Subject: Specialized Specimen Procedures

Medical Policy: 60.0 **Original Effective Date: 11-03-2023**

Status: New **Last Review Date: N/A**

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

WATS-3D (wide-area transepithelial sampling) is used as an adjunct to traditional forceps biopsy via white light endoscopy (Seattle Biopsy Protocol) for sampling tissue from patients with suspected or confirmed Barrett's Esophagus (BE).[1] It is also used adjunctively post endoscopic eradication therapy (EET).[2]

WATS-3D utilizes an endoscopic brush that obtains a wide-area transepithelial sample to include a larger surface area of the esophagus compared to the traditional forceps biopsy. These specimens allow for analysis of large sheets of cells while preserving the 3D features of the tissue. The specimen is then analyzed at CDx Diagnostics by a specialized 3D computer-analysis system that identifies abnormal cells and cell clusters which are then sent to the pathologists for further confirmation.

Coverage Determination

Prior Authorization is not required. Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

For Medicare, Medicaid and Commercial.

INDICATIONS:
The WATS-3D biopsy procedure for esophageal assessment, may be considered medically necessary as an adjunct to the traditional forceps biopsy (Seattle Biopsy Protocol) for **ANY** of the following indications:

- Diagnosis and evaluation of Barrett's Esophagus, low-grade dysplasia, or high-grade dysplasia.
  OR
- Surveillance of persons with chronic gastroesophageal reflux (GERD) disease.

The WATS-3D biopsy procedure not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

EXCLUSIONS:

- The use of WATS-3D without the use of traditional forceps biopsy via endoscopy (Seattle Biopsy Protocol).
- The Plan does NOT provide coverage for any Wide Area Transepithelial Sampling device not currently FDA-approved. These devices are considered experimental, investigational, or unproven.

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Covered Codes
88104	Cytopathology, fluids, washings or brushings, except cervical or vaginal
88112	Cytopathology, selective cellular enhancement technique with interpretation (eg, liquid based slide preparation method), except cervical or vaginal
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,

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

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee: Gray Clarke MD
Medical Director: Phung Vo, MD
Medical Director: Ana Maria Rael, MD
Date Approved: 12-13-2023

References

1. 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; doi: 10.14309/ctg.0000000000000422. [Cited 10/30/2023]
2. Fatima H, Wajid M, Hamade N, et al. Retrospective, observational, cross-sectional study of detection of recurrent Barrett's esophagus and dysplasia in post-ablation patients with adjunctive use of wide-area transepithelial sample (WATS-3D). Ann Gastroenterol. 2022; 35:1–7. [Cited 10/30/2023]
3. PubMed, NIH, Gross SA, Smith MS, Kaul V, Group USCWDS. Increased detection of Barrett's esophagus and esophageal dysplasia with adjunctive use of wide-area transepithelial sample with three-dimensional computer-assisted analysis (WATS), 19 March 2017; accepted: 6 November 2017. [Cited 10/30/2023]
4. HHS Public Access, American Gastroenterological Association (AGA), Clinical Practice Update on New Technology and Innovation for Surveillance and Screening in Barrett's Esophagus: Expert Review, Published in final edited form as:Clin Gastroenterol Hepatol. 2022 December; 20(12): 2696–2706.e1. doi:10.1016/j.cgh.2022.06.003. [Cited 10/30/2023]
5. NCCN, Esophageal and Esophagogastric Junction Cancers, Version 3.2023 — August 29, 2023. [Cited 10/30/2023]

Publication History

11/03/2023 Original effective date 11/03/2023. The use of wide-area transepithelial sampling with computer assisted 3-dimensional analysis (WATS3D) was evaluated by Technology Assessment Committee on 10/17/2023 for both screening and surveillance for all ALOB. Reviewed by PHP Medical Policy Committee on 11/03/2023. Codes will not require PA: 88104, 88112, 88305, 88312, 88361.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such. For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: ***Click here for Medical Policies***

Web links:
At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.