

## MEDICAL POLICY – 7.01.167

# Adjunctive Techniques for Screening and Surveillance of Barrett Esophagus and Esophageal Dysplasia

BCBSA Ref. Policy: 7.01.167

Effective Date: Oct. 1, 2023

Last Revised: Sept. 25, 2023

Replaces: N/A

RELATED MEDICAL POLICIES:

None

Select a hyperlink below to be directed to that section.

[POLICY CRITERIA](#) | [DOCUMENTATION REQUIREMENTS](#) | [CODING](#)  
[RELATED INFORMATION](#) | [EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

 Clicking this icon returns you to the hyperlinks menu above.

## Introduction

The esophagus is the muscular tube that allows food to pass from the throat to the stomach. Barrett’s esophagus (BE) is a condition where the cells that line the lower part of the esophagus change and look like the cells in the intestines. Barrett’s esophagus can lead to a condition called esophageal dysplasia. This is when the abnormal cells become pre-cancerous. These two conditions are diagnosed and monitored with an upper endoscopy and biopsy. An endoscopy uses a thin, flexible tube with a camera to look for problems in the digestive system. During an endoscopy, a tissue sample is taken (a biopsy) to check for changes in the cells. Another type of biopsy is called wide-area transepithelial sampling with three-dimensional analysis, or WATS3D. WATS3D uses a computer system to examine tissue samples. The use of WATS3D is unproven (investigational). More studies are needed to see if this testing improves health outcomes.

**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

Drug	Investigational
<b>Wide-area transepithelial sampling with three-dimensional computer-assisted analysis</b>	<b>Wide-area transepithelial sampling with three-dimensional computer-assisted analysis (WATS3D) is considered investigational for all indications, including but not limited to the screening and surveillance of Barrett esophagus and esophageal dysplasia</b>

## Coding

Code	Description
<b>CPT</b>	
88104	Cytopathology, fluids, washings or brushings, except cervical or vaginal; smears with interpretation
88305	Level IV - Surgical pathology, gross and microscopic examination Abortion - spontaneous/missed Artery, biopsy Bone marrow, biopsy Bone exostosis Brain/meninges, other than for tumor resection Breast, biopsy, not requiring microscopic evaluation of surgical margins Breast, reduction mammoplasty Bronchus, biopsy Cell block, any source Cervix, biopsy Colon, biopsy Duodenum, biopsy Endocervix, curettings/biopsy Endometrium, curettings/biopsy Esophagus, biopsy Extremity, amputation, traumatic Fallopian tube, biopsy Fallopian tube, ectopic pregnancy Femoral head, fracture Fingers/toes, amputation, non-traumatic Gingiva/oral mucosa, biopsy Heart valve Joint, resection Kidney, biopsy Larynx, biopsy Leiomyoma(s), uterine myomectomy - without uterus Lip, biopsy/wedge resection Lung, transbronchial biopsy Lymph node, biopsy Muscle, biopsy Nasal mucosa, biopsy Nasopharynx/oropharynx, biopsy Nerve, biopsy Odontogenic/dental cyst Omentum, biopsy Ovary with or without tube, non-neoplastic Ovary, biopsy/wedge resection Parathyroid gland Peritoneum, biopsy Pituitary tumor Placenta, other than third trimester Pleura/pericardium - biopsy/tissue Polyp, cervical/endometrial Polyp, colorectal Polyp, stomach/small intestine Prostate, needle biopsy Prostate, TUR Salivary gland, biopsy Sinus, paranasal biopsy Skin, other than cyst/tag/debridement/plastic repair Small intestine, biopsy Soft tissue, other than tumor/mass/lipoma/debridement Spleen Stomach, biopsy Synovium Testis, other than tumor/biopsy/castration Thyroglossal duct/brachial cleft cyst Tongue, biopsy Tonsil, biopsy Trachea, biopsy Ureter, biopsy Urethra, biopsy Urinary bladder, biopsy Uterus, with or without tubes and ovaries, for prolapse Vagina, biopsy Vulva/labia, biopsy



Code	Description
88312	Special stain including interpretation and report; Group I for microorganisms (e.g., acid fast, methenamine silver)
88361	Morphometric analysis, tumor immunohistochemistry (e.g., Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; using computer-assisted technology

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

NA

## Evidence Review

### Description

The wide-area transepithelial sampling with three-dimensional analysis (WATS3D) is performed during endoscopic examination of the esophagus. The computer-assisted brush biopsy procedure is intended as an adjunct to standard four-quadrant forceps biopsy for screening or surveillance of cancerous or precancerous esophageal lesions and Barrett esophagus (BE).

### Background

#### Barrett Esophagus

BE is a condition in which the squamous epithelium that normally lines the esophagus is replaced by specialized columnar-type epithelium known as intestinal metaplasia in response to irritation and injury caused by gastroesophageal reflux disease (GERD). Barrett esophagus occurs in the distal esophagus. It may involve any length of the esophagus, be focal or circumferential, and is visualized on endoscopy with a different color than background squamous mucosa. Confirmation of BE requires a biopsy of the columnar epithelium and microscopic identification



of intestinal metaplasia.<sup>1</sup> The prevalence of BE in the United States is estimated at 5.6%.<sup>2</sup> Risk factors associated with the development of BE include GERD, male gender, central obesity, and age over 50 years. The diagnosis of GERD is associated with a 10% to 15% risk of BE.<sup>3</sup> However, a population-based analysis from Sweden observed that 40% of the study cohort with esophageal cancer reported no prior history of GERD symptoms.<sup>4</sup>

## Cancer Risk and Management

Intestinal metaplasia is a precursor to esophageal adenocarcinoma, and individuals with BE are at a 40-fold increased risk for developing this disease compared to the general population.<sup>1</sup>

However, there are few data to guide recommendations about management and surveillance, and many issues are controversial. Guidelines from the American College of Gastroenterology (ACG)<sup>3</sup>, and a consensus statement from an international group of experts (Benign Barrett's and Cancer Taskforce) on the management of BE are published.<sup>5</sup> The ACG recommendations for surveillance are stratified by the presence and grade of dysplasia.

When no dysplasia is detected, ACG has reported the estimated risk of progression to cancer ranges from 0.2% to 0.5% per year and endoscopic surveillance every 3 to 5 years is recommended. For low-grade dysplasia, the estimated risk of progression is 0.7% per year, and endoscopic therapy is preferred; however, endoscopic surveillance every 12 months is considered an acceptable alternative. It is recommended that both options are discussed with the individual.<sup>3</sup> Precise estimates of cancer risk are not available for individuals with low-grade dysplasia due to large disparities among studies on its natural history. Interobserver variability in the diagnosis of low-grade dysplasia with standard biopsy may be responsible, with expert pathologists commonly downgrading initial diagnoses made by community pathologists.<sup>6</sup>

The Benign Barrett's and Cancer Taskforce consensus group did not endorse routine surveillance for people without dysplasia and was unable to agree on surveillance intervals for low-grade dysplasia.<sup>5</sup>

For high-grade dysplasia, the estimated risk of progression is about 7% per year, and ACG has recommended endoscopic eradication therapy, with the type of procedure dependent on patient age and life expectancy, comorbidities, the extent of dysplasia, local expertise in surgery and endoscopy, and patient preference.<sup>3</sup> Approximately 40% of individuals with high-grade dysplasia on biopsy are found to have associated carcinoma in the resection specimen.<sup>7</sup>

For individuals who are indefinite for dysplasia, a repeat endoscopy should be performed at 3 to 6 months following optimization of acid suppressive medications. A surveillance interval of 12



months is recommended if an indefinite for dysplasia reading is confirmed on repeat endoscopy in these individuals.<sup>3</sup> Many individuals who are indefinite for dysplasia show regression to nondysplastic BE with subsequent endoscopic evaluation. It is unclear whether some cases of regression are observed due to sampling error.<sup>8</sup>

## Summary of Evidence

For individuals with a history of BE who receive standard surveillance with adjunctive WATS3D, the evidence includes studies of diagnostic yield, a randomized controlled trial, a physician impact study, a decision analytic model, and a retrospective analysis of the manufacturer database. Relevant outcomes are test validity, overall survival, disease-specific survival, change in disease status, and quality of life. A meta-analysis reported incremental diagnostic yields of 6.9% and 2.4% for any dysplasia or esophageal adenocarcinoma (EAC) or high-grade dysplasia (HGD)/EAC,, respectively. These studies are limited by heterogeneity in classification and reporting of test results and selection bias stemming from the enrichment of individuals with a prior history of dysplasia. It is also unclear to what extent results obtained from academic centers are generalizable to community-based settings, where adherence to endoscopic biopsy guidelines is poor. In discordant cases where BE or dysplasia were identified only by WATS3D, significant physician management changes included initiation of invasive treatments. Health outcomes stemming from management changes were not reported, and risks associated with overdiagnosis, and overtreatment require elucidation. Follow-up data on disease progression in these individuals are limited. A retrospective analysis of the manufacturer database found a disease progression rate of 5.79% per patient-year (95% CI, 1.02% to 10.55%) for baseline low-grade dysplasia diagnoses via WATS3D sampling; however, study interpretation is limited as only 16 cases (0.33%) of progression defined as high-grade dysplasia or esophageal adenocarcinoma on follow-up forceps biopsy were identified. No direct evidence of clinical utility was identified. Because combined use of WATS3D with standard surveillance is intended to replace the current standard of care for guiding patient management decisions regarding initiation of treatment or surveillance, direct evidence of clinical utility is required. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals at increased risk of BE who undergo standard screening with adjunctive WATS3D, the evidence includes a meta-analysis of studies of diagnostic yield, a physician impact study, a decision analytic model, and a retrospective analysis of the manufacturer database. Relevant outcomes are test validity, overall survival, disease-specific survival, change in disease status, and quality of life. A meta-analysis reported incremental diagnostic yields of 7.2% and 2.1% for



any dysplasia/EAC or HGD/EAC, respectively. However, available studies have incomplete descriptions of selection criteria, and it is unclear whether study patients are at increased risk as defined by guideline recommendations for screening. In fact, two studies were enriched with women in whom screening is generally not recommended by society guidelines. These studies also noted that detected cases of BE in short-segment patients may reflect intestinal metaplasia of the cardia, which is thought to carry a significantly lower risk of cancer development compared to traditional BE. In discordant cases where BE or dysplasia were identified only by WATS3D, significant physician management changes included initiation of invasive treatments. Health outcomes from management changes were not reported, and risks associated with overdiagnosis and overtreatment require elucidation. Follow-up data on disease progression in these individuals are limited. A retrospective analysis of the manufacturer database found a disease progression rate of 5.79% per patient-year (95% CI, 1.02% to 10.55%) for baseline low-grade dysplasia diagnoses via WATS3D sampling; however, study interpretation is limited as only 16 cases (0.33%) of progression defined as high-grade dysplasia or esophageal adenocarcinoma on follow-up forceps biopsy were identified. No direct evidence of clinical utility was identified. Because combined use of WATS3D with standard screening is intended to replace the current standard of care for guiding patient management decisions regarding initiation of treatment or surveillance, direct evidence of clinical utility is required. 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
<b>Ongoing</b>			
<a href="#">NCT05056051</a>	Additive Value of Wide-Area Transepithelial Sampling (WATS3D) in Detection of Recurrence of Intestinal Metaplasia Following Endoscopic Eradication Therapy (EET) for Barrett's Esophagus-Related Neoplasia	200	June 2024 (recruiting)



NCT No.	Trial Name	Planned Enrollment	Completion Date
<a href="#">NCT04312633<sup>a</sup></a>	CDx Study 906: The Clinical Utility of WATS3D (Wide Area Transepithelial Sampling with Computer-Assisted 3-Dimensional Analysis): A 5-Year Prospective Registry	90000	Apr 2025 (recruiting)
<a href="#">NCT05530343</a>	A Multicenter Randomized Trial of Seattle Biopsy Protocol Versus Wide-Area Transepithelial Sampling in Patients With Barrett's Esophagus Undergoing Surveillance (The SWAT-BE Study)	2700	Mar 2026 (recruiting)
<a href="#">NCT05642338</a>	A Multicenter Prospective Cohort Study Comparing Random Biopsies Versus Wide-Area Transepithelial Brush-Sampling (WATS) for Surveillance of Barrett's Esophagus, the WATS-EURO2 Study	416	May 2027 (recruiting)
<b>Unpublished</b>			
<a href="#">NCT02988934<sup>a</sup></a>	The WATS3D (Wide Area Transepithelial Sample Biopsy with 3-Dimensional Computer-Assisted Analysis) U.S. Registry	3173/10000	Feb 2023 (terminated)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored 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 policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. 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 Gastroenterology

In 2016, the American College of Gastroenterology (ACG) published clinical guidelines on the diagnosis and management of BE based on a systematic literature review.<sup>3</sup> Guidelines state that "in patients with suspected BE, at least 8 random biopsies should be obtained to maximize the yield of [intestinal metaplasia] on histology. In patients with short (1-2 cm) segments of



suspected BE in whom 8 biopsies are unattainable, at least 4 biopsies per cm of circumferential BE, and 1 biopsy per cm in tongues of BE, should be taken (conditional recommendation, low level of evidence)." The guidelines also state that "the role of computer-assisted or wide-field 'brush biopsy' tissue acquisition for increasing the yield of dysplasia is currently under investigation."

In a 2022 guideline update,<sup>24</sup> the ACG stated that they could not make a recommendation on the use of WATS3D and noted that "it is difficult to know how much of the incremental benefit is truly due to more complete sampling of the mucosa by WATS-3D or better detection of dysplasia by the analysis algorithm and how much might be due to overdiagnosis of dysplasia and false-positive examinations by WATS-3D." Limitations of the existing evidence base were summarized, including a lack of studies on adjunctive use for surveillance when forceps biopsies are guided both by white light and chromoendoscopy, a lack of studies reproducing results using pathologists not employed by the manufacturer, and limited stratification of results by grade of dysplasia.

## **American Gastroenterological Association**

In 2022, the American Gastroenterological Association issued a clinical practice update addressing new technology and innovation for surveillance and screening in BE.<sup>25</sup> Best practice advice statements were issued based on a review of existing literature and expert opinion. However, statements were not formally rated based on quality of evidence or strength of recommendation. The update states that WATS3D may be used as an adjunctive technique to sample the suspected or established BE segment in addition to the Seattle biopsy protocol.

## **American Society of Gastrointestinal Endoscopy**

In 2019, the American Society of Gastrointestinal Endoscopy (ASGE) published guidelines addressing screening and surveillance of BE based on a systematic review and meta-analysis of the literature.<sup>11</sup> Recommendations were drafted at a meeting of the Standards of Practice Committee. The guidelines state that "in patients with known or suspected BE, we suggest using WATS-3D in addition to [white-light endoscopy] with Seattle protocol biopsy sampling compared with [white-light endoscopy] with Seattle protocol biopsy sampling alone (conditional recommendation, low quality of evidence)." The certainty of the recommendation was downgraded due to risk of bias, inconsistency, and indirectness. Definitions of dysplasia varied across studies, and most studies were manufacturer-funded. The guidelines also note that no



recommendation for WATS-3D was made at the initial face-to-face panel meeting. The conditional recommendation was issued following review of additional published literature and a phone conference.

## National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) guidelines on esophageal and esophagogastric junction cancers (v.2.2023) state that while WATS3D may help increase the detection of esophageal dysplasia in individuals with BE, the utility and accuracy of WATS3D for detecting high-grade dysplasia and adenocarcinoma in individuals with BE needs to be evaluated in larger phase III randomized trials.<sup>26</sup>

## Society of American Gastrointestinal and Endoscopic Surgeons

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Technology and Value Assessment Committee (TVAC) published expert panel recommendations following a safety and efficacy analysis of WATS3D in 2020.<sup>27</sup> Expert panel statements regarding the safety, efficacy, and value of WATS3D included:

- "No significant morbidity or mortality was reported within the literature associated with the WATS3D technology."
- "WATS3D increases diagnostic yield by 38-150% for Barrett's Esophagus, by 40-150% for Low Grade Dysplasia; and by 420% for High Grade Dysplasia; when compared to forceps biopsy alone."
- "WATS3D technique has very high inter-observer agreement for the pathological diagnosis of non-dysplastic and dysplastic Barrett's Esophagus."
- "Increased detection of pre-malignant diseases of the esophagus by the adjunctive use of WATS3D supports screening and surveillance by the adjunctive use of WATS3D during upper endoscopy in appropriate patients."

The committee also noted that "currently, WATS3D is not recommended as a stand-alone substitute for cold forcep biopsies," as the latter still offers the ability to sample specific areas of concern or visible lesions. Additionally, "further research into the use of the WATS3D system as an independent screening or diagnostic modality may be warranted."



## Medicare National Coverage

There is no national coverage determination.

## Regulatory Status

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). WATS3D (CDx Diagnostics), formerly known as EndoCDx, is 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.

## References

1. 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
2. Hirota WK, Loughney TM, Lazas DJ, et al. Specialized intestinal metaplasia, dysplasia, and cancer of the esophagus and esophagogastric junction: prevalence and clinical data. *Gastroenterology*. Feb 1999; 116(2): 277-85. PMID 9922307
3. 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
4. Lagergren J, Bergstrom 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
5. 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
6. Curvers WL, ten Kate FJ, Krishnadath KK, et al. Low-grade dysplasia in Barrett's esophagus: overdiagnosed and underestimated. *Am J Gastroenterol*. Jul 2010; 105(7): 1523-30. PMID 20461069
7. 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
8. Sinh P, Anaparthi R, Young PE, et al. Clinical outcomes in patients with a diagnosis of "indefinite for dysplasia" in Barrett's esophagus: a multicenter cohort study. *Endoscopy*. Aug 2015; 47(8): 669-74. PMID 25910065
9. Yantiss RK. Diagnostic challenges in the pathologic evaluation of Barrett esophagus. *Arch Pathol Lab Med*. Nov 2010; 134(11): 1589-600. PMID 21043812



10. CDx Diagnostics. WATS3D. 2023; <https://www.cdxdiagnostics.com/wats3d>. Accessed June 28, 2023.
11. Qumseya B, Sultan S, Bain P, et al. ASGE guideline on screening and surveillance of Barrett's esophagus. *Gastrointest Endosc.* Sep 2019; 90(3): 335-359.e2. PMID 31439127
12. 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
13. 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
14. Gross SA, Smith MS, Kaul V. Increased detection of Barrett's esophagus and esophageal dysplasia with adjunctive use of wide-area transepithelial sample with three-dimensional computer-assisted analysis (WATS). *United European Gastroenterol J.* May 2018; 6(4): 529-535. PMID 29881608
15. Smith MS, Ikononi 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
16. 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
17. Vennalaganti PR, Kaul V, Wang KK, et al. Increased detection of Barrett's esophagus-associated neoplasia using wide-area trans-epithelial sampling: a multicenter, prospective, randomized trial. *Gastrointest Endosc.* Feb 2018; 87(2): 348-355. PMID 28757316
18. 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.* Apr 04 2023. PMID 37023868
19. Corbett FS, Odze RD, McKinley MJ. Utility of wide-area transepithelial sampling with 3-dimensional computer-assisted analysis as an adjunct to forceps biopsy sampling in the surveillance of patients with Barrett's esophagus after endoscopic eradication therapy. *iGIE.* December 2022; 1(1): 33-43. DOI: 10.1016/j.igie.2022.10.011.
20. van Munster SN, Leclercq P, Haidry R, et al. Wide-area transepithelial sampling with computer-assisted analysis to detect high grade dysplasia and cancer in Barrett's esophagus: a multicenter randomized study. *Endoscopy.* Apr 2023; 55(4): 303-310. PMID 36150646
21. 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
22. 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
23. 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
24. Shaheen NJ, Falk GW, Iyer PG, et al. Diagnosis and Management of Barrett's Esophagus: An Updated ACG Guideline. *Am J Gastroenterol.* Apr 01 2022; 117(4): 559-587. PMID 35354777
25. Muthusamy VR, Wani S, Gyawali CP, et al. AGA Clinical Practice Update on New Technology and Innovation for Surveillance and Screening in Barrett's Esophagus: Expert Review. *Clin Gastroenterol Hepatol.* Dec 2022; 20(12): 2696-2706.e1. PMID 35788412
26. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers (v.2.2023). March 10, 2023; [https://www.nccn.org/professionals/physician\\_gls/pdf/esophageal.pdf](https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf). Accessed June 28, 2023.



27. 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

## History

Date	Comments
02/04/22	New policy, approved October 12, 2021, effective for dates of service on or after February 4, 2022, following 90-day provider notification. Policy created with literature review through July 2, 2021. Wide-area transepithelial sampling with three-dimensional computer-assisted analysis (WATS3D) is considered investigational for all indications, including but not limited to the screening and surveillance of Barrett esophagus and esophageal dysplasia.
01/01/23	Annual review, approved December 12, 2022. Policy updated with literature review through July 8, 2022; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
10/01/23	Annual review, approved September 25, 2023. Policy updated with literature review through June 28, 2023; references added. Policy statements unchanged.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2023 Premera All Rights Reserved.

**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.



