

**EFFECTIVE DATE:** 01|20|2009

**POLICY LAST UPDATED:** 06|17|2014

## OVERVIEW

This policy documents the coverage determination for the Detection of Circulating Tumor Cells (CTC) in the Management with Cancer. Circulating tumor cells (CTCs) are malignant cells that are found in the peripheral blood and originate from primary or metastatic tumors. CTCs could potentially provide prognostic information that could guide treatment decisions or aid in the monitoring of response to treatment.

## PRIOR AUTHORIZATION

Not applicable

## POLICY STATEMENT

### BlueCHiP for Medicare and Commercial

Detection of circulating tumor cells in the management of patients with cancer is considered not medically necessary as there is insufficient peer-reviewed literature that demonstrates that the procedure is effective.

## MEDICAL CRITERIA

Not Applicable

## BACKGROUND

Circulating tumor cells (CTCs) are malignant cells that are found in the peripheral blood and originate from primary or metastatic tumors. CTCs could potentially provide prognostic information that could guide treatment decisions or aid in the monitoring of response to treatment. Circulating tumor cells have been documented in multiple tumor types, such as breast, prostate, lung, and colorectal carcinomas; the largest body of data comes from studies of women with metastatic breast cancer. CTCs have also been investigated as an additional prognostic factor in non-metastatic breast cancer and could be used to determine the need for additional adjuvant chemotherapy.

Research over the past 10 years has focused on the development of methodologies with improved sensitivity and specificity. Physical techniques such as size filtration, density gradient centrifugation, and microscopic morphology continue to be used. However, biological techniques such as immunomagnetic isolation, flow cytometry, immunofluorescent microscopy, reverse transcriptase-polymerase chain reaction (RT-PCR), polymerase chain reaction (PCR), and fluorescence in situ hybridization (FISH) have been added to provide required specificity.

The CellSearch™ system (Veridex) is an example of immunofluorescent technology. The technique involves identification of the circulating tumor cells in blood, which are tagged using antibody-coated magnetic beads that recognize cell surface antigens. The cells are then labeled with fluorescent dyes, which can then be quantified by a semiautomated fluorescent-based microscopy system.

Note: This policy does not address techniques for the detection of bone marrow disseminated tumor cells (DTCs) or circulating cell-free DNA.

While studies have shown that the level of circulating tumor cells (generally using the cutoff >5 CTC per 7.5 mL blood) is associated with the presence of metastatic disease and prognosis, the prospective use of this information to impact care has not been demonstrated. Given that insufficient evidence is available to evaluate the impact on patient management or health outcomes and additional remaining questions eg, the optimal cutoff to use, the assessment of circulating tumor cells is considered not medically necessary.

#### COVERAGE

Benefits vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable services not medically necessary coverage/services.

#### CODING

##### Blue CHiP for Medicare and Commercial

The following CPT codes are considered not medically necessary:

86152 86153

#### RELATED POLICIES

None

#### PUBLISHED

Provider Update	Aug 2014
Provider Update	Sep 2013
Provider Update	May 2012
Provider Update	May 2011
Provider Update	May 2010
Provider Update	May 2009

#### REFERENCES

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3. Nole F, Munzone E, Zorzino L et al. Variation of circulating tumor cell levels during treatment of metastatic breast cancer: prognostic and therapeutic implications. *Ann Oncol* 2008; 19(5):891-7.
4. Pierga JY, Hajage D, Bachelot T et al. High independent prognostic and predictive value of circulating tumor cells compared with serum tumor markers in a large prospective trial in first-line chemotherapy for metastatic breast cancer patients. *Ann Oncol* 2012; 23(3-Jan):618-24.
5. Wang FB, Yang XQ, Yang S et al. A higher number of circulating tumor cells in peripheral blood indicates poor prognosis in prostate cancer patients-a meta-analysis. *Asian Pac J Cancer Prev* 2011; 12(10):2629-35.
6. de Bono J., Scher HI, Montgomery RB et al. Circulating tumor cells predict survival benefit from treatment in metastatic castration-resistant prostate cancer. *Clin Cancer Res* 2008; 14(19):6302-
7. Bidard FC, Mathiot C, Delaloue S et al. Single circulating tumor cell detection and overall survival in nonmetastatic breast cancer. *Ann Oncol* 2010; 21(4):729-33
8. National Government Services LCD FOR CIRCULATING TUMOR CELL (CTC) ASSAY (L32965), Effective Date October, 2013 Coverage Determination, including References

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