Medical Coverage Policy

Detection of Circulating Tumor Cells in the Management of Patients with Cancer

☐ Device/Equipment ☐ Drug ☐ Medical ☐ Surgery ☒ Test ☐ Other

Effective Date:	1/20/2009	Policy Last Updated:	2/21/2012

☐ **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 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 semi automated 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 2007 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**.

Medical Criteria:

Not applicable.

Policy:

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:

Providers filing for a circulating tumor cells test are required to file the service using the appropriate HCPCS code below:
S3711 Circulating tumor cell test

Also Known As:
CellSearch®
Circulating Tumor Cells

Related Topics:
Not applicable.

Published:
Provider Update, May 2009
Provider Update, May 2010
Provider Update, May 2011
Provider Update, May 2012

References:
Blue Cross Association Medical Policy Reference Manual. 2.04.37 Detection of Circulating Tumor Cells in the Management of Patients with Cancer. Section 5:2011. Accessed 01/23/12
http://bluewebportal.bcbs.com/global_assets/special_content/medical_policy/policymanual/policy.html?pnum=20437