Clinical Diagnostic Laboratory Services

Guideline Number: MPG185.22
Approval Date: October 13, 2021

Policy Summary

Overview

Clinical laboratory services involve the biological, microbiological, serological, chemical, immuno-hematological, 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: See the Medicare Preventive Services Chart for further details, specific coding criteria and sourcing.
- Cervical Cancer Screening with Human Papillomavirus (HPV) Tests: See NCD 210.2.1 and the Medicare Preventive Services Chart for further details, specific coding criteria and sourcing.
- Diabetes Screening: See the Medicare Preventive Services Chart for further details, specific coding criteria and sourcing.
- Prostate Cancer Screening: See NCD 210.1 and the Medicare Preventive Services Chart for further details, specific coding criteria and sourcing.
Pap Tests Screening: See NCD 210.2 and the Medicare Preventive Services Chart for further details, specific coding criteria and sourcing.

Colorectal Cancer Screening Tests: See NCD 210.3 and the Medicare Preventive Services Chart for further details, specific coding criteria and sourcing.

Screening for Hepatitis B Virus (HBV) Infection: See NCD 210.6 and the Medicare Preventive Services Chart for further details, specific coding criteria and sourcing.

Human Immunodeficiency Virus (HIV) Screening: See 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: See 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: See 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 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.

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### Modifier Description

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### 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 for 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**


- 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 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 4326, Change Request 11280, Dated June 28, 2019 Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Transmittal 4347, Change Request 11406, Dated August 2, 2019 Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Transmittal 10033, Change Request 11681, Dated April 3, 2020 Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Transmittal 10217, Change Request 11815, Dated July 8, 2020 Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Transmittal 10367, Change Request 11937, Dated September 24, 2020, Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Transmittal 10540, Change Request 12114, Dated December 31, 2020, January 2021 Integrated Outpatient Coder (I/OCE) Specifications Version 22.0
Transmittal 10575, Change Request 12080, Dated January 20, 2021, Calendar Year (CY) 2021 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Transmittal 10656, Change Request 12178, Dated March 9, 2021, Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Transmittal 10831, Change Request 12131, Dated June 2, 2021, Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
Transmittal 10853 Change Request 12285, Dated June 15, 2021, Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
Transmittal 10854, Change Request 12171, Dated June 15, 2021, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2021
Transmittal 10877, Change Request 12384, Dated July 15, 2021, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2021
Transmittal 10988, Change Request 12435, Dated September 10, 2021, Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
Transmittal 10997, Change Request 12436, Dated September 16, 2021, October 2021 Update of the Hospital Outpatient Prospective Payment System (OPPS)
Transmittal 11013 Change Request 12468, Dated October 1, 2021, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2022

MLN Matters
Article MM11280, July 2019 Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Article MM11406, October 2019 Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Article MM11598, January 2020 Calendar Year (CY) 2020 Annual Update for Clinical Laboratory Fee Schedule and Services Subject to Reasonable Charge Payment
Article MM11640, April 2020 Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendment (CLIA) Edits
Article MM11681, April 2020 Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Article MM11815, July 2020 Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Article MM11937, October 2020 Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Article MM12080, January 2021 Calendar Year (CY) 2021 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Article MM12131, HCPCS Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits, April 1, 2021
Article MM12178, April 2021 Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
Article MM12285 Revised, Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment, July 1, 2021
Article MM12384, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2021
Article MM12435, October 2021 Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
Article MM12468, Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2022

Medicare Advantage Policy Guidelines
Biomarkers in Cardiovascular Risk Assessment
Blood Platelet Transfusions (NCD 110.8)
Blood Product Molecular Antigen Typing
Blood Transfusions (NCD 110.7)
BRCA1 and BRCA2 Genetic Testing
Colorectal Cancer Screening Tests (NCD 210.3)
Cytogenetic Studies (NCD 190.3)
Diagnostic Pap Smears NCD 190.2)
Genetic Testing for Lynch Syndrome
Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management (NCD 190.11)
Histocompatibility Testing (NCD 190.1)
Human Tumor Stem Cell Drug Sensitivity Assays (NCD 190.7)
Lymphocyte Mitogen Response Assays (NCD 190.8)
Molecular Diagnostic Infectious Disease Testing
Molecular Pathology/Genetic Testing Reported with Unlisted Codes
Molecular Pathology/Molecular Diagnostics/Genetic Testing
Molecular Pathology Procedures for Human Leukocyte Antigen (HLA) Typing
Obsolete or Unreliable Diagnostic Tests (NCD 300.1)
Pharmacogenomic Testing for Warfarin Response (NCD 90.1)
Prostate Cancer Screening Tests (NCD 210.1)
Qualitative Drug Testing for Indications Other Than Mental Health
Screening for Cervical Cancer (NCD 210.2.1)
Screening for Hepatitis B Virus (HBV) Infection (NCD 210.6)
Screening for Hepatitis C Virus (HCV) In Adults (NCD 210.13)
Screening for Sexually Transmitted Infections (STIS) and High-Intensity Behavioral Counseling (HIBC) to Prevent STIS (NCD 210.10)
Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer (NCD 210.2)
Screening for the Human Immunodeficiency Virus (HIV) Infection (NCD 210.7)
Serologic Testing for Acquired Immunodeficiency Syndrome (AIDS) (NCD 190.9)
Sweat Test (NCD 190.5)
Tier 2 Molecular Pathology Procedures
Vitamin D Testing

UnitedHealthcare Commercial Policies
Cardiovascular Disease Risk Tests
Chemosensitivity and Chemoresistance Assays in Cancer
Chromosome Microarray Testing (Non-Oncology Conditions)
Genetic Testing for Cardiac Disease
Genetic Testing for Hereditary Cancer
Genetic Testing for Neuromuscular Disorders
Hepatitis Screening
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions
Omnibus Codes
Pharmacogenetic Testing
Preimplantation Genetic Testing
Preventive Care Services
Whole Exome and Whole Genome Sequencing

Other(s)
Clinical Diagnostic Laboratory Services, Medicare National Coverage Determinations (NCD) Coding Policy Manual and Change Report, October 2021 (See Revision History: Covered Code List PDF for October 2021)
Code of Federal Regulations, § 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions
CPT® Administrative Codes for Multianalyte Assays with Algorithmic Analyses (Updated July 1, 2021)
CPT® Proprietary Laboratory Analyses (PLA) Codes: Long Descriptors (Updated July 1, 2021)
CY 2021 Q1 Clinical Laboratory Fee Schedule
CY 2021 Q2 Clinical Laboratory Fee Schedule
CY 2021 Q3 Clinical Laboratory Fee Schedule
CY 2021 Q4 Clinical Laboratory Fee Schedule
Decision Memo for Screening for Colorectal Cancer-Stool DNA Testing (CAG-00440N), CMS Website
Medicare Preventive Services

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.

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<td>● Updated language pertaining to CPT code 0139U; removed notation indicating code is not covered when submitted with screening diagnosis</td>
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**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.