Clinical Diagnostic Laboratory Services

Guideline Number: MPG185.35
Approval Date: January 10, 2024

Terms and Conditions

Table of Contents **Page**

Related Medicare Advantage Policy Guidelines

- See References

Related Medicare Advantage Reimbursement Policies

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

Related Medicare Advantage Coverage Summary

- Genetic Testing

Policy Summary

See Purpose

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 beneficiary as described in 42 CFR 410.32(a), or by a qualified nonphysician practitioner.

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 beneficiary 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 beneficiary. 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).

Guidelines

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.
- Failure to provide documentation of the medical necessity of tests might result in denial of claims. The documentation may include notes documenting relevant signs, symptoms, or abnormal findings that substantiate the medical necessity for ordering the tests. In addition, failure to provide independent verification that the test was ordered by the treating physician (or qualified nonphysician practitioner) through documentation in the physician's office might result in denial.
- 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 unless other medical documentation justifying the necessity is submitted with the claim.
- 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, unless it is submitted with documentation justifying increased frequency.
- 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 guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit 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 Code	
Clinical Diagnostic Laboratory Services: CPT/HCPCS Code List	☐

Coding Clarification:
The following coding clarification applies to the Non-Covered Diagnosis Code List below:

- Diagnosis code Z36.89 is excluded from Non-Coverage for CPT codes 86790 and 86794 when reported for Zika Virus Testing by PCR and ELISA Methods.

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. ☐

References

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 190.12 Urine Culture, Bacterial
NCD 190.13 Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring)
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 190.26 Carcinoembryonic Antigen
NCD 190.27 Human Chorionic Gonadotropin
NCD 190.28 Tumor Antigen by Immunoassay - CA 125
NCD 190.29 Tumor Antigen by Immunoassay - CA 15-3/CA 27.29
NCD 190.30 Tumor Antigen by Immunoassay - CA 19-9
NCD 190.31 Prostate Specific Antigen
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

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 11208, Change Request 12573, Dated January 20, 2022, Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
Transmittal 11221, Change Request 12612, Dated January 27, 2022, Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
Transmittal 11305, Change Request 12666, Dated March 24, 2022, April 2022 Update of the Hospital Outpatient Prospective Payment System (OPPS)
Transmittal 11398, Change Request 12737, Dated May 4, 2022, Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
Transmittal 11408, Change Request 12747, Dated May 12, 2022, Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July 2022 Update
Transmittal 11465, Change Request 12803, Dated June 23, 2022, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2022
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 12389, Change Request 13467, Dated November 30, 2023, Calendar Year (CY) 2024 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
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

MLN Matters

Article MM12468, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2022
Article MM12575, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for April 2022
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

Medicare Advantage Policy Guidelines

Biomarkers in Cardiovascular Risk Assessment
Blood Product Molecular Antigen Typing
Genetic Testing for Cardiovascular Disease
Molecular Diagnostic Infectious Disease Testing
Molecular Pathology/Genetic Testing Reported with Unlisted Codes
Molecular Pathology/Molecular Diagnostics/Genetic Testing
Pharmacogenomics Testing
Tier 2 Molecular Pathology Procedures
Vitamin D Testing

Others

2023 Medicare National Physician Fee Schedule - October Release
Code of Federal Regulations, § 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions
Clinical Laboratory Fee Schedule
ICD-10-CM Official Guidelines for Coding and Reporting FY 2022 – UPDATED April 1, 2022 (October 1, 2021 - September 30, 2022), subsection on Coronavirus infections
Medicare Preventive Services
National Coverage NCD Report Results

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
01/10/2024	**Related Policies** • Removed reference link to the UnitedHealthcare Medicare Advantage Policy Guideline titled *Human Tumor Stem Cell Drug Sensitivity Assays (NCD 190.7)*

Date	Summary of Changes

	Applicable Codes
	CPT Codes
	• Added 0019M, 0083U, 0105U, 0248U, 0404U, 0406U, 0407U, 0408U, 0412U, 0414U, 0415U, 0418U, 81535, 81536, and 89240
	• Added notation to indicate:
	  ○ 0019M, 0083U, 0105U, 0248U, 0404U, 0406U, 0407U, 0408U, 0412U, 0414U, 0415U, 0418U, 81535, 81536, and 89240 are "not covered when submitted with a screening diagnosis"
	  ○ 0014M was "deleted Jan. 1, 2024"
	  ○ 0066U was deleted Oct. 1, 2023"
	• Removed 0370U, 0371U, 0372U, 0374U, 0378U, 0380U, and 0386U
	Non-Covered Diagnosis Codes
	• Added Z11.52, Z58.81, Z58.89, Z59.10, Z59.11, Z59.12, Z59.19, Z83.710, Z83.711, Z83.718, and Z83.719
	• Added notation to indicate:
	  ○ Z59.1 was "deleted Mar. 31, 2023"
	  ○ Z83.71 was "deleted Sep. 30, 2023"
	Supporting Information
	• Updated *References* section to reflect the most current information
	• Archived previous policy version MPG185.34

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 above 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.