

Human Tumor Stem Cell Drug Sensitivity Assays (NCD 190.7)

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Related Medicare Advantage Policy Guidelines

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Related Medicare Advantage Reimbursement Policies

- [Clinical Laboratory Improvement Amendments \(CLIA\) ID Requirement Policy, Professional](#)
- [Laboratory Services Policy, Professional](#)

Related Medicare Advantage Coverage Summary

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Policy Summary

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Overview

Human tumor stem cell drug sensitivity assays involve exposure of human tumor stem cell colonies grown in tissue culture to anticancer drugs and observing for cytotoxic effects. Their purpose is to screen potential anticancer drugs and predict the effects of these drugs on tumors of individual patients, to allow the selection of the most effective drug or drugs for that patient.

The Fluorescent Cytoprint Assay, a miniaturized organ culture system for cancer chemosensitivity testing, allows for qualitative visual estimation of cell kill using low power microscopy and a non-cytotoxic fluorescence probe for cell viability.

Tumor chemosensitivity and chemoresistance assays (CSRAs)

Medicare addresses the following chemosensitivity and chemoresistance assay:

- ChemoFx®

Chemosensitivity Assays

A chemotherapy sensitivity assay determines if a tumor growth is inhibited by a known chemotherapy drug or drug combination. Thus, the intent of the chemosensitivity assay is to assist the oncologist with effective chemotherapy agent selection.

Other names for chemosensitivity assays include non-clonogenic or clonogenic cytotoxic drug resistance assays, tumor stem cell assays, human tumor stem cell drug sensitivity assays and differential staining cytotoxic assays. The available chemosensitivity assays listed in this policy isolate tumor cells, incubate the cells with drugs, and evaluate and interpret cell survival. The difference in these assays is determined by the processing method.

Medicare addresses the following chemosensitivity assays:

- DiSC assay (Differential staining cytotoxicity assay)
- ATP (Adenosine Triphosphate) assay
- MTT (Methyl Thiazolyl Tetrazolium) assay
- HDRA[®] (AntiCancer Inc) Assay
- EVA-PCD[®] (Rational Therapeutics) assay

Chemoresistance Assays

A chemoresistance assay determines “extreme drug resistance” when tumor cell cultures are exposed to high concentrations of selected agent(s) for long exposure times. A chemoresistance assay is used to deselect potentially ineffective therapeutic agents.

Medicare addresses the following chemoresistance assay:

- Oncotech EDR[®] (Exiqon Diagnostics)

Guidelines

Human tumor drug sensitivity assays are considered experimental, and therefore, not covered under Medicare at this time.

The clinical application of the assay, based on testing in tumor microorgans rather than in clones derived from single cells, is considered experimental, and therefore, not covered under Medicare at this time.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
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 (Effective 01/01/2020) [See the Medicare Advantage Policy Guideline titled Category III 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
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	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (List separately in addition to code for primary procedure)
84999	Unlisted chemistry procedure
86849	Unlisted immunology procedure
89240	Unlisted miscellaneous pathology test

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References

CMS National Coverage Determinations (NCDs)

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

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
In Vitro Chemosensitivity & Chemoresistance Assays				
L34554 In Vitro Chemosensitivity & Chemoresistance Assays	A56871 Billing and Coding: In Vitro Chemosensitivity & Chemoresistance Assays	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L37628 In Vitro Chemosensitivity & Chemoresistance Assays	A56071 Billing and Coding: In Vitro Chemosensitivity & Chemoresistance Assays	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L37630 In Vitro Chemosensitivity & Chemoresistance Assays	A56073 Billing and Coding: In Vitro Chemosensitivity & Chemoresistance Assays	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
General Molecular Diagnostic Tests				
L35000 Molecular Pathology Procedures	A56199 Billing and Coding: Molecular Pathology Procedures	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L36021 Molecular Diagnostic Tests (MDT)	A56973 Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)	CGS	KY, OH	KY, OH
L35160 MoIDX: Molecular Diagnostic Tests (MDT)	A57526 Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MoIDX: Molecular Diagnostic Tests (MDT)	A57527 Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L35025 MoIDX: Molecular Diagnostic Tests (MDT)	A56853 Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 MoIDX: Molecular Diagnostic Tests (MDT)	A57772 Billing and Coding: MoIDX: Molecular Diagnostic Tests (MDT)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
Retired				
L36634 In Vitro Chemosensitivity & Chemoresistance Assays Retired 07/01/2020	A56710 Billing and Coding: In Vitro Chemosensitivity & Chemoresistance Assays Retired 07/01/2020	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L33777 Non-covered Services Retired 07/01/2020	A57743 Billing and Coding: Non-covered Services Retired 07/01/2020	First Coast	FL, PR, VI	FL, PR, VI

CMS Benefit Policy Manual

[Chapter 15; § 80-80.1.3 Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests](#)

CMS Claims Processing Manual

[Chapter 16; § 20-40 Calculation of Payment Rates-Clinical Laboratory Test Fee Schedules, Special Payment Considerations, Billing for Clinical Laboratory Tests; § 70 Clinical Laboratory Improvement Amendments \(CLIA\) Requirements](#)

UnitedHealthcare Commercial Policy

[Chemosensitivity and Chemoresistance Assays in Cancer](#)

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	Template Update <ul style="list-style-type: none">Reformatted policy; transferred content to new template
01/13/2021	Policy Summary <i>Tumor Chemosensitivity and Chemoresistance Assays (CSRAs)</i> <ul style="list-style-type: none">Removed language indicating the intent of chemosensitivity and chemoresistance assays is to assist oncologists with the selection of chemotherapy drugs at initial diagnosis and tumor recurrence in order to avoid ineffective chemotherapy toxicity Guidelines <ul style="list-style-type: none">Removed language indicating all steps of the chemosensitivity and chemoresistance assays are not covered by Medicare for all neoplastic diseases, including either all solid tumors or blood borne dyscrasias (e.g., leukemia's, myelodysplastic disorders) Supporting Information <ul style="list-style-type: none">Updated <i>References</i> section to reflect the most current informationArchived previous policy version MPG145.05

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).