

Circulating Tumor Cells (CTC) Assays

LCD ID L34273

LCD Title

Pathology and Laboratory: Circulating Tumor Cells (CTC) Assays

Jurisdiction

Tennessee

Original Effective Date

For services performed on or after 10/01/2015

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CMS National Coverage Policy

- Title XVIII of the Social Security Act, Section 1833(e). This section states that no payment shall be made to any provider for any claims that lack the necessary information to process the claim.
- Title XVIII of the Social Security Act, Section 1862(a)(1)(A). This section allows coverage and payment for only those services that are considered to be reasonable and medically necessary, i.e., reasonable and necessary are those tests used in the diagnosis and management of illness or injury or to improve the function of a malformed body part.
- Title XVIII of the Social Security Act, Section 1862(a)(1)(D). Investigational or experimental
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- 42 CFR Section 410.32(a) indicates diagnostic tests are payable only when the physician who is treating the beneficiary for a specific medical problem uses the results in such treatment.
- Medicare Program Integrity Manual (Pub 100-08), Chapter 13. Local Coverage Determinations.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Indications

This LCD addresses limited coverage for the CellSearch[®] Circulating Tumor Cell (CTC) (Veridex, LLC) assay. All other methods for CTC detection, including PCR (RTPCR) assays, are non-covered.

CTCs represent the point in the metastatic process of solid tumors when cells from a primary tumor invade, detach, disseminate, colonize and proliferate in a distant site. Detection of elevated CTCs during therapy is an accurate indication of subsequent rapid disease progression and mortality in breast, colorectal and prostate cancer.

The assay is reported as a numerical result where five or more cells per 7.5 ml of whole blood predicts worse prognosis in patients with known recurrent breast and prostate cancer, and three or more cells are predictive of shorter Progression Free Survival (PFS) and Overall Survival (OS) in metastatic colorectal cancer.

CTC 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
 - Baseline – limited to once prior to initiation of tumor-type specific chemotherapy.
 - During chemotherapy treatment – may be performed once during chemotherapy.
 - Following chemotherapy treatment – may be repeated at end of chemotherapy.
 - Surveillance with no chemotherapy treatments - may be repeated each year.

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination.

Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph: N/A

Group 1 Codes:

- 86152** **Cell enumeration & id**
- 86153** **Cell enumeration phys interp**

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: The correct use of an ICD-10-CM code listed in the "ICD-10 Codes that Support Medical Necessity" section does not guarantee coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this LCD.

ICD-10 codes must be coded to the highest level of specificity. Consult the 'Official ICD-10-CM Guidelines for Coding and Reporting' in the current ICD-10-CM book for correct coding guidelines. This LCD does not take precedence over the Correct Coding Initiative (CCI).

Group 1 Codes:

| Group 1 Codes | |
|--|--|
| ICD-10 CODE | DESCRIPTION |
| C18.0 - C21.8- Opens in a new window | Malignant neoplasm of cecum - Malignant neoplasm of overlapping sites of rectum, anus and anal canal |
| C50.011 - C50.929- Opens in a new window | Malignant neoplasm of nipple and areola, right female breast - Malignant neoplasm of unspecified site of unspecified male breast |
| C61 | Malignant neoplasm of prostate |

Associated Information

Documentation Requirements

1. All 'Indications' must be clearly documented in the patient's medical record and made available to Medicare upon request.
2. Documentation must support the frequency of testing as outlined in the 'Limitations' and 'Utilization Guidelines' sections.
3. Documentation must support a valid order and CMS 'signature requirements' as described in the Medicare Program Integrity Manual (Pub. 100-08), Chapter 3.

Utilization Guidelines

1. Services performed for excessive frequency are not reasonable and necessary. Patients should be treated on an individual basis as indicated by the response to treatment. The intent of the following guidelines is to provide the maximum amount of tests required to adequately follow disease progression or treatment response.
2. This contractor expects physicians to limit CTC testing to only times when the CTC information may change treatment.
3. Frequency
 - Baseline – limited to once prior to initiation of tumor-type specific chemotherapy.
 - During chemotherapy treatment – may be performed once during chemotherapy.
 - Following chemotherapy treatment – may be repeated at end of chemotherapy.
 - Surveillance with no chemotherapy treatments - may be repeated each year.
4. This contractor would expect to see no further CTC testing after the transition to palliative/hospice care.
5. Services exceeding the above utilization parameter may be subject to medical review or auto-adjudication.

Sources of Information and Basis for Decision

- Budd, G.T., et al., "Circulating Tumor Cells Versus Imaging-Predicting Overall Survival in Metastatic Breast Cancer" *Clin Cancer Res.* 2006;12(21):pp. 6403-6409.
- Cohen, S.J., et al., "Prognostic Significance of Circulating Tumor Cells in Patients with Metastatic Colorectal Cancer," *Annals of Oncol.* 2009;20(7):pp. 1223-1229.
- Cohen, S.J., et al., "Relationship of Circulating Tumor Cells to Tumor Response, Progression-Free Survival, and Overall Survival in Patients with Metastatic Colorectal Cancer," *J Clin Oncol.* 2008;26(19):pp. 3213-3221.
- Consultation with the representatives to the Carrier Advisory Committee and other Medicare contractors.
- Danila, D. C, et al., "Circulating Tumor Cell Number and Prognosis in Progressive Castration-Resistant Prostate Cancer". *Clin Cancer Res.*2007;13(23)pp. 7053-7058.

- Danila, D.C., et al., "Circulating Tumor Cells (CTC) in Patients With Metastatic Castration Resistant Prostate Cancer (CRPC) Receiving Abiraterone Acetate (AA) After Failure of Docetaxel-Based Chemotherapy," *J Clin Oncol.* 2009;p. 27:15s (suppl; abstr 5049).
- de Bono, J.S., et al., "Circulating Tumor Cells Predict Survival Benefit from Treatment in Metastatic Castration-Resistant Prostate Cancer," *Clin Cancer Res.* 2008;14(19):pp. 6302-6309.
- Harris, L., et al., "American Society of Clinical Oncology 2007 Update of Recommendations for the Use of Tumor Markers in Breast Cancer," *J Clin Oncol.* 2007;25(33):pp. 5287-5312.
- Hayes, D.F., Smerage, J., "Is There a Role for Circulating Tumor Cells in the Management of Breast Cancer?" *Clinical Cancer Res.* 2008;14(12):pp. 3646-3650.
- Other Medicare Contractor's Local Coverage Determinations.
- Petrelli, N.J., et al., "Clinical Cancer Advances 2009: Major Research Advances in Cancer Treatment, Prevention, and Screening - A Report From the American Society of Clinical Oncology," *J Clin Oncol.* 2009;27(35):pp. 6052-6069.

Local Coverage Determination (LCD) Disclaimer

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