Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP340

Section: Medical Benefit Policy

Subject: Wide Area Transepithelial Sampling (WATS)

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Wide Area Transepithelial Sampling (WATS)

II. Purpose/Objective:

To provide a policy of coverage regarding

III. Responsibility:

A. Medical Directors

B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.

- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:
WATS3D (Wide Area Transepithelial Sampling) is a procedure that is used as an adjunct to the Seattle biopsy protocol for early detection of Barrett's esophagus in patients suspected to have or are confirmed with Barrett's Esophagus (BE). The system is comprised of brush sampling that obtains trans-epithelial specimens covering a larger area of the BE segment compared to traditional forceps biopsy. The system allows for evaluation of deeper glandular epithelium commonly found in Barrett's esophagus through the full-thickness epithelial sample and 3-D computer analysis. The computer analysis uses a neural network, high-speed scanning system that identifies abnormal cells based on cellular morphology and molecular diagnostics.

INDICATIONS:
Wide Area Transepithelial Sampling (WATS) for the diagnosis and evaluation of Barrett's esophagus, low or high-grade dysplasia is considered medically necessary

LIMITATIONS:
This service is covered only for services using FDA-approved devices.

EXCLUSIONS:
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.** The Geisinger Technology Assessment Committee determined there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these devices on health outcomes when compared to established treatments or technologies.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Wide Area Transepithelial Sampling (WATS)
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

88104 Cytopathology, fluids, washings or brushings, except cervical or vaginal; smears with interpretation
88112 Cytopathology, fluid requiring thin layer preparation
88305 Surgical pathology, gross and microscopic examination
88312 Special stain including interpretation and report
88361 Morphometric analysis, tumor immunohistochemistry (e.g., Her2neu, estrogen receptor/progesterone receptor), quantitative, each antibody, using computer-assisted technology

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
Geisinger Technology Assessment Triage Group. Wide Area Transepithelial Sampling (WATS). January 2021

Vennalaganti PR, Kanakadandi VN, et al. Inter-Observer Agreement among Pathologists Using Wide-Area Transepithelial Sampling With Computer-Assisted Analysis in Patients With Barrett's Esophagus. Am J Gastroenterol. 2015 Sep;110(9):1257-60.

Johanson JF, Frakes J, Eisen D. Computer-assisted analysis of abrasive transepithelial brush biopsies increases the effectiveness of esophageal screening: a multicenter prospective clinical trial by the EndoCDx Collaborative Group. Dig Dis Sci. 2011;56:767-72.

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. 2018;87(2):348-355.

Gross SA, Smith MS, Kaul V, US Collaborative WATS3D Study Group. 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 Gastroenterlogy Journal. 2018;6(4):529-535

Smith MS, Ikonomi E, Bhuta R, et al and the US Collaborative WATS Study Group. 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.2019;32(3):doy099.

Kaul V, Gross S, Corbett SF et al. The clinical utility of wide area transepithelial sampling with 3-dimensional computer-assisted analysis (WATS3D) in identifying Barrett's esophagus and associated neoplasia. Dis Esophagus 2020;

DeMeester S, Smith C, Severson P, et al. Multi-Center Randomized Trial Comparing Standard Forceps Biopsies to Wide-Area Transepithelial Sampling Brush for Finding Intestinal Metaplasia and Dysplasia in the Esophagus and Gastroesophageal Junction: 353. American Journal of Gastroenterology 2019;114:S207-S208

Raphael KL, Stewart M, Sejpal DV, et al. Adjunctive Yield of Wide-Area Transepithelial Sampling for Dysplasia Detection After Advanced Imaging and Random Biopsies in Barrett's Esophagus. Clin Transl Gastroenterol 2019;10:e00107.

Shaheen, N.J., Smith, M., Goldblum, J. et al. Progression of Barrett's esophagus (BE) and dysplasia detected by wide area transepithelial sampling with computer-assisted 3D analysis (WATS3D) confirms the clinical significance of crypt dysplasia. Am J Gastroenterol. 2018;113:s172.

Singer ME and Smith MS. Wide Area Transepithelial Sampling with Computer-Assisted Analysis (WATS3D) Is Cost-Effective in Barrett's Esophagus Screening. Dig Dis Sci 2020

Kumar VCS, Harne P, et al. Wide-area transepithelial sampling in adjunct to forceps biopsy increases the absolute detection rates of Barrett's oesophagus and oesophageal dysplasia: a meta-analysis and systematic review. BMJ Open Gastro 2020;7:e000494.

Docimo Jr S, Al-Mansour M, Tsuda S. SAGES TAVAC safety and efficacy analysis WATS3D (CDx Diagnostics,Suffern, NY). Surgical Endoscopy, 2020.

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. Clinical and Translational Gastroenterology 2021;12(12):e00422

Codipilly DC, Chandar AK et al. Wide-area transepithelial sampling for dysplasia detection in Barrett's esophagus: a systematic review and meta-analysis. Gastrointestinal Endoscopy 2022;95(1): 51-59.e7

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. 2022; 95(3):410-418.e1

This policy will be revised as necessary and reviewed no less than annually.

Devised: 2/21

Revised:

Reviewed: 2/22, 2/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies