

Clinical Diagnostic Laboratory Services

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[➔ Instructions for Use](#)

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Coverage Rationale

Overview

Clinical laboratory services involve the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as set forth at 42 CFR part 493. Section 1862(a)(1)(A) of the Act provides that Medicare payment may not be made for services that are not reasonable and necessary. Clinical laboratory services must be ordered and used promptly by the physician who is treating the member as described in 42 CFR 410.32(a), or by a qualified nonphysician practitioner.

CMS National Coverage Determinations (NCDs)

National Coverage Determinations (NCDs) exist for clinical lab services, and compliance with these policies is required where applicable. For specific NCDs, refer to the references for [CMS National Coverage Determinations \(NCDs\)](#).

CMS Local Coverage Determinations (LCDs) and Articles

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist for clinical lab services, and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the [Medicare Coverage Database](#).

Guidelines

Medicare distinguishes ‘screening’ from ‘diagnostic uses’ of tests. ‘Screening’ is testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present, and the member has not been exposed to a disease. In contrast, ‘diagnostic’ testing is testing to rule out or to confirm a suspected diagnosis because of a sign and/or symptom in the member. In these cases, the sign or symptom should be used to explain the reason for the test. Some laboratory tests are covered by the Medicare program for screening purposes (for example, NCD # 210.1, Prostate Cancer Screening Tests).

Examples of Medicare Preventive Lab Services:

- Cardiovascular Disease Screening Tests: Refer to the [Medicare Preventive Services Chart](#) for further details, specific coding criteria, and sourcing.
- Cervical Cancer Screening with Human Papillomavirus (HPV) Tests: Refer to NCD 210.2.1 and the [Medicare Preventive Services Chart](#) for further details, specific coding criteria, and sourcing.
- Diabetes Screening: Refer to the [Medicare Preventive Services Chart](#) for further details, specific coding criteria, and sourcing.
- Prostate Cancer Screening: Refer to NCD 210.1 and the [Medicare Preventive Services Chart](#) for further details, specific coding criteria, and sourcing.
- Pap Tests Screening: Refer to NCD 210.2 and the [Medicare Preventive Services Chart](#) for further details, specific coding criteria, and sourcing.
- Colorectal Cancer Screening Tests: Refer to NCD 210.3 and the [Medicare Preventive Services Chart](#) for further details, specific coding criteria, and sourcing.
- Screening for Hepatitis B Virus (HBV) Infection: Refer to NCD 210.6 and the [Medicare Preventive Services Chart](#) for further details, specific coding criteria, and sourcing.
- Human Immunodeficiency Virus (HIV) Screening: Refer to NCD 210.7 and the [Medicare Preventive Services Chart](#) for further details, specific coding criteria, and sourcing.
- Sexually Transmitted Infection (STI) & High Intensity Behavioral Counseling (HIBC) to Prevent STIs: Refer to NCD 210.10 and the [Medicare Preventive Services Chart](#) for further details, specific coding criteria, and sourcing.
- Screening for Hepatitis C Virus (HCV) in Adults: Refer to NCD 210.13 and the [Medicare Preventive Services Chart](#) for further details, specific coding criteria, and sourcing.

Nationally Non-Covered Indications

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review. Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states " ...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury...". Furthermore, it has been longstanding CMS policy that **"tests that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered unless explicitly authorized by statute"**.

In addition:

- Tests for administrative purposes, including exams required by insurance companies, business establishments, government agencies, or other third parties, are not covered.
- Tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered by statute.
- A claim for a test for which there is a national coverage policy will be denied as not reasonable and necessary if the claim is submitted without an ICD-10-CM code or narrative diagnosis listed as covered in the policy.
- If a national coverage policy identifies a frequency expectation, a claim for a test that exceeds that expectation may be denied as not reasonable and necessary.
- Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary.
- Failure of the clinical laboratory performing the test to have the appropriate Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate will result in denial of claims.

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 policy does not imply that the service described by the code is a covered or non-covered health service; however, language may be included in the listing below to indicate if a code is non-covered. 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/HCPCS Codes

[Clinical Diagnostic Laboratory Services: CPT/HCPCS Code List](#)

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Coding Clarifications: The following coding clarifications applies to the *Non-Covered Diagnosis Code List* below:

- Diagnosis code Z36.89 is excluded from non-coverage for CPT codes 86790, 86794, 87662, 87798, and 87801 when reported for Zika Virus Testing by polymerase chain reaction and enzyme-linked immunoassay methods.
- Diagnosis code Z11.3 is excluded from non-coverage for CPT codes 87480, 87510, 87660, 87661, and 87801.
- Diagnosis code Z04.81 is excluded from non-coverage for CPT code 87801.

Non-Covered Diagnosis Code

[Non-Covered Diagnosis Codes List](#)

This list contains ICD-10 diagnosis codes that are **never covered when given as the primary reason for the test**. If a code from this section is given as the reason for the test and you know or have reason to believe the service may not be covered, call UnitedHealthcare to issue an Integrated Denial Notice (IDN) to the member and you. The IDN informs the member of their liability for the non-covered service or item and appeal rights. You must make sure the member has received the IDN prior to rendering or referring for non-covered services or items in order to collect payment.

Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the policies below and searching the [Medicare Coverage Database](#), if no NCD, LCD, or LCA is found, refer to the criteria as noted in the [Coverage Rationale](#) section above.

CMS National Coverage Determinations (NCDs)

Pathology NCDs

[NCD 190.1 Histocompatibility Testing](#)

[NCD 190.2 Diagnostic Pap Smears](#)

[NCD 190.3 Cytogenetic Studies](#)

[NCD 190.5 Sweat Test](#)

[NCD 190.6 Hair Analysis](#)

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

[NCD 190.8 Lymphocyte Mitogen Response Assays](#)

[NCD 190.9 Serologic Testing for Acquired Immunodeficiency Syndrome \(AIDS\)](#)

[NCD 190.10 Laboratory Tests - CRD Patients](#)

Laboratory NCDs

[Clinical Diagnostic Laboratory Services, Medicare National Coverage Determinations \(NCD\) Coding Policy Manual and Change Report](#) (Refer to current Lab Code Lists and Report)

[NCD 190.14 Human Immunodeficiency Virus \(HIV\) Testing \(Diagnosis\)](#)

[NCD 190.15 Blood Counts](#)

[NCD 190.16 Partial Thromboplastin Time \(PTT\)](#)

[NCD 190.17 Prothrombin Time \(PT\)](#)

[NCD 190.18 Serum Iron Studies](#)

[NCD 190.19 Collagen Crosslinks, any Method](#)

[NCD 190.20 Blood Glucose Testing](#)

[NCD 190.21 Glycated Hemoglobin/Glycated Protein](#)

[NCD 190.22 Thyroid Testing](#)

[NCD 190.23 Lipid Testing](#)

[NCD 190.24 Digoxin Therapeutic Drug Assay](#)

[NCD 190.25 Alpha-fetoprotein](#)

[NCD 190.32 Gamma Glutamyl Transferase](#)

[NCD 190.33 Hepatitis Panel/Acute Hepatitis Panel](#)

[NCD 190.34 Fecal Occult Blood Test](#)

Prevention Lab NCDs

[NCD 210.1 Prostate Cancer Screening Tests](#)

[NCD 210.2 Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer](#)

[NCD 210.2.1 Screening for Cervical Cancer with Human Papillomavirus \(HPV\)](#)

[NCD 210.3 Colorectal Cancer Screening Tests](#)

[NCD 210.6 Screening for Hepatitis B Virus \(HBV\) Infection](#)

[NCD 210.7 Screening for the Human Immunodeficiency Virus \(HIV\) Infection](#)

[NCD 210.10 Screening for Sexually Transmitted Infections \(STIs\) and High-Intensity Behavioral Counseling \(HIBC\) to Prevent STIs](#)

[NCD 210.13 Screening for Hepatitis C Virus \(HCV\) in Adults](#)

Other Lab NCDs

[NCD 90.1 Pharmacogenomic Testing for Warfarin Response](#)

[NCD 90.2 Next Generation Sequencing \(NGS\)](#)

[NCD 190.11 Home Prothrombin Time/International Normalized Ratio \(PT/INR\) Monitoring for Anticoagulation Management](#)

[NCD 300.1 Obsolete or Unreliable Diagnostic Tests](#)

Medicare Administrative Contractor (MAC) With Corresponding States/Territories	
MAC Name (Abbreviation)	States/Territories
CGS Administrators, LLC (CGS)	KY, OH
First Coast Service Options, Inc. (First Coast)	FL, PR, VI
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC (Noridian)	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY
Novitas Solutions, Inc. (Novitas)	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX, VA**
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA**, WV
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE

Notes

*Wisconsin Physicians Service Insurance Corporation: Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers.

**For the state of Virginia: Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction.

CMS Benefit Policy Manual

[Chapter 15; § 80.1-80.1.3 Clinical Laboratory Services.](#)

[Chapter 15; § 280 Preventive and Screening Services, § 280.2.1 Colorectal Cancer Screening, § 280.4 Screening Pap Smears.](#)

CMS Claims Processing Manual

[Chapter 16, § 10.2 General Explanation of Payment; § 20 Calculation of Payment Rates-Clinical Laboratory Test Fee Schedules; § 40 Billing for Clinical Laboratory Tests; § 120 Clinical Laboratory Services Based on the Negotiated Rulemaking.](#)

[Chapter 18; § 30 Screening Pap Smears, § 40 Screening Pelvic Examinations, § 50 Prostate Cancer Screening Tests and Procedures, § 60 Colorectal Cancer Screening, § 90 Diabetes Screening, § 100 Cardiovascular Disease Screening, § 130 Human Immunodeficiency Virus \(HIV\) Screening Tests, § 170.1 Healthcare Common Procedure Coding System \(HCPCS\) Codes for Screening for STIs and HIBC to Prevent STIs.](#)

CMS Transmittal(s)

[Transmittal 12691, Change Request 13672, Dated June 20, 2024, Changes to the Laboratory National Coverage Determination \(NCD\) Edit Software for October 2024.](#)

[Transmittal 12694, Change Request 13487, Dated June 21, 2024, Expand Diabetes Screening and Diabetes Definitions Policy Update in the Calendar Year 2024 Physician Fee Schedule Final Rule \(Medicare Benefits Policy\)](#)

[Transmittal 12694, Change Request 13487, Dated June 21, 2024, Expand Diabetes Screening and Diabetes Definitions Policy Update in the Calendar Year 2024 Physician Fee Schedule Final Rule \(Medicare Claims Processing\)](#)

[Transmittal 12816, Change Request 13784, Dated August 29, 2024, October 2024 Update of the Hospital Outpatient Prospective Payment System \(OPPS\).](#)

[Transmittal 12817, Change Request 13785, Dated August 29, 2024, Changes to the Laboratory National Coverage Determination \(NCD\) Edit Software for January 2025.](#)

[Transmittal 12992, Change Request 13889, Dated December 13, 2024, Calendar Year \(CY\) 2025 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment.](#)

[Transmittal 13097, Change Request 13939, Dated March 20, 2025, International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determinations \(NCDs\)—July 2025.](#)

[Transmittal 13102, Change Request 13959, Dated March 13, 2025, Healthcare Common Procedure Coding System \(HCPCS\) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments \(CLIA\) Edits.](#)

[Transmittal 13104, Change Request 13966, Dated March 13, 2025, Quarterly Update for Clinical Laboratory Fee Schedule \(CLFS\) and Laboratory Services Subject to Reasonable Charge Payment.](#)

[Transmittal 13192, Change Request 14055, Dated April 24, 2025, Quarterly Update for Clinical Laboratory Fee Schedule \(CLFS\) and Laboratory Services Subject to Reasonable Charge Payment.](#)

[Transmittal 13359, Change Request 14153, Dated August 13, 2025, Changes to the Laboratory National Coverage Determination \(NCD\) Edit Software for October 2025.](#)

[Transmittal 13404, Change Request 14226, Dated December 17, 2025, Changes to the Laboratory National Coverage Determination \(NCD\) Edit Software for January 2026.](#)

[Transmittal 13514, Change Request 14312, Dated December 5, 2025, Calendar Year \(CY\) 2026 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment.](#)

[Transmittal 13619, Change Request 14372, Dated February 20, 2026, Healthcare Common Procedure Coding System \(HCPCS\) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments \(CLIA\) Edits.](#)

[Transmittal 13639, Change Request 14371, Dated February 20, 2026, Quarterly Update for Clinical Laboratory Fee Schedule \(CLFS\) and Laboratory Services Subject to Reasonable Charge Payment.](#)

MLN Matters

[Article MM13613, Clinical Laboratory Fee Schedule & Laboratory Services Reasonable Charge Payment: Quarterly Update: July 2024.](#)

[Article MM13620, HCPCS Codes & Clinical Laboratory Improvement Amendments Edits: October 2024.](#)

[Article MM13889, Clinical Laboratory Fee Schedule: 2025 Annual Update.](#)

[Article MM 13959, HCPCS Codes & Clinical Laboratory Improvement Amendments Edits: April 2025.](#)

[Article MM 13966, Clinical Laboratory Fee Schedule & Laboratory Services Subject to Reasonable Charge Payment: April 2025 Quarterly Update](#)

[Article MM 14055, Clinical Laboratory Fee Schedule & Laboratory Services Subject to Reasonable Charge Payment: July 2025 Update.](#)

[Article MM 14153, Laboratory National Coverage Determination Edit Software Updates: October 2025.](#)

[Article MM 14226, Laboratory National Coverage Determination Edit Software: January 2026 Update.](#)

[Article MM 14312, Clinical Laboratory Fee Schedule: 2026 Annual Update.](#)

[Article MM 14371, Clinical Laboratory Fee Schedule & Laboratory Services Subject to Reasonable Charge Payment: April 2026 Update.](#)

[Article MM 14372, HCPCS Codes & Clinical Laboratory Improvement Amendments Edits: April 2026.](#)

Others

[Medicare National Physician Fee Schedule.](#)

[Code of Federal Regulations, § 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.](#)

[Clinical Laboratory Fee Schedule.](#)

[Medicare Preventive Services.](#)

[National Coverage NCD Report Results.](#)

Policy History/Revision Information

Date	Summary of Changes
05/01/2026	<p>Applicable Codes</p> <p><i>CPT/HCPCS Codes Not Covered When Submitted With Screening Diagnosis</i></p> <ul style="list-style-type: none"> Added 0600U, 0601U, 0602U, 0604U, 0605U, 0606U, 0607U, 0608U, 0609U, 0610U, 0611U, 0612U, 0613U, 81354, 81524, 84999, 87182, and 87183 Removed 0354U Added notation to indicate 0361U was “deleted Dec. 31, 2025” <p>Centers for Medicare and Medicaid Services (CMS) Related Documents</p> <p><i>CMS Transmittal(s)</i></p> <ul style="list-style-type: none"> Added reference link to:

Date	Summary of Changes
	<ul style="list-style-type: none"> ○ Transmittal 13619, Change Request 14372, Dated February 20, 2026, Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits ○ Transmittal 13639, Change Request 14371, Dated February 20, 2026, Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment ● Removed reference link to: <ul style="list-style-type: none"> ○ Transmittal 12519, Change Request 13541, Dated February 22, 2024, Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment ○ Transmittal 12653, Change Request 13620, Dated May 23, 2024, Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits ○ Transmittal 12657, Change Request 13613, Dated May 24, 2024, Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment <p>MLN Matters</p> <ul style="list-style-type: none"> ● Added reference link to: <ul style="list-style-type: none"> ○ Article MM 14153, Laboratory National Coverage Determination Edit Software Updates: October 2025 ○ Article MM 14226, Laboratory National Coverage Determination Edit Software: January 2026 Update ○ Article MM 14312, Clinical Laboratory Fee Schedule: 2026 Annual Update ○ Article MM 14371, Clinical Laboratory Fee Schedule & Laboratory Services Subject to Reasonable Charge Payment: April 2026 Update ○ Article MM 14372, HCPCS Codes & Clinical Laboratory Improvement Amendments Edits: April 2026 ● Removed reference link to: <ul style="list-style-type: none"> ○ Article MM13467, Clinical Laboratory Fee Schedule: 2024 Annual Update: January 2024 ○ Article MM13487, Diabetes Screening & Definitions Update: CY 2024 Physician Fee Schedule Final Rule ○ Article MM13541, Clinical Laboratory Fee Schedule & Laboratory Services Reasonable Charge Payment: Quarterly Update: April 2024 <p>Supporting Information</p> <ul style="list-style-type: none"> ● Archived previous policy version MMP185.44

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

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

Medicare Advantage Policies are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates. This Policy is provided for informational purposes and does not constitute medical advice. It is intended to serve only as a general reference and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. 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 this policy. For more information on a specific member's benefit coverage, call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).

Medicare Advantage Policies 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 Policies at any time by publishing a new version on this website. Medicare source materials used to develop these policies may include, but are not limited to, CMS statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. The information presented in this Policy is believed to be accurate and current as of the date of publication. Where there is a conflict between this document and Medicare source materials, the Medicare source materials apply. Medicare Advantage Policies are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

Providers are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies 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.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate's requirements need to be followed.