Medica Central Coverage Policy

Policy Name:	**In Vitro Chemosensitivity and Chemoresistance Assays MP9760**
Effective Date:	**11/01/2025**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

In vitro chemosensitivity and chemoresistance assays are investigative and unproven, and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description

In vitro chemosensitivity and chemoresistance assays, also known as chemoresponse assays, are tests designed to assess tumor response to specific chemotherapeutic agents under laboratory conditions. The tumor cells used for testing are obtained from the patient by biopsy or surgery. The tissue may be taken from the primary tumor, before or after chemotherapy, or from a recurring tumor or metastasis. Sensitivity assays are intended to allow selection of the chemotherapeutic agent, or combination of agents, to which a patient's tumor is most sensitive. By contrast, resistance assays focus on identifying drugs to which the tumor is resistant. Assay-guided chemotherapy has been proposed as an alternative to empiric therapy (i.e., the selection of chemotherapeutic agents based on critical evaluation of outcome evidence from well-designed clinical trials) as a means to individualize cancer therapy.

A variety of assays exist, including, but not limited to, the ChemoFx® Assay (Precision Therapeutics, Inc., Pittsburgh, PA), Correct Chemo® (Diatech Oncology, Nashville, TN), also known as the Microculture Kinetic (MiCK®) assay, histoculture drug response assay (HDRA), DiSC assay (differential staining cytotoxicity assay), the thymidine incorporation assay, fluorescence (cytoprint) assays, the 3-(4,5-dimethyl-2-thiazolyl)-2, 5-diphenyl-2H tetrazolium bromide (MTT) assay, the adenosine triphosphate (ATP) bioluminescence assay, and the extreme drug resistance (EDR) assay. These assays differ in their processing and the techniques used to measure sensitivity or resistance. However, all follow a common set of four basic steps: isolation of cells; incubation of cells with drugs; assessment of cell survival; and interpretation of the results.

Results are reported as drug sensitive, drug resistant, or intermediate. Agents identified as drug sensitive are purported to be potentially effective in vivo chemotherapies, resulting in improved clinical outcomes and prolonged survival. Drugs identified as resistant are purported to be potentially ineffective chemotherapies, thus eliminating ineffective treatment regimens and sparing the patient unnecessary toxicity.

FDA Approval

In vitro chemosensitivity and chemoresistance assays are performed in research and commercial laboratories, which are regulated by and certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Therefore, FDA premarket approval is not required.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

- **0083U** - Oncology, response to chemotherapy drugs using motility contrast tomography, fresh or frozen tissue, reported as likelihood of sensitivity or resistance to drugs or drug combinations
- **0564T** - Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on percent of cytotoxicity observed, a minimum of 14 drugs or drug combinations

	Committee/Source	Date(s)
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