

Policy: MP102

Section: Medical Benefit Policy

Subject: Morphometric Tumor Analysis

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Morphometric Tumor Analysis

II. Purpose/Objective:

To provide a policy of coverage regarding Morphometric Tumor Analysis

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:

Morphometric analysis utilizes a quantitative image analysis system to assess a tissue sample after the diagnosis of malignancy has been established by histopathology. Morphometric analysis is not diagnostic of malignancy, but once the diagnosis is established, can assist in the prediction of prognosis and treatment planning for certain types of cancer. A quantitative image analysis system (light or fluorescent microscopy with quantitative morphometry and computerized data reduction) is used to assess the tissue sample. Plastic or paraffin embedded sections of specimen are prepared and an imaging instrument analyzes the nuclear ploidy for the chromosome make-up of the cell nuclei. The individual tumor cells can be microscopically visualized and analyzed with the exclusion of surrounding stroma, inflammatory cells and normal tissue thus giving a specific determination of phenotypes and receptor content.

INDICATIONS:

Prognosis and treatment planning in diagnoses such as but not limited to:

1. Malignant neoplasms of any of the following:
 - A. Liver and intrahepatic bile ducts
 - B. Spleen
 - C. Bronchus or Lung
 - D. Breast
 - E. Prostate
 - F. Urinary organs (such as the kidney or bladder)
 - G. Adrenal glands
2. Secondary malignant neoplasms of any of the following:
 - A. Lung
 - B. Adrenal glands
 - C. Large intestine and Rectum
 - D. Liver
 - E. Digestive organs
 - F. Urinary organs (such as the kidney or bladder)
 - G. Breast
 - H. Genital organs
3. Carcinoma in situ of the following:
 - A. Colon
 - B. Liver and Biliary system
 - C. Digestive organs
 - D. Bronchus and Lung
 - E. Breast
 - Breast
 - G. Prostate
 - H. Bladder
4. Lymphomas (Non-Hodgkins)
5. Ulcer of the esophagus
6. Regional enteritis (with dysplasia)
7. Ulcerative colitis (with dysplasia)

EXCLUSIONS:

Utilization for conditions other than those specified in this policy.

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.

CODING ASSOCIATED WITH: Morphometric analysis

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

- 88358 Morphometric analysis; tumor
- 88360 Morphometric analysis, tumor immunohistochemistry (e.g, her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, each antibody; manual
- 88361 Morphometric analysis, tumor immunohistochemistry, quantitative or semiquantitative, each antibody, using computer assisted technology
- 88367 Morphometric analysis, in situ hybridization, using computer assisted technology
- 88368 manual
- 88369 Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe.
- 88373 Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each additional single probe stain procedure.
- 88374 Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer- assisted technology, per specimen; each multiplex probe
- 88377 Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) manual, per specimen; each multiplex probe stain procedure

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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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Ikeguchi M, Cai J, Oka S, Gomyou Y, Tsujitani S, Maeta M, Kaibara N. "Nuclear profiles of cancer cells reveal the metastatic potential of gastric cancer". *J Pathol.* 2000 Sep;192(1):19-25.

Tseleni-Balafouta S, Kavantzias N, Paraskevaki H, Davaris P. "Computerized morphometric study on fine needle aspirates of cellular follicular lesions of the thyroid". *Anal Quant Cytol Histol.* 2000 Aug;22(4):323-6.

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Ishikawa F, Saito N, et. al., "Nuclear morphometric analysis of T2 lesions of the rectum - a simple, reproducible method for predicting malignancy potential". *American Journal of Surgery.* 183(6):686-691. June 2002.

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

Devised: 2/03

Revised: 2/04 (Coding), 2/06 (references), 2/07, 2/08 (wording); 7/09 (limitation revised), 8/11(indications added)

Reviewed: 2/05, 2/09, 7/10, 7/12, 8/13, 8/14, 8/15, 8/16, 7/17, 6/18, 7/19, 7/20, 7/21, 7/22, 7/23, 7/24

CMS UM Oversight Committee Approval: 12/23, 7/24

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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>

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