Medical Coverage Policy | Detection of Circulating Tumor Cells in the Management of Patients with Cancer

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 site 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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