

## Corporate Medical Policy

### Detection of Circulating Tumor Cells

<b>File Name:</b>	detection_of_circulating_tumor_cells
<b>Origination:</b>	2/2005
<b>Last CAP Review:</b>	3/2012
<b>Next CAP Review:</b>	3/2013
<b>Last Review:</b>	3/2012

#### Description of Procedure or Service

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The prognosis of cancer patients is often determined by the occurrence of metastatic disease.

Studies have suggested that the presence of circulating tumor cells in patients with metastatic carcinoma is associated with short survival. The detection of circulating tumor cells might be useful for assessing prognosis and guiding cancer therapy.

#### 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 nonmetastatic breast cancer and could be used to determine the need for additional adjuvant chemotherapy.

#### Detection Methods

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.

This policy does not address techniques for the detection of disseminated tumor cells, e.g., in bone marrow.

#### Regulatory Status

The CellSearch™ system (Veridex) has received U.S. Food and Drug Administration (FDA) marketing clearance through the 510(k) process for monitoring metastatic breast cancer (January 2004), for monitoring metastatic colorectal cancer (November 2007), and for monitoring metastatic

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prostate cancer (February 2008). Veridex LLC, a Johnson & Johnson company, markets the CellSearch system. It uses automated instruments manufactured by Immunicorp. for sample preparation (Cell Tracks® AutoPrep) and analysis (CellSpotterAnalyzer®), together with supplies, reagents, and epithelial cell control kits manufactured by Veridex. As of April 2011, this remains the only FDA-cleared system for assessing circulating tumor cells, and the indications for its use are unchanged.

## **Related Policies:**

Assays of Genetic Expression to Determine Prognosis in Patients with Breast Cancer  
Gene Based Test for Screening, Detection and/or Management of Prostate Cancer  
Biomarker Genes for the Detection of Lymph Node Metastases

*\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

## **Policy**

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**Detection and quantification of circulating tumor cells is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.**

## **Benefits Application**

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## **When Detection of Circulating Tumor Cells is covered**

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Not applicable.

## **When Detection of Circulating Tumor Cells is not covered**

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Detection and quantification of circulating tumor cells is considered **investigational** in the management of patients with cancer.

BCBSNC does not provide coverage for investigational services.

## **Policy Guidelines**

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While levels of circulating tumor cells may be associated with the presence of metastatic disease and prognosis, the prospective use of this information to impact care has not been demonstrated. There is insufficient evidence to evaluate the impact of this technology on net health outcomes.

This test would only be performed at a limited number of reference laboratories.

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## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 0279T, 0280T,*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.37, 11/9/2004

Cristofanilli M, Budd GT, Ellis MJ, et al. (2004, August). Circulating tumor cells, disease progression, and survival in metastatic breast cancer. *The New England Journal of Medicine*. 351(8):781-91.

Specialty Matched Consultant Advisory Panel - 4/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.37, 10/10/06

Specialty Matched Consultant Advisory Panel - 4/2007

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.37, 2/14/08

Specialty Matched Consultant Advisory Panel 4/2009

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.37, 5/13/2010

Specialty Matched Consultant Advisory Panel 3/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.37, 5/12/2011

Specialty Matched Consultant Advisory Panel – 3/2012

## Policy Implementation/Update Information

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2/17/05 New policy written. Detection of circulating tumor cells is not covered. It is considered investigational. Notification given 2/17/2005. Policy effective date 4/21/2005.

5/5/05 Specialty Matched Consultant Advisory Panel meeting 4/14/2005. No changes to criteria. References added.

5/21/07 Specialty Matched Consultant Advisory Panel meeting 4/25/2007. No changes to policy. References added.

6/4/07 Changed policy number from MED1097 to MED1483.

1/5/09 Added new CPT code S3711 to the "Billing/Coding" section.

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5/18/09 Specialty Matched Consultant Advisory Panel meeting 4/21/09. No changes to policy statement. References added. (btw)

6/22/10 Policy Number(s) removed (amw).

4/26/11 Specialty Matched Consultant Advisory Panel review March 30, 2011. "Description" section revised. No change to policy statement. "Policy Guidelines" updated. References added. (btw)

8/16/11 Reference added. (btw)

1/1/12 Added new 2012 CPT codes, 0279T and 0280T to "Billing/Coding" section. (btw)

4/17/12 Specialty Matched Consultant Advisory Panel review 3/21/2012. No change to policy, Deleted HCPCS code S3711 from Billing/Coding section. (btw)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.