



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 01/20/26
LAST REVIEW DATE: 01/20/26
CURRENT EFFECTIVE DATE: 01/20/26
LAST CRITERIA REVISION DATE: 01/20/26
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 1ST QTR 2027

ADJUNCTIVE TECHNIQUES FOR SCREENING, SURVEILLANCE, AND RISK CLASSIFICATION OF BARRETT ESOPHAGUS AND ESOPHAGEAL DYSPLASIA

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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Description:

Several adjunctive technologies and tests are available for screening, surveillance, and risk stratification of Barrett esophagus (BE). The wide-area transepithelial sampling with three-dimensional analysis (WATS3D) is performed during the endoscopic examination of the esophagus, using a computer-assisted brush biopsy procedure as an adjunct to standard four-quadrant forceps biopsy. TissueCypher is a tissue systems pathology test that analyzes biopsy samples to predict the risk of progression to high-grade dysplasia or esophageal adenocarcinoma in patients with BE. EsoCheck is a non-endoscopic cell collection device used in conjunction with EsoGuard, a DNA methylation test, to detect BE and esophageal dysplasia. These technologies and tests are intended to complement standard procedures in the screening, surveillance, and risk stratification of individuals with BE or at risk of developing BE. Esopredict is a DNA methylation assay that assesses the risk of progression to high-grade dysplasia or esophageal adenocarcinoma in individuals with BE.

On May 31, 2019, the FDA approved Lucid Diagnostics Inc.'s EsoCheck Cell Collection Device (K222366) for use in collecting and retrieving surface cells of the esophagus in adults and adolescents aged 22 years and older (product code: EOX). An update to the PMA (K230339) was posted on February 7, 2023 which provided a revised indication for the use in the collection and retrieval of surface cells of the esophagus in the general population of adults and adolescents, 12 years of age and older.

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 (CLIA). The EsoGuard (Lucid Diagnostics), TissueCypher (Castle BioSciences), and WATS3D (CDx Diagnostics), formerly known as EndoCDx, and Esopredict (Previs which is now part of Castle BioSciences) are available under the auspices of the CLIA. Laboratories that offer laboratory-developed tests must be licensed by the CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

Criteria:

- EsoCheck for the screening and surveillance of Barrett esophagus and esophageal dysplasia 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

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- Esoguard for the screening and surveillance of Barrett esophagus and esophageal dysplasia 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

- Esopredict for assessing the risk progression to high-grade dysplasia or esophageal adenocarcinoma in individuals with Barrett esophagus 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

- TissueCypher for assessing the risk of progression to high-grade dysplasia or esophageal adenocarcinoma in individuals with Barrett esophagus 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

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- Wide-area transepithelial sampling with three-dimensional computer-assisted analysis (WATS3D) 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 indications include, *but are not limited to*:

- The screening and surveillance of Barrett esophagus
- The screening and surveillance of esophageal dysplasia.

Resources:

Literature reviewed 01/20/26. We do not include marketing materials, poster boards and non-published literature in our review

Resources prior to 01/20/26 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Anandasabapathy S, Sontag S, Graham DY, et al. Computer-assisted brush-biopsy analysis for the detection of dysplasia in a high-risk Barrett's esophagus surveillance population. *Dig Dis Sci*. Mar 2011; 56(3): 761-6. PMID 20978843
2. Bennett C, Moayyedi P, Corley DA, et al. BOB CAT: A Large-Scale Review and Delphi Consensus for Management of Barrett's Esophagus With No Dysplasia, Indefinite for, or Low-Grade Dysplasia. *Am J Gastroenterol*. May 2015; 110(5): 662-82; quiz 683. PMID 25869390
3. Castle Biosciences. TissueCypher. How It Works. 2025; <https://castlebiosciences.com/tests/prognostic/tissuecypher/how-it-works>. Accessed October 20, 2025.
4. CDx Diagnostics. WATS3D. 2024; <https://www.cdxdiagnostics.com/wats3d>. Accessed October 20, 2025.
5. Codipilly DC, Krishna Chandar A, Wang KK, et al. Wide-area transepithelial sampling for dysplasia detection in Barrett's esophagus: a systematic review and meta-analysis. *Gastrointest Endosc*. Jan 2022; 95(1): 51-59.e7. PMID 34543648

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8. Davison JM, Goldblum J, Grewal US, et al. Independent Blinded Validation of a Tissue Systems Pathology Test to Predict Progression in Patients With Barrett's Esophagus. *Am J Gastroenterol*. Jun 2020; 115(6): 843-852. PMID 32079863
9. DeMeester S, Smith C, Severson P, et al. Multicenter randomized controlled trial comparing forceps biopsy sampling with wide-area transepithelial sampling brush for detecting intestinal metaplasia and dysplasia during routine upper endoscopy. *Gastrointest Endosc*. Jun 2022; 95(6): 1101-1110.e2. PMID 34902373
10. Diehl DL, Khara HS, Akhtar N, et al. TissueCypher Barrett's esophagus assay impacts clinical decisions in the management of patients with Barrett's esophagus. *Endosc Int Open*. Mar 2021; 9(3): E348-E355. PMID 33655033
11. Docimo S, Al-Mansour M, Tsuda S. SAGES TAVAC safety and efficacy analysis WATS 3D (CDx Diagnostics, Suffern, NY). *Surg Endosc*. Sep 2020; 34(9): 3743-3747. PMID 32162125
12. Duits LC, Khoshiwal AM, Frei NF, et al. An Automated Tissue Systems Pathology Test Can Standardize the Management and Improve Health Outcomes for Patients With Barrett's Esophagus. *Am J Gastroenterol*. Nov 01 2023; 118(11): 2025-2032. PMID 37307529
13. Englehardt R, Samarasena JB, Bildzukewicz NA, et al. Real world experience and clinical utility of esoguard - interim data from the lucid registry. *medRxiv*. 2023:2023.2009.2026.23296162. doi:10.1101/2023.09.26.23296162
14. Fayter D, Corbett M, Heirs M, et al. A systematic review of photodynamic therapy in the treatment of pre-cancerous skin conditions, Barrett's oesophagus and cancers of the biliary tract, brain, head and neck, lung, oesophagus and skin. *Health Technol Assess*. Jul 2010; 14(37): 1-288. PMID 20663420
15. Frei NF, Konte K, Bossart EA, et al. Independent Validation of a Tissue Systems Pathology Assay to Predict Future Progression in Nondysplastic Barrett's Esophagus: A Spatial-Temporal Analysis. *Clin Transl Gastroenterol*. Oct 2020; 11(10): e00244. PMID 33108124
16. Greer KB, Blum AE, Faulx AL, et al. Nonendoscopic Screening for Barrett's Esophagus and Esophageal Adenocarcinoma in At-Risk Veterans. *Am J Gastroenterol*. Mar 01 2025; 120(3): 545-553. PMID 38989889

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18. Hamblin R, Lee VT, deGuzman BJ, Verma S, Aklog L. Clinical utility of esoguard as an efficient triage test for diagnosing barretts esophagus in on-duty firefighters. medRxiv. 2023:2023.2008.2016.23294176. doi:10.1101/2023.08.16.23294176
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21. Kaul V, Gross S, Corbett FS, et al. Clinical utility of wide-area transepithelial sampling with three-dimensional computer-assisted analysis (WATS3D) in identifying Barrett's esophagus and associated neoplasia. *Dis Esophagus.* Dec 07 2020; 33(12). PMID 32607543
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23. Lagergren J, Bergström R, Lindgren A, et al. Symptomatic gastroesophageal reflux as a risk factor for esophageal adenocarcinoma. *N Engl J Med.* Mar 18 1999; 340(11): 825-31. PMID 10080844
24. Laun S, Pierre F, Kim S, et al. Analytical Validation of Esopredict, an Epigenetic Prognostic Assay for Patients with Barrett's Esophagus. *Diagnostics (Basel).* Sep 10 2024; 14(18). PMID 39335682
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26. Laun SE, Kann L, Braun J, et al. Validation of an Epigenetic Prognostic Assay to Accurately Risk-Stratify Patients With Barrett Esophagus. *Am J Gastroenterol.* Aug 14 2024; 120(6): 1296-1306. PMID 39140473
27. Lister D, Fine A, Maheshwari S, et al. Clinical utility study of esoguard on samples collected with esocheck as a triage test for endoscopy to identify barretts esophagus interim data of the first 275 subjects. medRxiv. 2023:2023.2008.2031.23294916. doi:10.1101/2023.08.31.23294916
28. Lister D, Fine A, Maheshwari S, et al. Real-World Clinical Utility of a Methylated DNA Biomarker Assay on Samples Collected with a Swallowable Capsule-Balloon for Detection of Barrett's Esophagus (BE). *Medicina (Kaunas).* Dec 13 2024; 60(12). PMID 39768931

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29. Lucid Diagnostics. Lucid Diagnostics Launches Next-Generation EsoGuard Esophageal DNA Test. 2023; <https://ir.luciddx.com/2023-11-09-Lucid-Diagnostics-Launches-Next-Generation-EsoGuard-R-Esophageal-DNA-Test-and-Announces-Upcoming-Investor-Day>. Accessed October 20, 2025.
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32. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers (v.4.2025). August 22, 2025; https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed October 20, 2025.
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36. Shaheen NJ, Falk GW, Iyer PG, et al. ACG Clinical Guideline: Diagnosis and Management of Barrett's Esophagus. *Am J Gastroenterol*. Jan 2016; 111(1): 30-50; quiz 51. PMID 26526079
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38. Shaheen NJ, Odze RD, Singer ME, et al. Adjunctive Use of Wide-Area Transepithelial Sampling-3D in Patients With Symptomatic Gastroesophageal Reflux Increases Detection of Barrett's Esophagus and Dysplasia. *Am J Gastroenterol*. Oct 01 2024; 119(10): 1990-2001. PMID 38635377
39. Shaheen NJ, Smith MS, Odze RD. Progression of Barrett's esophagus, crypt dysplasia, and low-grade dysplasia diagnosed by wide-area transepithelial sampling with 3-dimensional computer-assisted analysis: a retrospective analysis. *Gastrointest Endosc*. Mar 2022; 95(3): 410-418.e1. PMID 34537193
40. Singer ME, Smith MS. Wide Area Transepithelial Sampling with Computer-Assisted Analysis (WATS 3D) Is Cost-Effective in Barrett's Esophagus Screening. *Dig Dis Sci*. May 2021; 66(5): 1572-1579. PMID 32578042



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42. Smith MS, Ikonomi E, Bhuta R, et al. Wide-area transepithelial sampling with computer-assisted 3-dimensional analysis (WATS) markedly improves detection of esophageal dysplasia and Barrett's esophagus: analysis from a prospective multicenter community-based study. *Dis Esophagus*. Mar 01 2019; 32(3). PMID 30541019
43. Spechler SJ, Sharma P, Souza RF, et al. American Gastroenterological Association medical position statement on the management of Barrett's esophagus. *Gastroenterology*. Mar 2011; 140(3): 1084-91. PMID 21376940
44. Trindade AJ, Odze RD, Smith MS, et al. Benefit of adjunctive wide-area transepithelial sampling with 3-dimensional computer-assisted analysis plus forceps biopsy based on Barrett's esophagus segment length. *Gastrointest Endosc*. Sep 2023; 98(3): 316-325. PMID 37023868
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Coding:

CPT: 0108U, 0114U, 81479, 88104, 88305, 88312, 88361

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History:

<u>Date:</u>	<u>Activity:</u>
01/20/26	Approve guideline
01/15/26	Review with revisions

Policy Revisions:



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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 nilinígíí 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 ilinígóó. 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.

