



ADMINISTRATIVE POLICY STATEMENT

Ohio Medicaid

Policy Name & Number	Date Effective
Esophageal Brush Biopsy-OH MCD-AD-1340	3/01/2024
Policy Type	
ADMINISTRATIVE	

Administrative Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Administrative Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Administrative Policy Statement. If there is a conflict between the Administrative Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject

Esophageal Brush Biopsy

B. Background

Barrett's esophagus (BE) is a metaplastic change of the distal esophagus, whereby the normal squamous epithelium is replaced by specialized columnar epithelium with goblet cells. This change, where the squamous cells of the esophagus begin to resemble cells of the stomach, is associated with chronic gastroesophageal reflux disease (GERD). It is estimated that 5%–12% of patients with chronic GERD symptoms will also exhibit BE. BE is the only known precursor lesion of esophageal adenocarcinoma (EAC). Last year, the American Cancer Society estimated 20,640 new esophageal cancer cases diagnosed (16,510 in men and 4,130 in women).

The most definitive, accurate, and reliable method for diagnosing esophageal lesions is esophageal endoscopy and the Seattle protocol-based, four-quadrant forceps biopsy (FB).

A new technique for detection of BE is wide-area transepithelial sampling with computer-assisted three-dimensional analysis (WATS3D). WATS3D, formerly known as EndoCDx, is a computer-assisted biopsy, adjunct to standard forceps biopsy of the esophagus, which claims to increase analysis accuracy of the tissue area sampled and therefore increases the yield of patients' tissue identified with abnormality in the esophagus. Unlike standard cytology brushes that are typically soft and primarily designed to gently remove spontaneously exfoliated squamous cells in the esophagus, the WATS3D biopsy is specifically designed using an abrasive brush which is deployed during endoscopy to consistently sample deeper layers of the more firmly attached glandular epithelium found in Barrett's esophagus.

WATS3D has been criticized for its susceptibility to false-negative or false-positive findings that could lead to the delay of appropriate therapy or to the administration of unnecessary therapy respectively, which represents a potential safety concern. Monitoring patients over time is needed to address these concerns.

C. Definitions

- **Barrett's Esophagus (BE)** – A pre-malignant condition that places patients at risk for esophageal adenocarcinoma (EAC).
- **Esophageal Adenocarcinoma (EAC)** – One of the two most common types of esophageal cancer along with squamous cell carcinoma.
- **Gastroesophageal Reflux Disease (GERD)** – A condition occurring when a muscle at the end of the esophagus does not close properly, allowing stomach contents to leak back, or reflux, into the esophagus and irritate it.

D. Policy

- I. CareSource considers esophageal brush biopsy using wide-area transepithelial sampling with computer-assisted three-dimensional analysis (WATS3D) experimental and investigational for screening, diagnosis, or surveillance of cancerous or pre-cancerous esophageal lesions because of insufficient evidence.
- II. Any claims for esophageal brush biopsy will be denied.
- III. CareSource may request documentation of services performed. Appropriate and complete documentation must be presented at the time of review to validate medical necessity. If medical necessity is not confirmed based on the documentation submitted, recoupment may occur.

E. Conditions of Coverage

NA

F. Related Policies/Rules

Experimental, Investigational and Other Non-Covered Services

G. Review/Revision History

	DATE	ACTION
Date Issued	10/11/2023	New Policy. Approved at Committee
Date Revised		
Date Effective	3/01/2024	
Date Archived		

H. References

1. American Cancer Society. Key Statistics for Esophageal Cancer. Accessed September 14, 2023. www.cancer.org.
2. Health Technology Evaluation. Wide-Area Transepithelial Sampling Biopsy for Detection of Barrett's Esophagus/Esophageal Dysplasia. Accessed September 14, 2023. www.evidence.hayesinc.com.
3. Odze RD, Goldblum J, Kaul V. Role of Wide-Area Transepithelial Sampling With 3D Computer-Assisted Analysis in the Diagnosis and Management of Barrett's Esophagus. *Clin Transl Gastroenterol*. 2021;12(12):e00422. Published 2021 Dec 7. doi:10.14309/ctg.0000000000000422.
4. Shaheen NJ, Falk GW, Iyer PG, et al. Diagnosis and Management of Barrett's Esophagus: An Updated ACG Guideline. *Am J Gastroenterol*. 2022;117(4):559-587. doi:10.14309/ajg.0000000000001680.
5. Spechler SJ. Barrett's esophagus: Surveillance and management. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed September 14, 2023. www.uptodate.com.
6. Suresh Kumar VC, Harne P, Patthipati VS, et al. Wide-area transepithelial sampling in adjunct to forceps biopsy increases the absolute detection rates of Barrett's

The ADMINISTRATIVE Policy Statement detailed above has received due consideration as defined in the ADMINISTRATIVE Policy Statement Policy and is approved.

- oesophagus and oesophageal dysplasia: a meta-analysis and systematic review. *BMJ Open Gastroenterol.* 2020;7(1):e000494. doi:10.1136/bmjgast-2020-000494. PMID: 32928869.
7. Yip HC, Chiu PW. Endoscopic diagnosis and management of early squamous cell carcinoma of esophagus. *J Thorac Dis.* 2017;9(Suppl 8):S689-S696. doi:10.21037/jtd.2017.06.57.

Approved ODM 11/16/2023

The ADMINISTRATIVE Policy Statement detailed above has received due consideration as defined in the ADMINISTRATIVE Policy Statement Policy and is approved.