

# Laboratory Tests and Services

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[Instructions for Use](#)

Table of Contents	Page
<a href="#">Coverage Guidelines</a> .....	1
• <a href="#">General Coverage</a> .....	1
• <a href="#">Covered Clinical Diagnostic Laboratory Tests and Services</a> ....	1
• <a href="#">Home Blood Draws</a> .....	1
• <a href="#">Molecular Diagnostic Tests</a> .....	2
• <a href="#">Vitamin D Assays</a> .....	2
• <a href="#">Chemosensitivity and Chemoresistance Assays</a> .....	2
• <a href="#">Non-Covered Laboratory Tests and Services</a> .....	2
<a href="#">Definitions</a> .....	3
<a href="#">Supporting Information</a> .....	3
<a href="#">Policy History/Revision Information</a> .....	4
<a href="#">Instructions for Use</a> .....	4

Related Medicare Advantage Policy Guidelines
• <a href="#">Clinical Diagnostic Laboratory Services</a>
• <a href="#">Vitamin D Testing</a>

## Coverage Guidelines

Laboratory tests and services are covered when Medicare coverage criteria are met.

**Note:** The guidelines in this Coverage Summary are for specific procedures only. For procedures not addressed in this Coverage Summary, refer to the [Medicare Coverage Database](#) to search for applicable coverage policies (National Coverage Determination, Local Coverage Determinations and Local Coverage Articles). (Accessed December 6, 2023)

### General Coverage

Laboratory services (inpatient or outpatient) are covered in support of basic health care services to be used in the screening or detection of disease and determined to be reasonable and medically necessary.

Refer to the [Medicare Benefit Policy Manual, Chapter 15, §80.1 – Clinical Laboratory Services](#).

For quality standards for all Laboratory testing, refer to the Medicare Clinical Laboratory Improvement Amendments (CLIA) website at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>. (Accessed December 6, 2023)

### Covered Clinical Diagnostic Laboratory Tests and Services

Clinical diagnostic Laboratory tests and services are covered when criteria are met. Applicable NCDs are available at the [Lab National Coverage Determinations \(NCDs\) Alphabetical Index](#). (Accessed December 6, 2023)

### Home Blood Draws (Venipunctures)

Medically necessary home blood draws (venipunctures) by an independent Laboratory technician are covered in the following circumstances:

- Patient is confined to home or other place of residence used as his or his home when the specimen is a type which would require the skills of a Laboratory technician (e.g., where a Laboratory technician draws a blood specimen). For definition of homebound, refer to the [Medicare Benefit Policy Manual, Chapter 7, §30.1.1 – Patient Confined to the Home](#).
- Patient's place of residence is an institution, only if:
  - The patient was confined to the facility; and
  - The facility did not have on duty personnel qualified to perform the service.

**Note:** Specimen which would require only the services of a messenger and would not require the skills of a Laboratory technician (e.g., urine or sputum), a specimen pickup service would not be considered medically necessary.

Refer to the [Medicare Benefit Policy Manual, Chapter 15, §80.1.3 – Independent Laboratory Service to a Patient in the Patient's Home or an Institution](#).

(Accessed December 6, 2023)

## Molecular Diagnostic Tests (MDT)

Refer to the Coverage Summary titled [Molecular Pathology/Molecular Diagnostics/Genetic Testing](#).

## Vitamin D Assays (CPT Code 82306)

Medicare does not have a National Coverage Determination (NCD) for vitamin D assays. Local Coverage Determinations (LCDs)/Local Coverage Article (LCAs) **exist for all states/territories** and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for [Vitamin D Assay Test](#).

## Chemosensitivity and Chemoresistance Assays (CSRAs)

### *Human Tumor Stem Cell Drug Sensitivity Assay*

The NCD for Human Tumor Stem Cell Drug Sensitivity Assay (190.7) addresses 2 distinct types of assays:

- Human tumor stem cell drug sensitivity assays; and
- Fluorescent cytoprint assays

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 micro organs rather than in clones derived from single cells, is considered experimental, and therefore, not covered under Medicare at this time.

Refer to the [NCD for Human Tumor Stem Cell Drug Sensitivity Assays \(190.7\)](#). (Accessed December 6, 2023)

### *Other Chemosensitivity and Chemoresistance Assays (CSRAs)*

Examples include but are not limited to Oncotech Extreme Drug Resistance (EDR) assay, DiSC (Differential staining cytotoxicity) assay, ATP (Adenosine Triphosphate) assay, MTT (Methyl Thiazolyl Tetrazolium) assay, HYDRA<sup>®</sup> (AntiCancer Inc.) assay, EVA-PCD (Rational Therapeutics) assay, and ChemoFx<sup>®</sup> assay.

Medicare does not have a National Coverage Determination (NCD) for CSRAs. Local Coverage Determinations (LCDs)/Local Coverage Article (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for [Other Chemosensitivity and Chemoresistance Assays](#).

**For coverage guidelines for states/territories with no LCDs/LCAs**, refer to the UnitedHealthcare Commercial Medical Policy titled [Category III Codes](#).

**Note:** After checking the [Other Chemosensitivity and Chemoresistance Assays](#) table and searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

(Accessed December 6, 2023)

## Non-Covered Laboratory Tests and Services

**Laboratory tests and services that are not reasonable and necessary are not covered.** Refer to the [Medicare Benefit Policy Manual, Chapter 16, §20 – Services Not Reasonable and Necessary](#). Examples include but are not limited to:

Laboratory Tests and Services

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Page 2 of 5

Approved 09/13/2023

- Autopsy
  - Employer or legally required drug or alcohol testing
  - Genetic testing to determine predisposition to an inherited disease (carrier status) or when the test will not be used to determine the care of member
  - Serum testing for genetic predisposition for Huntington's Chorea
  - Pre-marital blood testing
  - School admissions and athletic requirement for Laboratory testing
- (Accessed December 6, 2023)

Also refer to the Coverage Summary titled [Molecular Pathology/Molecular Diagnostics/Genetic Testing](#).

## Definitions

**Laboratory:** Any facility which performs Laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. [Medicare Benefit Policy Manual, Chapter 15, §80.1 – Clinical Laboratory Services](#). (Accessed December 6, 2023)

## Supporting Information

Vitamin D Assay Test				
Accessed December 6, 2023				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L33996 (A56798)	<a href="#">Vitamin D Assay Testing</a>	Part A and B MAC	CGS Administrators, LLC	KY, OH
L33771 (A56841)	<a href="#">Vitamin D: 25 hydroxy, includes fraction(s), if performed</a>	Part A and B MAC	First Coast Service Options, Inc.	FL, PR, VI
L37535 (A57736)	<a href="#">Vitamin D Assay Testing</a>	Part A and B MAC	National Government Services, Inc.	CT, IL, MN, NY, ME, MA, NH, RI, WI, VT
L34051 (A57719)	<a href="#">Vitamin D Assay Testing</a>	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, ID, OR, WA, AZ, MT, ND, SD, UT WY
L36692 (A57718)	<a href="#">Vitamin D Assay Testing</a>	Part A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV
L34914 (A56416)	<a href="#">Assays for Vitamins and Metabolic Function</a>	Part A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L39391 (A59170)	<a href="#">Billing and Coding: Vitamin D Assay Testing</a>	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
L34658 (A57484)	<a href="#">Vitamin D Assay Testing</a>	Part A and B MAC	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE
<a href="#">Back to Guidelines</a>				

Other Chemosensitivity and Chemoresistance Assays				
Accessed December 6, 2023				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L37628 (A56071)	<a href="#">In Vitro Chemosensitivity &amp; Chemoresistance Assays</a>	Part A and B MAC	Noridian Healthcare Solutions, LLC	AS, CA, GU, HI, MP, NV

## Other Chemosensitivity and Chemoresistance Assays

Accessed December 6, 2023

LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L37630 (A56073)	<a href="#">In Vitro Chemosensitivity &amp; Chemoresistance Assays</a>	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, ID, OR, WA, AZ, MT, ND, SD, UT WY
L34554 (A56871)	<a href="#">In Vitro Chemosensitivity &amp; Chemoresistance Assays</a>	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV

[Back to Guidelines](#)

## Policy History/Revision Information

Date	Summary of Changes
05/01/2024	<p><b>Coverage Guidelines</b></p> <ul style="list-style-type: none"> <li>Updated reference link to reflect the current policy title for <i>Molecular Pathology/Molecular Diagnostics/Genetic Testing</i></li> </ul>
09/13/2023	<p><b>Template Update</b></p> <ul style="list-style-type: none"> <li>Updated <i>Instructions for Use</i></li> </ul> <p><b>Coverage Guidelines</b></p> <p><b>Chemosensitivity and Chemoresistance Assays (CSRAs)</b></p> <p>Other Chemosensitivity and Chemoresistance Assays (CSRAs)</p> <ul style="list-style-type: none"> <li>Updated default guidelines for states/territories with no Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs): <ul style="list-style-type: none"> <li>Added reference link to the UnitedHealthcare Commercial Medical Policy titled <i>Category III Codes</i></li> <li>Removed reference link to the Noridian LCD for <i>In Vitro Chemosensitivity &amp; Chemoresistance Assays (L37630)</i></li> </ul> </li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Archived previous policy version MCS053.07</li> </ul>

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The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing the items or services in this coverage summary have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in

circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, UnitedHealthcare applies internal coverage criteria in the UnitedHealthcare commercial policies referenced in this coverage summary. The coverage criteria in these commercial policies was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

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