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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit 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. The results are thought to provide useful information for physicians to plan the best course of treatment for each patient's unique diagnosis.

INDICATIONS: FOR MEDICARE AND MEDICAID BUSINESS SEGMENT:
*REQUIRES PRIOR MEDICAL DIRECTOR or DESIGNEE AUTHORIZATION

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

The Plan considers the use of advanced molecular topographic genotyping (including but not limited to RedPath Pathfinder TG, PancraGen™) medically necessary for pancreatic cyst/mass when all of the following criteria are met:

- Documented evidence of an indeterminate diagnosis of malignancy remains after traditional pathologic and microscopic staining and analysis has been performed; AND
- The testing will result in a targeted, patient specific treatment plan with effective utilization of healthcare resources.

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 RedPath Pathfinder TG) medically necessary when used as a “first-line” pathology analysis.

For the 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.

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 supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


ECRI Institute Hotline (online) 4/27/2012.


Centers for Medicare & Medicaid. Local Coverage Article RedPath-PathFinderTG-Provider Bulletin (A51681)


Thiruvengadam N, Park WG. Systematic review of pancreatic cyst fluid biomarkers: the path forward. Clinical and Translational Gastroenterology 2015;6;e88


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)

Reviewed: 10/08, 10/09, 12/12, 12/13, 12/15; 11/17, 11/18, 11/19