CellSearch Circulating Tumor Cell Count for Breast Cancer Prognosis

Introduction

CellSearch circulating tumor cell count is addressed by this guideline.

Procedures addressed

The inclusion of any procedure code in this table does not imply that the code is under management or requires prior authorization. Refer to the specific Health Plan's procedure code list for management requirements.

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What are circulating tumor cells

Definition

Circulating tumor cells (CTCs) are cells whose source is unknown, but may have broken away from tumor tissue and are circulating in the blood stream. CTCs are rare in healthy individuals, but often present in people with metastatic cancer.

CTCs and breast cancer

The presence of CTCs in breast cancer patients may predict metastasis of an aggressive primary tumor.

A 2004 study found that individuals undergoing treatment for metastatic breast cancer with greater than or equal to 5 CTCs/7.5 mL had shorter progression-free survival (PFS) and shorter overall survival (OS) than individuals with less than 5 CTCs/7.5 mL.

The results of these and other studies suggest that measuring CTCs could be a useful prognostic tool for individuals with metastatic breast cancer.

CTCs may be measured before the start of therapy, and then after each therapy cycle (usually 4-5 weeks).
Test information

Introduction

The CellSearch® Circulating Tumor Cells Test measures CTC levels in the blood of breast cancer patients to identify risk for distant metastasis.\(^3\)

CellSearch

The purpose of CellSearch is to distinguish normal cells from CTCs with fluorescent nucleic acid dye.\(^3\)

Results are generally reported at number of CTCs per 7.5 ml of whole blood.\(^2,4\)

It has been reported that CellSearch correctly measures the levels of CTCs in 99.7% of breast cancer patients.\(^1\)

CellSearch was cleared by the FDA in 2004.\(^4\)

Guidelines and evidence

Introduction

This section includes relevant guidelines and evidence pertaining to circulating tumor cells.

American Society of Clinical Oncology

The American Society of Clinical Oncology (ASCO, 2016) states the following regarding circulating tumor cells:\(^5\)


Criteria

Introduction

Requests for CellSearch circulating tumor cell count are reviewed using these criteria.

Criteria

This test is considered investigational and/or experimental.

- Investigational and experimental (I&E) molecular and genomic (MolGen) tests refer to assays involving chromosomes, DNA, RNA, or gene products that have insufficient data to determine the net health impact, which typically means there is
insufficient data to support that a test accurately assesses the outcome of interest (analytical and clinical validity), significantly improves health outcomes (clinical utility), and/or performs better than an existing standard of care medical management option. Such tests are also not generally accepted as standard of care in the evaluation or management of a particular condition.

- In the case of MolGen testing, FDA clearance is not a reliable standard given the number of laboratory developed tests that currently fall outside of FDA oversight and FDA clearance often does not assess clinical utility.

References

Introduction

These references are cited in this guideline.


