 07/24/24
NEXT ANNUAL REVIEW DATE: 3RD QTR 2025	**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 Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria 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.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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MOLECULAR TESTING IN THE MANAGEMENT OF PULMONARY NODULES

Description:

Plasma-based proteomic screening and gene expression profiling of bronchial brushing are molecular tests available in the diagnostic workup of pulmonary nodules. To rule out malignancy, invasive diagnostic procedures such as computed tomography-guided biopsies, bronchoscopies, or video-assisted thoracoscopic procedures are often required, but each carry procedure-related complications ranging from postprocedure pain to pneumothorax. Molecular diagnostic tests have been proposed to aid in risk-stratifying individuals to eliminate or necessitate the need for subsequent invasive diagnostic procedures.

Pulmonary Nodules

Pulmonary nodules are a common clinical problem that may be found incidentally on a chest x-ray or computed tomography (CT) scan or during lung cancer screening studies of smokers. The primary question after the detection of a pulmonary nodule is the probability of malignancy, with subsequent management of the nodule based on various factors such as the radiographic characteristics of the nodules (e.g., size, shape, density) and individual factors (e.g., age, smoking history, previous cancer history, family history, environmental/occupational exposures). The key challenge in the diagnostic workup for pulmonary nodules is appropriately ruling in individuals for invasive diagnostic procedures and ruling out individuals who should forego invasive diagnostic procedures. However, due to the low positive predictive value of pulmonary nodules detected radiographically, many unnecessary invasive diagnostic procedures and/or surgeries are performed to confirm or eliminate the diagnosis of lung cancer.

Plasma-Based Proteomic Screening for Pulmonary Nodules

Plasma-based proteomic screening has been investigated to risk-stratify pulmonary nodules as likely benign to increase the number of individuals who undergo serial CT scans of their nodules (active surveillance), instead of invasive procedures such as CT-guided biopsy or surgery. Additionally, proteomic testing may also determine a likely malignancy in clinically low-risk or intermediate-risk pulmonary nodules, thereby permitting earlier detection in a subset of individuals.

Nodify XL2 (BDX-XL2) is a plasma-based proteomic screening 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. The test helps physicians identify lung nodules that are likely benign or at lower risk of cancer. If the test yields a "likely benign" or "reduced risk" result, patients may choose active surveillance via serial CT scans to monitor the pulmonary nodule. Earlier generations of the Nodify XL2 test include Xpresys Lung®
and Xpresys Lung 2®.

Nodify CDT® is a proteomic test that uses multi-analyte immunoassay technology to measure autoantibodies associated with tumor antigens. The test helps physicians identify lung nodules that are likely malignant or at higher risk of cancer. Patients with a "high level" Nodify CDT test result have a higher risk of malignancy than predicted by clinical factors alone; invasive diagnostic procedures would be indicated in these cases.

The Nodify XL2 and Nodify CDT tests are therefore only used in the management of pulmonary nodules to rule out or rule in, invasive diagnostic procedures; they do not diagnose lung cancer. These tests are offered together as Biodesix's Nodify Lung® testing strategy, but physicians may also choose to order each test independently.

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MOLECULAR TESTING IN THE MANAGEMENT OF PULMONARY NODULES

Description:

REVEAL Lung Nodule Characterization (MagArray) is a plasma-protein biomarker test that may aid clinicians in characterizing indeterminate pulmonary nodules (4 to 30 mm) in current smokers 25 years of age and older. The test is based on a multianalyte assay with a proprietary algorithmic analysis using immunoassay, microarray, and magnetic nanoparticle detection techniques to obtain laboratory data for calculation of the risk score for lung cancer. The REVEAL Lung Nodule Characterization is presented on a scale from 0 to 100 with a single cut point at 50. The score is based on the measurement of 3 clinical factors (age, sex, and nodule diameter) and 3 proteins (epidermal growth factor receptor, prosurfactant protein B, and tissue inhibitor of metalloproteinases 1) associated with the presence of lung cancer. It may aid a clinician in the decision to perform a biopsy or to consider routine monitoring. It is not intended as a screening or stand-alone diagnostic assay.

Gene Expression Profiling for an Indeterminate Bronchoscopy Result
The first generation Percepta Bronchial Genomic Classifier was a 23-gene, GEP test that analyzed genomic changes in the airways of current or former smokers to assess a individual's risk of having lung cancer, without the direct testing of a pulmonary nodule. This classifier was designed to be a “rule-out” test for intermediate-risk patients. The second generation Percepta Genomic Sequencing Classifier was developed to serve as both a “rule-in” test and a “rule-out” test, thereby increasing its potential utility in improving risk stratification. The test is indicated for current and former smokers following an indeterminate bronchoscopy result to determine the subsequent management of pulmonary nodules (e.g., active surveillance or invasive diagnostic procedures), and does not diagnose lung cancer.

Criteria:

- Plasma-based proteomic screening in individuals with undiagnosed pulmonary nodules detected by computed tomography is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

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

  - Nodify CDT®
  - Nodify XL2® (BDX-XL2)
  - REVEAL Lung Nodule Characterization (MagArray)

MOLECULAR TESTING IN THE MANAGEMENT OF PULMONARY NODULES

Criteria:

- Gene expression profiling on bronchial brushings in individuals with indeterminate bronchoscopy results from undiagnosed pulmonary nodules is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

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

  - Percepta® Genomic Sequencing Classifier

Resources:

Literature reviewed 07/24/24. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 07/24/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Biodesix. Nodify Lung: Lung Nodule Management. 2023. Accessed March 27, 2024. https://www.biodesix.com/our-tests/nodify-lung

2. Detterbeck FC, Lewis SZ, Diekemper R, Addrizzo-Harris D, Alberts WM. Executive Summary: Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest*. May 2013;143(5 Suppl):7S-37S. doi:10.1378/chest.12-2377

3. Ferguson JS, Van Wert R, Choi Y, et al. Impact of a bronchial genomic classifier on clinical decision making in patients undergoing diagnostic evaluation for lung cancer. *BMC Pulm Med*. May 17 2016;16(1):66. doi:10.1186/s12890-016-0217-1

4. Gould MK, Donington J, Lynch WR, et al. Evaluation of individuals with pulmonary nodules: when is it lung cancer? Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest*. May 2013;143(5 Suppl):e93S-e120S. doi:10.1378/chest.12-2351

5. Kearney P, Hunsucker SW, Li XJ, Porter A, Springmeyer S, Mazzone P. An integrated risk predictor for pulmonary nodules. *PLoS One*. 2017;12(5):e0177635. doi:10.1371/journal.pone.0177635

6. Lee HJ, Mazzone P, Feller-Kopman D, et al. Impact of the Percepta Genomic Classifier on Clinical Management Decisions in a Multicenter Prospective Study. *Chest*. Jan 2021;159(1):401-412. doi:10.1016/j.chest.2020.07.067

7. Li XJ, Hayward C, Fong PY, et al. A blood-based proteomic classifier for the molecular characterization of pulmonary nodules. *Sci Transl Med*. Oct 16 2013;5(207):207ra142. doi:10.1126/scitranslmed.3007013

8. Mazzone P, Dotson T, Wahidi MM, et al. Clinical validation and utility of Percepta GSC for the evaluation of lung cancer. *PLoS One*. 2022;17(7):e0268567. doi:10.1371/journal.pone.0268567

9. Mazzone PJ, Sears CR, Arenberg DA, et al. Evaluating Molecular Biomarkers for the Early Detection of Lung Cancer: When Is a Biomarker Ready for Clinical Use? An Official American Thoracic Society Policy Statement. *Am J Respir Crit Care Med*. Oct 1 2017;196(7):e15-e29. doi:10.1164/rccm.201708-1678ST

10. National Comprehensive Cancer Network. NCCN Guidelines Version 2. 2024: Non-Small Cell Lung Cancer. 2023. Accessed March 25, 2024. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf

11. National Comprehensive Cancer Network. NCCN Guidelines Version 3.2024: Small Cell Lung Cancer. 2023. Accessed March 26, 2024. https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf

12. Pritchett MA, Sigal B, Bowling MR, et al. Assessing a biomarker's ability to reduce invasive procedures in patients with benign lung nodules: Results from the ORACLE study. *PLoS One*. 2023;18(7):e0287409. doi:10.1371/journal.pone.0287409

13. Rivera MP, Mehta AC, Wahidi MM. Establishing the diagnosis of lung cancer: Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest*. May 2013;143(5 Suppl):e142S-e165S. doi:10.1378/chest.12-2353

14. Silvestri GA, Tanner NT, Kearney P, et al. Assessment of Plasma Proteomics Biomarker's Ability to Distinguish Benign From Malignant Lung Nodules: Results of the PANOPTIC (Pulmonary Nodule Plasma Proteomic Classifier) Trial. *Chest*. Sep 2018;154(3):491-500. doi:10.1016/j.chest.2018.02.012

15. Silvestri GA, Vachani A, Whitney D, et al. A Bronchial Genomic Classifier for the Diagnostic Evaluation of Lung Cancer. *N Engl J Med*. Jul 16 2015;373(3):243-51. doi:10.1056/NEJMoa1504601

16. Tanner NT, Springmeyer SC, Porter A, et al. Assessment of Integrated Classifier's Ability to Distinguish Benign From Malignant Lung Nodules: Extended Analyses and 2-Year Follow-Up Results of the PANOPTIC (Pulmonary Nodule Plasma Proteomic Classifier) Trial. *Chest*. Mar 2021;159(3):1283-1287. doi:10.1016/j.chest.2020.10.069

17. Trivedi NN, Arjomandi M, Brown JK, et al. Risk assessment for indeterminate pulmonary nodules using a novel, plasma-protein based biomarker assay. *Biomed Res Clin Pract*. Dec 2018;3(4)doi:10.15761/brcp.1000173

18. Vachani A, Hammoud Z, Springmeyer S, et al. Clinical Utility of a Plasma Protein Classifier for Indeterminate Lung Nodules. *Lung*. Dec 2015;193(6):1023-7. doi:10.1007/s00408-015-9800-0

19. Vachani A, Pass HI, Rom WN, et al. Supplemental Materials for Validation of a Multi-Protein Plasma Classifier to Identify Benign Lung Nodules. April, 2015. Accessed April 1, 2022. https://cdn-links.lww.com/permalink/jto/a/jto_10_4_2015_01_07_massion_jto-d-14-00912_sdc1.pdf

20. Vachani A, Pass HI, Rom WN, et al. Validation of a multiprotein plasma classifier to identify benign lung nodules. *J Thorac Oncol*. Apr 2015;10(4):629-37. doi:10.1097/JTO.0000000000000447

21. Vachani A, Whitney DH, Parsons EC, et al. Clinical Utility of a Bronchial Genomic Classifier in Patients With Suspected Lung Cancer. *Chest*. Jul 2016;150(1):210-8. doi:10.1016/j.chest.2016.02.636

22. Veracyte. Percepta Genomic Sequencing Classifier for your patients. 2023. Accessed March 27, 2024. https://lung.veracyte.com/percepta-gsc/for-your-patients/

23. Whitney DH, Elashoff MR, Porta-Smith K, et al. Derivation of a bronchial genomic classifier for lung cancer in a prospective study of patients undergoing diagnostic bronchoscopy. *BMC Med Genomics*. May 6 2015;8:18. doi:10.1186/s12920-015-0091-3

Coding:

CPT: 0080U, 0092U, 0364U, 81554, 83520, 84999

History:	**Date:**	**Activity:**
Medical Policy Panel (ad hoc)	07/24/24	Review with revisions
Medical Policy Panel	07/05/23	Review with revisions
Medical Policy Panel	08/30/22	Approved guideline (Effective 9/19/22)
Medical Director (Dr. Deering)	08/19/22	Development

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Policy Revisions:

07/24/24	Added	"REVEAL Lung Nodule Characterization (MagArray) is a plasma-protein biomarker test that may aid clinicians in characterizing indeterminate pulmonary nodules (4 to 30 mm) in current smokers 25 years of age and older. The test is based on a multianalyte assay with a proprietary algorithmic analysis using immunoassay, microarray, and magnetic nanoparticle detection techniques to obtain laboratory data for calculation of the risk score for lung cancer. The REVEAL Lung Nodule Characterization is presented on a scale from 0 to 100 with a single cut point at 50. The score is based on the measurement of 3 clinical factors (age, sex, and nodule diameter) and 3 proteins (epidermal growth factor receptor, prosurfactant protein B, and tissue inhibitor of metalloproteinases 1) associated with the presence of lung cancer. It may aid a clinician in the decision to perform a biopsy or to consider routine monitoring. It is not intended as a screening or stand-alone diagnostic assay." To the Description section; "Nodify CDT®" and "REVEAL Lung Nodule Characterization (MagArray)" to the Criteria.
07/24/24	Revised	"BDX-XL2 (Nodify XL2®)" to "Nodify XL2® (BDX-XL2)" in the Criteria.
07/24/24	Updated	Resources section.
07/05/23	Added:	"Insufficient evidence to support improvement of the net health outcome; or", and "Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or" to experimental or investigational criteria
07/05/23	Revised:	"Percepta® Bronchial Genomic Classifier" to "Percepta® Genomic Sequencing Classifier" in gene expression profiling criteria statement; "Insufficient evidence to support improvement outside the investigational setting" from #3 to #5 in experimental or investigational criteria
07/05/23	Updated:	Description, Resources, and Coding sections

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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 nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. Ata' halne'ígíí kojį' bich'į' 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 تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.

MOLECULAR TESTING IN THE MANAGEMENT OF PULMONARY NODULES

Multi-Language Interpreter Services:

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:
اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و
اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799
[تماس حاصل نمایید.

Assyrian:
[illegible] Blue Cross Blue Shield of Arizona [illegible]
[illegible] 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona
คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799