

Policy: MP225

Section: Medical Benefit Policy

Subject: Circulating Tumor Cell Testing

I. Policy: Circulating Tumor Cell Testing

II. Purpose/Objective:

To provide a policy of coverage regarding Circulating Tumor Cell Testing

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

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:

Circulating tumor cells have been proposed as a method to assess response to chemotherapy rather than relying on changes in imaging studies (i.e., CT scans). Additionally, the presence of circulating tumor cells has been investigated as a prognostic factor in women with breast cancer without metastases to determine the need for additional adjuvant chemotherapy.

FOR MEDICARE and Medicaid BUSINESS SEGMENTS ONLY:

Circulating tumor cell assay is covered for Medicare and Medicaid Business segments when the following criteria are met:

CTA is indicated for an established diagnosis of:

1. Breast cancer;
2. Colorectal cancer;
3. Prostate cancer.

LIMITATIONS:

1. All methods for CTC enrichment/detection other than the CellSearch® CTC assay, including PCR (RT-PCR) assays, are non-covered as they are considered investigational.
2. CTC testing will be limited to metastatic breast, colorectal and prostate cancer. CTC testing for all other malignant diagnoses will be denied as not reasonable and necessary.
3. All assays for CTC are non-covered for routine screening or prognosis.
4. No further CTC testing would be expected after the transition to palliative/hospice care.
5. Frequency: It would not be expected that chemotherapy changes are sufficiently frequent enough such that it is not expected for the CTC to be performed more than four times per year for a beneficiary.

EXCLUSIONS:

Unless mandated, the Plan does **NOT** provide coverage for the use Circulating Tumor Cell Testing for any indication, except for lines of business noted above, 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 technology 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:

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

86152 Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood).

86153 Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood); physician interpretation and report, when required.

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

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

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- Medicare Benefit Policy Manual - Pub. 100-02
- Medicare National Coverage Determinations Manual - Pub. 100-03
- Correct Coding Initiative - Medicare Contractor Beneficiary and Provider Communications Manual - Pub.100-09, Chapter 5
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This policy will be revised as necessary and reviewed no less than annually.

Devised: 12/04/08

Revised: 8/12, 12/12 (Medicare criteria), 12/13 (Medicare LCD criteria), 12/14

Reviewed: 12/09, 12/10, 12/11, 12/15, 12/16, 11/17, 11/18