of Tennessee

Policy

Reimbursement Policy

In Vitro Chemoresistance and Chemosensitivity Assays

I. Policy Description

In vitro chemotherapy sensitivity and resistance assays refer to any in vitro laboratory analysis that is performed specifically to evaluate whether tumor growth is inhibited by a known chemotherapy drug or, more commonly, a panel of drugs (Hatok et al., 2009; Schrag et al., 2004).

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

1) In vitro chemosensitivity assays (e.g., histoculture drug response assay, fluorescent cytoprint assay) **DO NOT MEET COVERAGE CRITERIA**.
2) In vitro chemoresistance assays (e.g., extreme drug resistance [EDR] assays) **DO NOT MEET COVERAGE CRITERIA**.

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of

1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
86849	Unlisted immunology procedure
88104	Cytopathology, fluids, washings or brushings, except cervical or vaginal; smears with interpretation
88199	Unlisted cytopathology procedure
88305	Level IV - Surgical pathology, gross and microscopic examination
88313	Special stain including interpretation and report; Group II, all other (eg, iron, trichrome), except stain for microorganisms, stains for enzyme constituents, or immunocytochemistry and immunohistochemistry
88358	Morphometric analysis; tumor (eg, DNA ploidy)
89050	Cell count, miscellaneous body fluids (eg, cerebrospinal fluid, joint fluid), except blood;
89240	Unlisted miscellaneous pathology test
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 Proprietary test: Onco4D™ Lab/manufacturer: Animated Dynamics, Inc.
0248U	Oncology spheroid cell culture in 3D microenvironment, 12 drug panel, brain or brain metastasis response prediction for each drug Proprietary test: 3D Predict Glioma Lab/Manufacturer: KIYATEC®, Inc
0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report Proprietary test: Theralink® Reverse Phase Protein Array (RPPA) Lab/Manufacturer: Theralink® Technologies, Inc
0285U	Oncology, response to radiation, cell-free DNA, quantitative branched chain DNA amplification, plasma, reported as a radiation toxicity score Proprietary test: RadTox™ cfDNA test Lab/Manufacturer: DiaCarta Clinical Lab/DiaCarta Inc
0435U	Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on cytotoxicity percentage observed, minimum of 14 drugs or drug combinations. Proprietary test: ChemoID® Lab/Manufacturer: ChemoID® Lab, Cordgenics, LLC

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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