

Policy: MP262

Section: Medical Benefit Policy

Subject: Microarray-based Gene Expression testing for Cancer of Unknown Origin

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Microarray-based Gene Expression testing for Cancer of Unknown Origin

II. Purpose/Objective:

To provide a policy of coverage regarding Microarray-based Gene Expression testing for Cancer of Unknown Origin

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:

Microarray-based gene expression testing measures the expression of more than 1,500 genes, and compares the similarity of the gene expression profile of a cancer of unknown primary to a database of known profiles from 15 tissues with more than 60 histologic morphologies. The test provides a score which is a measure of similarity of the gene expression profile of the specimen to the profile of the 15 known tumors in the database. Scores range from 0 (very low similarity) to 100 (very high similarity). Single similarity scores greater than or equal to 30 indicate that this is likely the tissue of origin. Similarity scores between 5 and 30 are considered indeterminate, and scores of less than 5 rule out that tissue type as the likely origin.

LIMITATIONS:

For Medicare and Medicaid business segments:

Palmetto GBA, the contractor that administers Medicare in California, has issued a positive coverage policy for FDA-approved microarray-based gene expression testing (e.g., Pathwork® Tissue of Origin Test, CancerTYPE ID® Test.). The Palmetto GBA coverage policy is applicable for all Medicare patients nationally.

MEDICARE BUSINESS SEGMENT:

Per Local Carrier Determination Biomarkers for Oncology (L34796) the Rosetta Cancer Origin Test™, CancerTYPE ID® Test is “considered reasonable and necessary in the pathologic diagnoses of cancer of unknown primary when a conventional surgical pathology/imaging work-up is unable to identify a primary neoplastic site. Other applications of this technology are non-covered and considered investigational in the use of diagnosis of specific tumor types such as NSCLC and renal cancers.”

EXCLUSIONS:

Unless mandated coverage exists, the Plan does **NOT** provide coverage for the use of microarray-based expression testing for cancer of unknown origin, including but not limited to Pathwork® Tissue of Origin Test, Pathwork TOO Frozen Array; CancerTYPE ID® Test, Rosetta Cancer Origin test; miRview®; ProOnc TumorSourceDX™, DecisionDX-G-CIMP to evaluate the site of origin of a tumor of unknown primary, and to distinguish a primary from a metastatic tumor because it is considered experimental, investigational or unproven. 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:

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.

81479 Unlisted molecular pathology procedure (RosettaGX Cancer Origin test)

81504 Oncology(tissue of origin), microarray gene expression profiling of >2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores

81540 Oncology (tumor of unknown origin) mRNA, gene expression profiling by real-time RT-PCR of 92 genes (87 content and 5 housekeeping) to classify tumor into main cancer type and subtype, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a probability of a predicted main cancer type and subtype (CancerTYPE ID)

81599 Unlisted multianalyte with algorithmic analyses (RosettaGX Cancer Origin test)

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.

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

Devised: 2/12

Revised: 11/14 (added Medicare indication), 11/15 (added CancerTYPE ID® Test); 1/17

Reviewed: 2/13, 2/14, 12/17, 12/18, 12/19, 12/20, 12/21, 12/22

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>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.