Chemotherapy Sensitivity and Resistance Assays (CSRA)

Disclaimer:
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For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare & Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website: http://www.cms.gov. Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

DEFINITION

Chemosensitivity and chemoresistance assays (CSRA) describe laboratory tests that were designed to identify the most effective chemotherapy treatment regimens following an in-vitro analysis of a specific malignancy. The purpose of CSRA is to allow individualized treatment plans that could maximize treatment and improve health outcome. The four basic steps involved in CSRA include isolating cells from the tumor, incubating the cells with the regimens, assessing cell survival and interpreting the results. Although several CSRAs have been developed, only two are commercially available in the US: the Microculture-Kinetic (MiCK) assay (DiaTech Oncology, Franklin, TN) and the ChemoFx® assay (Precision Therapeutics, Inc., Pittsburgh, PA).

COVERAGE CRITERIA

Chemotherapy sensitivity and chemoresistance assays (CSRA) may NOT be medically necessary because this technology is experimental and/or investigational. Data published in peer-reviewed medical literature are insufficient in demonstrating that the use of CSRA has any...
MEDICAL BACKGROUND

Cancer remains the second leading cause of death in the US despite monumental advances in recent years in cancer detection and treatment. As more cancer therapies have become available, the selection process of treatment course has become increasingly clinically important. The purpose of chemosensitivity and chemoresponse assays (CSRA) is to provide clinicians with decision support in the selection of treatment regimens following an in vitro analysis of tumor cells with considered therapies. Despite the potential clinical importance of CSRA, years have data have failed to demonstrate the clinical importance of these in vitro tests in optimizing cancer treatment. A 2008 Hayes Medical Technology report found insufficient data to recommend its use given a lack of evidence from clinical trials that CSRA improves patient management or clinical outcomes. Since the publication of this archived report, Hayes has published two follow-up reports in which the two specific commercially available tests in the US were independently analyzed: the Microculture-Kinetic (MiCK) assay (DiaTech Oncology, Franklin, TN) and the ChemoFx® assay (Precision Therapeutics, Inc., Pittsburgh, PA). Hayes found insufficient data in its 2014 Search and Summary report to make a determination regarding the clinical utility of the MiCK assay. A technology brief evaluating the clinical utility of the ChemoFx® assay yielded a D rating for ovarian cancer. The agency for Healthcare Research and Quality did not recommend the use of CSRA in women with advanced breast cancer in its most recently published 2014 practice guidelines. The National Comprehensive Cancer Network likewise did not recommend the use of CSRA in its 2014 recommendations for ovarian and fallopian tube cancer treatment guidelines.

A literature search of recently published evidence did not demonstrate overpowering evidence following the publication of national guidelines and Hayes Medical Technology Reports. A 2014 review confirmed that the majority of evidence has been single site retrospective studies, but still recommended the use of CSRA along with clinical factors and other testing in order to facilitate individualized care for patients with ovarian cancer. However, several authors of this study are paid employees or have received honoraria from Precision Therapeutics, Inc., the maker of ChemoFx®. Higher quality evidence needs to be published in order to better understand the clinical value of CSRA, and also which particular assays are suitable for the in vitro analysis of particular cancer types.

Despite several years of chemoresponse assay development and clinical experience with these assays, studies have largely been confined to single-institutional, retrospective evaluations. Recent large, prospective, multi-site clinical studies that correlate ChemoFx assay results with overall and progression-free survival in both primary and recurrent ovarian cancers indicate that the assay may offer significant clinical benefit for patients, is predictive of treatment outcomes, and is potentially economically beneficial by reducing the chance that ineffective chemotherapy is administered. This overview supports the inclusion of chemoresponse assay results, along with other clinical factors and biomarkers, to support the individualized selection of effective chemotherapy agents for treatment of patients with ovarian cancer.
REGULATORY INFORMATION

Kentucky – No legislative mandates were found for coverage of chemosensitivity testing.
Indiana – No legislative mandates were found for coverage of chemosensitivity testing.
Tennessee – No legislative mandates were found for coverage of chemosensitivity testing.

COVERAGE DETAIL

CODING INFORMATION

CODES INCLUDE BUT MAY NOT BE LIMITED TO THE FOLLOWING:

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REFERENCES

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