

CLINICAL DIAGNOSTIC LABORATORY SERVICES

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[Terms and Conditions](#) ⓘ

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POLICY SUMMARY

See [Purpose](#) ⓘ

Overview

UnitedHealthcare is committed to promoting the appropriate use of preventive benefits.

Medicare covers a broad range of legislatively mandated preventive services to prevent disease, detect disease early when it is most treatable and curable, and manage disease so that complications can be avoided. These services can be found on CMS's website, see [Medicare Preventive Services](#). Any preventive services and tests not listed on the CMS Preventive Services webpage are considered non-covered screening (preventive) tests or services which are not a benefit of the Medicare program.

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 a 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". Screening services, such as pre-symptomatic genetic tests and services, are those used to detect an undiagnosed disease or disease predisposition, and as such are not a Medicare benefit and not covered by Medicare. Similarly, Medicare may not reimburse the costs of tests/examinations that assess the risk for and/or of a condition unless the risk assessment clearly and directly effects the management of the patient.

Also included in this policy are the Lab NCD links. See the resource section of this policy for the specific links by test type. A claim for a test for which there is a national coverage or local medical review policy will be denied as not reasonable and necessary if it 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 or local 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. The CPT/HCPCS table in the coding section of this policy illustrates the impact to each lab code for CMS mandated preventive services, Lab NCDs and any code impacted when billed in the absence of signs, symptoms or complaints.

Guidelines

Examples of Preventive Lab Services and Screenings covered by UnitedHealthcare:

- Cardiovascular Disease Screenings: See the [Medicare Preventive Services Chart](#) for further details, specific coding criteria and sourcing.
- Diabetes Screening Tests: See the [Medicare Preventive Services Chart](#) for further details, specific coding criteria and sourcing.
- Prostate Cancer Screening/PSA Blood Test: See NCD 210.1 for further details, specific coding criteria and sourcing.

- Pap Tests (Lab Portion Only): See NCD 210.2 and the [Medicare Preventive Services Chart](#) for further details, specific coding criteria and sourcing.
- Fecal Occult Blood Test to screen for Colorectal Cancer: See NCD 210.3 for further details, specific coding criteria and sourcing.
- Stool DNA Testing: See NCD 210.3 for further details, specific coding criteria and sourcing.
- Screening for Hepatitis B Virus (HBV) Infection: See NCD 210.6 for further details, specific coding criteria and sourcing.
- Human Immunodeficiency Virus (HIV) Screening: See NCD 210.7 for further details, specific coding criteria and sourcing.
- Screening for Sexually Transmitted Illnesses (STI): See NCD 210.10 for further details, specific coding criteria and sourcing.
- Screening for Hepatitis C Virus (HCV) in Adults: See NCD 210.13 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"**.

APPLICABLE CODES

The following list(s) of 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.

CPT/HCPCS Codes

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

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Modifier	Description
33	Preventive services
QW	CLIA (Clinical Laboratory Improvement Amendments) waived test
TS	Follow-up service

Non-Covered ICD-10 Diagnosis Codes

[Non-Covered ICD-10 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.

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 LCDs, NCDs, 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.

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 190.7 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, July, 2020](#) (See *Covered Code Lists*)

[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 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](#)

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](#)

[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 Transmittals

[Transmittal 457, Change Request 3677, Dated 01/28/2005 \(Diabetes Screening Tests\)](#)
[Transmittal 3701, Change Request 9946, Dated 02/03/2017 \(Healthcare Common Procedure Coding System \(HCPCS\) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments \(CLIA\) Edits\)](#)
[Transmittal 3763, Change Request 10075, Dated 04/28/2017 \(Payment for Moderate Sedation Services Furnished with Colorectal Cancer Screening Tests\)](#)
[Transmittal 3783, Change Request 10122, Dated 05/26/2017 \(July 2017 Update of the Hospital Outpatient Prospective Payment System \(OPPS\)\)](#)
[Transmittal 3848, Change Request 10199, Dated 08/25/2017 \(Updates to Pub. 100-04, Chapter 18 Preventive and Screening Services and Chapter 32 Billing Requirements for Special Services and Publication 100-03, Chapter 1 Coverage Determinations Part 4\)](#)
[Transmittal 3872, Change Request 10309, Dated October 6, 2017 Changes to the Laboratory National Coverage Determination \(NCD\) Edit Software for January 2018](#)
[Transmittal 4090, Change Request 10875, July 20, 2018 Quarterly Update for Laboratory Fee Schedule](#)
[Transmittal 4139, Change Request 10941, Dated September 28, 2018 Changes to the Laboratory National Coverage Determination \(NCD\) Edit Software for January 2019](#)
[Transmittal 4265, Change Request 11224, Dated March 22, 2019 Changes to the Laboratory National Coverage Determination \(NCD\) Edit Software for July 2019](#)
[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 4475, Change Request 11593, Dated December 13, 2019 Changes to the Laboratory National Coverage Determination \(NCD\) Edit Software for April 2020](#)
[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](#)

MLN Matters

[Article MM10409, Calendar Year 2018 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment](#)
[Article MM10642, July 2018 Update Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment](#)
[Article MM10941, Changes to Laboratory NCD Edit Software for January 2019](#)
[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 SE18001, Dated 03/29/2018 Proper Coding for Specimen Validity Testing Billed in Combination with Drug Testing](#)

UnitedHealthcare Commercial Policies

[Cardiovascular Disease Risk Tests](#)
[Hepatitis Screening](#)
[Omnibus Codes](#)

Others

[Clinical Diagnostic Laboratory Services, Medicare National Coverage Determinations \(NCD\) Coding Policy Manual and Change Report, October 2018](#)
[Clinical Diagnostic Laboratory Services, Medicare National Coverage Determinations \(NCD\) Coding Policy Manual and Change Report, January 2019](#)
[Clinical Diagnostic Laboratory Services, Medicare National Coverage Determinations \(NCD\) Coding Policy Manual and Change Report, April 2019](#)
[Clinical Diagnostic Laboratory Services, Medicare National Coverage Determinations \(NCD\) Coding Policy Manual and Change Report, July 2019](#)

[Clinical Diagnostic Laboratory Services, Medicare National Coverage Determinations \(NCD\) Coding Policy Manual and Change Report, October 2019](#)
[Clinical Diagnostic Laboratory Services, Medicare National Coverage Determinations \(NCD\) Coding Policy Manual and Change Report, January, 2020](#)
[Clinical Diagnostic Laboratory Services, Medicare National Coverage Determinations \(NCD\) Coding Policy Manual and Change Report, April, 2020](#)
[Clinical Diagnostic Laboratory Services, Medicare National Coverage Determinations \(NCD\) Coding Policy Manual and Change Report, July, 2020](#)
[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.

Date	Action/Description
07/08/2020	<p>Applicable Codes</p> <p>HCPCS Codes</p> <ul style="list-style-type: none"> Added HCPCS codes U0003 and U0004 <p>CPT Codes</p> <ul style="list-style-type: none"> Added CPT codes 0014M, 0172U, 0173U, 0174U, 0175U, 0176U, 0177U, 0178U, 0179U, 0180U, 0181U, 0182U, 0183U, 0184U, 0185U, 0186U, 0187U, 0188U, 0189U, 0190U, 0191U, 0192U, 0193U, 0194U, 0195U, 0196U, 0197U, 0198U, 0199U, 0200U, 0201U, 0202U, 0223U, 0224U, 86328, 86769, and 87426 Modified notation pertaining to CPT codes 0124U, 0125U, 0126U, 0127U, and 0128U to indicate code was "deleted June 30, 2020" Revised description for CPT code 0165U <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>References</i> section to reflect the most current information Archived previous policy version MPG185.16

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](#).