Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP205

Section: Medical Benefit Policy

Subject: Advanced Molecular Topographic Genotyping

Applicable Lines of Business

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

I. Policy: Advanced Molecular Topographic Genotyping

II. Purpose/Objective:

To provide a policy of coverage regarding Advanced Molecular Topographic Genotyping

III. Responsibility:

A. Medical Directors

B. Medical Management Department

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:
Advanced molecular topographic genotyping combines advanced molecular genetics with current pathology practices for a definitive diagnosis from existing specimens. These molecular tests are intended to be used adjunctively when a definitive pathologic diagnosis cannot be made due to inadequate tissue or indeterminate findings. The intention of this testing should be to inform appropriate surveillance or surgical strategies for each patient's unique diagnosis.

Several societies (AGA, ACG, ACR) have guidelines for monitoring of pancreatic cysts and indications for surgical resection, that are primarily based on expert consensus and radiologic features. The American Gastroenterological Association (Vege, et al., 2015) have no recommendations for use of topographic genotyping for evaluating pancreatic cysts. Other guidelines (NCCN, 2015; Vege, et al., 2015; Del Chiaro, et al., 2013; Sahani, et al., 2013; Tanaka, et al., 2012) have no firm recommendations for topographic genotyping for assessing indeterminate pancreatic cysts.

The current standard is to consider molecular studies to predict likelihood of malignant transformation. Cytology and CEA studies alone can increase cyst classification accuracy to 70% yet are noted to have inadequate sensitivity and specificity to diagnose advanced neoplasia. NGS studies of cyst fluid have improved accuracy in the diagnosis of cyst type (eg: cystadenomas do not require follow up) as well as risk classification of IPMN (intraductal papillary mucinous neoplasms). Early studies demonstrate that a combination of KRAS/GNAS gene variants with TP53, PIK3CA, and PTEN have 88% sensitivity and 97% specificity to diagnose IPMNs with advanced neoplasia (high-grade dysplasia or adenocarcinoma).

Interspace Diagnostics (formerly called RedPath) offers 2 tests that use the PathFinderTG® platform (PancraGEN® and BarreGEN®). PancreaSeq® is a similar test performed through UPMC Medical Laboratory.

Per the manufacturer: BarreGEN® is a molecular based assay that quantifies the mutational load (ML) in esophageal specimens obtained from patients who have BE. ML provides a measure of cumulative genomic instability (DNA damage). In looking at key genomic loci in patients with BE and assessing DNA damage in tumor suppressor genes associated with progression to HGD and esophageal cancer, the risk of more advanced disease can be determined.

FOR MEDICARE AND MEDICAID BUSINESS SEGMENT:

INDICATIONS:
<u>*REQUIRES PRIOR MEDICAL DIRECTOR or DESIGNEE AUTHORIZATION</u>

Consideration for coverage is limited to the Medicare Business Segment, in compliance with CMS directives.

Per the Medical intermediary, PathfinderTG® PancraGen™

Per the Medical intermediary, PathfinderTG® PancraGen™ PancreaSeq® will be considered medically reasonable and necessary when selectively used as an occasional second-line diagnostic supplement:

- only where there remains clinical uncertainty as to either the current malignancy or the possible malignant potential of the pancreatic cyst based upon a comprehensive first-line evaluation; **AND**
- a decision regarding treatment (e.g. surgery) has NOT already been made based on existing information.

The specific requirements for medical necessity involve:

- Highly-concise affirmation, documented in the medical record, that a decision regarding treatment has not already been made and that the results of the molecular evaluation will assist in determining if more aggressive treatment than what is being considered is necessary.
- Previous first-line diagnostics, such as, but not restricted to, the following have demonstrated:
    - A pancreatic cyst fluid carcinoembryonic antigen (CEA), which is greater than or equal to 200 ng/ml, suggesting a mucinous cyst, but is not diagnostic.
    - Cyst cytopathologic or radiographic findings, which raise the index of malignancy suspicion, but where second-line molecular diagnostics is expected to be more compelling in the context of a surgical vs. non-surgical care plan.

EXCLUSIONS:
For the Medicare and Medicaid Business Segment, the Plan does NOT consider the use of advanced molecular topographic genotyping (including but not limited to Interspace Diagnostics Pathfinder TG®, PancraGEN®, PancraSeq®, BarreGEN®) medically necessary when used as a "first-line" pathology analysis.

Specific criteria of Non-coverage to include either:

- Image guided needle aspiration of the pancreatic cyst or cystic component of a mass lesion or dilated duct demonstrate definitive diagnosis of malignancy by cytology; **OR**
- Cytology not showing malignancy but meets AGA guidelines to reach a definitive diagnosis of benign disease. Lesions must be:
    - Under 1 cm;
    - Lack a solid component;
    - Lack concerning cytology features;
    - Lack main pancreatic duct dilatation of > 1cm in diameter with absence of abrupt change in duct diameter;
    - Have fluid CEA level not exceeding 5 ng/ml

FOR NON-MEDICARE BUSINESS SEGMENT:

The Plan does **NOT** provide coverage for advanced molecular topographic genotyping (including but not limited to RedPath Pathfinder TG, PancraGen™) because it is considered **experimental, investigational or unproven.** The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests 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: Advanced molecular topographic genotyping
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

84999 Unlisted Chemistry procedure

LINE OF BUSINESS:
Eligibility and contract specific benefit 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.

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

Devised: 10/2007
Revised: 12/10 (exclusion), 12/11(added indication), 12/14 (removed Medicaid); 12/16 (added genotyping test); 11/23 (specify Medicare coverage and exclusion language)

Reviewed: 10/08, 10/09**,** 12/12, 12/13, 12/15; 11/17, 11/18, 11/19, 11/20, 11/21, 11/22