Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Description:
Studies have suggested that the presence of circulating tumor cells (CTC) in patients with metastatic carcinoma is associated with short survival. Quantifying circulating tumor cells might be a useful technique to provide an immediate assessment of response to chemotherapy rather than relying on changes in imaging studies (i.e., computed tomography scans). Finally, the presence of circulating tumor cells has been investigated as an additional prognostic factor in women with breast cancer without metastases, which could be used to determine the need for additional adjuvant chemotherapy. The CellSearch™ System (Veridex) is an example of such a technology. The technique involves identification of the circulating tumor cells, 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.

Veridex LLC, a Johnson & Johnson company, markets the CellSearch System. It uses automated instruments manufactured by Immunicon Corp. for sample preparation (Cell Tracks® AutoPrep) and analysis (CellSpotterAnalyzer®), together with supplies, reagents, and epithelial cell control kits manufactured by Veridex. The technology has received U.S. Food and Drug Administration 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 prostate cancer (February 2008).

None of the studies identified through the literature search have evaluated the clinical impact (clinical utility) through prospective use of this assay in clinical care. The American Society of Clinical Oncology update of recommendations for the use of tumor markers in breast cancer indicates that the measurement of circulating tumor cells should not be used to make the diagnosis of breast cancer or to influence any treatment decisions in those with breast cancer. Given the insufficient evidence to evaluate the impact on net health outcome this approach is considered not medically necessary.
Medicare
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. Therefore, CTC will be limited to metastatic breast, colorectal and prostate cancer.
The assay findings are verified by a pathologist and issued in a report as a numerical result where more than 5 cells per 7.5 ml of whole blood predicts worse prognosis in patients with known recurrent breast and prostate cancer, and more than 3 cells are predictive of shorter progression free survival (PFS) and overall survival (OS) in metastatic colorectal cancer.

Medical Criteria:
None

Policy:
BlueCHiP for Medicare
CellSearch (Veridex) circulating tumor cell assay detection is covered for diagnosis of neoplasm of breast, colon or prostate (ICD-9 codes listed in the Coding section below).

CTC testing for all other malignant diagnoses are considered not medically necessary as its clinical efficacy has not been established.

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers.

Commercial Products
Detection of circulating tumor cells in the management of patients with cancer is considered not medically necessary as its clinical efficacy has not been established.

Coverage:
Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for the definition of "Not Medically Necessary" services.

Coding:
Effective 07/01/2013, the following CPT codes are medically necessary for BlueCHiP for Medicare for one of the diagnosis code listed below and not medically necessary for commercial products:
86152 Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood)
Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood); physician interpretation and report, when required

**ICD-9 Neoplasm of Breast/Colon**

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**ICD-10**

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**Also Known As:**
- CellSearch®
- Circulating Tumor Cells
- Tumor Markers

**Related Topics:**
- None

**Published:**
- Provider Update, September 2013
- Provider Update, May 2012
- Provider Update, May 2011
- Provider Update, May 2010
- Provider Update, May 2009

**References:**


**Review History:**
- 7/16/2013: Annual review covered for BlueChiP for Medicare with diagnosis of neoplasm of breast or colon
This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member’s subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice.