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Medicare Advantage Policy Manual

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Chemoresistance and Chemosensitivity Assays (CSRAs)

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

A chemotherapy sensitivity (*chemosensitivity*) assay determines if a tumor growth is inhibited by a known chemotherapy drug or drug combination. A *chemoresistance* assay determines "extreme drug resistance" when tumor cell cultures are exposed to high concentrations of selected agent(s) for long exposure times. Therefore, the intent of chemosensitivity and chemoresistance assays is to avoid ineffective chemotherapy toxicity and assist with the selection of chemotherapy drugs at initial diagnosis and tumor recurrence. (*Noridian LCD L37630*)

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	<p>For chemotherapy and drug sensitivity assays that use cultured tumor stem cells (i.e., the Fluorescent Cytoprint Assay, Chemold [0564T, 0435U]):</p> <ul style="list-style-type: none"> ✓ Human Tumor Stem Cell Drug Sensitivity Assays (190.7)
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles	<p>For chemosensitivity and resistance assays (CSRAs) other than the ChemoFX® Assay (see below) or CSRAs not addressed by the above NCD or LCDs below:</p> <ul style="list-style-type: none"> ✓ In Vitro Chemosensitivity & Chemoresistance Assays (L37630) (Companion article A56073 can be accessed directly from the LCD) <p>(See also the LCD for Special Histochemical Stains and Immunohistochemical Stains (L36353), specifically the section for “IHC for Chemosensitivity and Resistance Tumor Profiling” within the LCD)</p> <p>**See the “Public Version(s)” section of the LCD for links to prior versions.</p>
Non-Noridian Healthcare Solutions LCDs and Articles	<p>Note: Medicare guidelines state jurisdiction for coverage determinations for diagnostic laboratory services is by the contractor assigned jurisdiction over the service area in which the tests are performed.^[1,2]</p> <p>The Onco4D™ test is performed by Animated Dynamics, Inc. (Indiana). Therefore, the Medicare contractor for Indiana (Wisconsin Physician Services, Jurisdiction 8, or J-8) is responsible for establishing coverage determinations.</p> <p>For the Onco4D™ test:</p> <ul style="list-style-type: none"> ✓ Wisconsin LCD Lab: Special Histochemical Stains and Immunohistochemical Stains (L36805) (See statement, “Chemosensitivity profile tumor panels, regardless of whether it is performed by IHC or chromogenic in-situ hybridization (CISH), is not reasonable and necessary for the reasons cited above and is not a Medicare covered service.”) <p>The 3D Predict Glioma test is performed by KIYATEC, Inc. (South Carolina). Therefore, the Medicare contractor for South Carolina (Palmetto GBA, Jurisdiction M, or J-M) is responsible for establishing coverage determinations.</p> <p>For the 3D Predict Glioma test:</p>

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- ✓ In Vitro Chemosensitivity & Chemoresistance Assays ([L34554](#))

**See the “Public Version(s)” section of the LCD for links to prior versions.

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Medicare coverage guidance is not available for chemosensitivity or chemoresistance testing for some service areas (e.g., ChemoFX®, performed by Helomics [previously Precision Therapeutics, Inc.], in Pittsburgh, PA). Therefore, the health plan’s medical policy is applicable.

Note: The health plan’s medical policy is consistent with other Medicare NCD and Medicare Contractor LCDs with respect to non-coverage of CSRA testing.

In Vitro Chemoresistance and Chemosensitivity Assays, Laboratory, [Policy No. 06](#) (see “NOTE” below)

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. ([Medicare IOM Pub. No. 100-04, Ch. 23, §30 A](#)). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence**. ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan’s evidence-assessment process (see Cross References).

CROSS REFERENCES

[Genetic and Molecular Diagnostics – Testing for Cancer Diagnosis, Prognosis, and Treatment Selection, Genetic Testing](#), Policy No. M-GT83

[Laboratory and Genetic Testing for Use of 5-Fluorouracil \(5-FU\) in Patients with Cancer](#), Laboratory, Policy No. M-64

[Investigational \(Experimental\) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services](#), Medicine, Policy No. M-149

REFERENCES

1. Medicare Claims Processing Manual, Chapter 1 - General Billing Requirements, [§10.1.5.4 - Independent Laboratories](#)
2. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, [§90.4.1 - MAC with Exclusive Jurisdiction over a Medicare Item or Service](#)

CODING

Codes	Number	Description
CPT	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
	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
	0248U	Oncology, spheroid cell culture in a 3D microenvironment, 12 drug panel, brain- or brain metastasis-response prediction for each drug
	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
	0511U	Oncology (solid tumor), tumor cell culture in 3D microenvironment, 36 or more drug panel, reported as tumor-response prediction for each drug
	0525U	Oncology, spheroid cell culture, 11-drug panel (carboplatin, docetaxel, doxorubicin, etoposide, gemcitabine, niraparib, olaparib, paclitaxel, rucaparib, topotecan, veliparib) ovarian, fallopian, or peritoneal response prediction for each drug
	81535	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination
	81536	; each additional single drug or drug combination (List separately in addition to code for primary procedure)
	84999	Unlisted chemistry procedure
	86849	Unlisted immunology procedure
	87999	Unlisted microbiology procedure
	88199	Unlisted cytopathology procedure
	89240	Unlisted miscellaneous pathology test
HCPCS	None	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

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.