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

Blue Cross Blue Shield of Rhode Island

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 07|21|2015

OVERVIEW

This policy documents the coverage determination for the Detection of Circulating Tumor Cells (CTC) in the Management of Patients with Cancer. Circulating tumor cells 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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

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.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND

Circulating tumor cells 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 CTCs 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 (e.g., the optimal cutoff to use for various conditions) the assessment of CTCs is considered not medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

The following CPT codes are considered not medically necessary when billed with a diagnosis code listed in the attachment:

86152 **86153**

ICD-10 Codes:

ICD-10 Codes.pdf

RELATED POLICIES

None

PUBLISHED

Provider Update, August 2015
Provider Update, August 2014
Provider Update, September 2013
Provider Update, May 2012
Provider Update, May 2011
Provider Update, May 2010
Provider Update, May 2009

REFERENCES

1. Zhang L, Riethdorf S, Wu G et al. Meta-analysis of the prognostic value of circulating tumor cells in breast cancer. Clin Cancer Res 2012; 18(20):5701-10.

2. Cristofanilli M, Budd GT, Ellis MJ et al. Circulating tumor cells, disease progression and survival in metastatic breast cancer. N Engl J Med 2004; 351(8-Jan):781-91.

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, Delaloge S et al. Single circulating tumor cell detection and overall survival in nonmetastatic breast cancer. Ann Oncol 2010; 21(4):729-33

8. Huang X, Gao P, Song Y, et al. Meta-analysis of the prognostic value of circulating tumor cells detected with the CellSearch System in colorectal cancer. BMC Cancer. 2015; 15:202. PMID 25880692

9. CellSearch Brochure. https://www.cellsearchctc.com/sites/default/files/docs/cellsearch-ctc-test-brochure.pdf. Accessed May 5, 2015

10. Bork U, Rahbari NN, Scholch S, et al. Circulating tumour cells and outcome in non-metastatic colorectal cancer: a prospective study. Br J Cancer. Apr 14 2015; 112(8):1306-1313. PMID 25867263

11. National Government Services LCD FOR CIRCULATING TUMOR CELL (CTC) ASSAY (L32965), http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=32965&ContrId=303&ver=17&ContrVer=1&CntrctrSelected=303*1&Cntrctr=303&s=47&DocType=Active&LCntrctr=295*1&bc=AggAAAIAAAAAAA%3d%3d&

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS