

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.

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 the Centers of Medicare and Medicaid Services (CMS) policies, when available. 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 CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and 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.

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)*	For chemotherapy and drug sensitivity assays related to <u>stem cell tumors</u> (i.e., the Fluorescent Cytoprint Assay):

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- ✓ Human Tumor Stem Cell Drug Sensitivity Assays ([190.7](#))

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*

For ***chemosensitivity and resistance assays (CSRAs) other than the ChemoFX® Assay (see below) or CSRAs performed on any other class of tumors not addressed by the above NCD:***

- ✓ In Vitro Chemosensitivity & Chemoresistance Assays ([L37630](#))

(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)

**Scroll to the “Public Version(s)” section at the bottom of the LCD for links to prior versions if necessary.

Non-Noridian Healthcare Solutions LCDs and LCAs*

Note: The ChemoFX® test is performed by Precision Therapeutics, Inc., (Pittsburgh, PA). 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] Therefore, the Medicare contractor for Pennsylvania (Novitas Solutions, Inc., Jurisdiction L, or J-L) is responsible for establishing coverage determinations.

For the ***ChemoFX® Assay:***

- ✓ Novitas LCD for In Vitro Chemosensitivity & Chemoresistance Assays ([L36634](#))

Note: The Onco4D™ test is performed by Animated Dynamics, Inc. (Indiana). 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] Therefore, the Medicare contractor for Indiana (Wisconsin Physician Services, Jurisdiction 8, or J-8) is responsible for establishing coverage determinations.

For the ***Onco4D™ test:***

- ✓ Wisconsin LCD for Special Histochemical Stains and Immunohistochemical Stains ([L36805](#)) (See the statement in this LCD that reads, “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.”)

**Scroll to the “Public Version(s)” section at the bottom of the LCD for links to prior versions if necessary.

CROSS REFERENCES

[Genetic and Molecular Diagnostics – Single Gene or Variant Testing](#), Genetic Testing, Policy No. M-20

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

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	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
	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
HCPCS	None	

***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 web sites outside of the health plan's web control as these sites are not maintained by the health plan.