Clinical Diagnostic Laboratory Services

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➲ Instructions for Use

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Related Medicare Advantage Reimbursement Policies

- Clinical Laboratory Improvement Amendments (CLIA) ID Requirement Policy, Professional
- Laboratory Services Policy, Professional
- Molecular Pathology Policy, Professional and Facility

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 PCR and ELISA 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 11594, Change Request 12885, Dated September 9, 2022, October 2022 Update of the Hospital Outpatient Prospective Payment System (OPPS)
Transmittal 11604, Change Request 12870, Dated September 16, 2022, Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
Transmittal 11700, Change Request 12888, Dated November 10, 2022, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2023
Transmittal 11734, Change Request 13026, Dated December 8, 2022, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for April 2023
Transmittal 11735, Change Request 13024, Dated December 8, 2022, Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
Transmittal 12021, Change Request 13195, Dated May 4, 2023, Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment

Transmittal 12113, Change Request 13269, Dated June 29, 2023, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2023
Transmittal 12210, Change Request 13321, Dated August 17, 2023, Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
Transmittal 12219, Change Request 13350, Dated August 24, 2023, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2024
Transmittal 12226, Change Request 13339, Dated August 31, 2023, October 2023 Integrated Outpatient Code Editor (I/OCE) Specifications Version 24.3
Transmittal 12227, Change Request 13340, Dated August 31, 2023, October 2023 Update of the Hospital Outpatient Prospective Payment System (OPPS)
Transmittal 12426, Change Request 13467, Dated December 21, 2023, Calendar Year (CY) 2024 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
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 12600, Change Request 13487, Dated May 2, 2024, Expand Diabetes Screening and Diabetes Definitions Policy Update in the Calendar Year 2024 Physician Fee Schedule Final Rule (Medicare Benefits Policy)
Transmittal 12600, Change Request 13487, Dated May 2, 2024, Expand Diabetes Screening and Diabetes Definitions Policy Update in the Calendar Year 2024 Physician Fee Schedule Final Rule (Medicare Claims Processing)
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
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 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

MLN Matters

Article MM12803, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2022
Article MM12888, Revised, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2023
Article MM13023, Clinical Laboratory Fee Schedule: CY 2023 Annual Update
Article MM13024, HCPCS Codes & Clinical Laboratory Improvement Amendments Edits: April 2023
Article MM13269, ICD-10 & Other Coding Revisions to Laboratory National Coverage Determinations: October 2023 Update
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
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

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
02/01/2025	**Applicable Codes** ***CPT Codes*** • Removed U0001, U0002, U0003, U0004, U0005, 0224U, 0226U, 86328, 86408, 86409, 86413, 86769, 87426, 87428, 87593, 87635, and 87811 ***Non-Covered Diagnosis Codes*** • Added Z59.71 and Z59.72 • Added notation to indicate Z59.7 was "deleted Sep. 30, 2024" • Removed Z11.52 **Supporting Information** • Archived previous policy version MMP185.39

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, please 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.