Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP341

Section: Medical Benefit Policy

Subject: TissueCypher® Barrett's Esophagus Assay

Applicable Lines of Business

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

I. Policy: TissueCypher® Barrett's Esophagus Assay

II. Purpose/Objective:

To provide a policy of coverage regarding TissueCypher® Barrett's Esophagus Assay

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:
The TissueCypher® Barrett's Esophagus Assay is a laboratory test to help identify individuals who are appropriate candidates for minimally invasive endoscopic eradication therapy by predicting development of high-grade dysplasia and esophageal adenocarcinoma in patients with Barrett's esophagus. This multi-analyte assay and analysis evaluates the expression of nine specific protein-based biomarkers and morphology-based biomarkers in the context of tissue architecture in esophageal biopsies obtained during an upper GI endoscopy and reports the probability of progression to esophageal adenocarcinoma within five years of the endoscopy.

INDICATIONS:
TissueCypher is considered medically necessary for the evaluation of esophageal pinch biopsies (or endoscopic mucosal resection (EMR) specimens) of patients confirmed to have Barrett's esophagus with histology of no dysplasia, indefinite for dysplasia, or low-grade dysplasia.

EXCLUSIONS:
All of the following services are considered **experimental, investigational or unproven.** There is insufficient evidence in the peer-reviewed published medical literature to establish the safety and effectiveness of these services on health outcomes when compared to established treatments or technologies.

- esophageal microbiota evaluation for detection of Barrett's Esophagus
- Evaluation of mitochondrial DNA deletions for detection of Barrett's Esophagus
- SOX2 expression testing for prediction of neoplastic progression in Barrett's Esophagus
- Use of markers of intestinal phenotype (CDX2, Das-1, Hep Par 1, SOX9, and villin)
- Use of mucin glycoprotein immunostains
- Use of mutation analysis for risk assessment and diagnosis of Barrett's Esophagus

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: TissueCypher® Barrett's Esophagus Assay
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

0108U Gastroenterology (Barrett's esophagus), whole slide digital imaging, including morphometric analysis, computer assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX 2, CD45RO, HIF1a, HER 2, K20) and morphology, formalin fixed paraffin embedded tissue, algorithm reported as risk of progression to high grade dysplasia or cancer.

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:

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Hao, J. et al. A Cost-Effectiveness Analysis of an Adenocarcinoma Risk Prediction Multi-Biomarker Assay for Patients with Barrett's Esophagus. ClinicoEconomics and Outcomes Research, 2019. 11: p. 623-635.

Levine, DM, et al. A genome-wide association study identifies new susceptibility loci for esophageal adenocarcinoma and Barrett's esophagus. Nat Genet, 2013. 45(12): p. 1487-93.

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Prichard, JW, et al. TissueCypher: A Systems Biology Approach to Anatomic Pathology. J Pathol Inform, 2015;6(1):48.

Iyer PG, Codipilly DC, et al. Prediction of Progression in Barrett's Esophagus Using a Tissue Systems Pathology Test: A Pooled Analysis of International Multicenter Studies. Clin Gastroenterol Hepatol. 2022 Feb 22;S1542-3565(22)00190-2.

Diehl DL, Khara HS, Akhtar N, Critchley-Thorne RJ. TissueCypher Barrett's esophagus assay impacts clinical decisions in the management of patients with Barrett's esophagus. Endosc Int Open. 2021;9(3):E348-E355.

Khoshiwal AM, Frei NF, et al. The Tissue Systems Pathology Test Outperforms Pathology Review in Risk Stratifying Patients With Low-Grade Dysplasia. Gastroenterology. Aug 30, 2023

Duits, Lucas C. Khoshiwal, Amir M. Frei, Nicola F et al. An Automated Tissue Systems Pathology Test Can Standardize the Management and Improve Health Outcomes for Patients With Barrett's Esophagus. The American Journal of Gastroenterology July 14, 2023

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

Devised: 10/20,

Revised:

Reviewed: 10/21, 10/22, 10/23