UnitedHealthcare® Medicare Advantage
Reimbursement Policy
CMS 1500
UB04
Policy Number 2022R9049A

Molecular Pathology Policy, Professional and Facility

IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage reimbursement 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.

This reimbursement policy applies to all health care services billed on UB04 forms (CMS 1450) and to those billed on CMS 1500 forms. Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general resource regarding UnitedHealthcare's Medicare Advantage reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare Medicare Advantage may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare Medicare Advantage enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the facility or other provider contracts, the enrollee's benefit coverage documents**, and/or other reimbursement, medical or drug policies. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare Medicare Advantage due to programming or other constraints; however, UnitedHealthcare Medicare Advantage strives to minimize these variations.

UnitedHealthcare Medicare Advantage may modify this reimbursement policy at any time to comply with changes in CMS policy and other national standard coding guidelines by publishing a new version of the reimbursement policy on this website. However, the information presented in this reimbursement policy is accurate and current as of the date of publication. UnitedHealthcare Medicare Advantage encourages physicians and other health care professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Facilities can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier. UnitedHealthcare's Medicare Advantage reimbursement policies do not include notations regarding prior authorization requirements.

** For more information on a specific enrollee's benefit coverage, please call the customer service number on the back of the member ID card.

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Application

This reimbursement policy applies to all Medicare Advantage products for laboratory services reported using the UB04 and CMS 1500 form or its electronic equivalent or its successor form.

Policy

Overview

This policy describes the information required when claims are submitted with Molecular Pathology procedure codes. Molecular Pathology Codes (MoPath) are a series of CPT codes published by the AMA describing Molecular Diagnostic Tests (MDT). UnitedHealthcare Medicare Advantage utilizes the Optum® Genomics Payment Manager. The Optum Genomics Payment Manager evaluates DEX™ Diagnostics Exchange test identification codes (DEX Z- Code™)— a set of codes that uniquely identify discrete genetic tests – to determine Medicare-sourced reimbursement values.

All services described in this policy may be subject to additional UnitedHealthcare Medicare Advantage reimbursement policies including, but not limited to, the Clinical Laboratory Improvement Amendments (CLIA) ID Requirement Policy, the Laboratory Services Policy, the Add-on Codes Policy, Medically Unlikely Edit (MUE) Policy and the Rebundling and NCCI Edits Policy.

Reimbursement Guidelines

Molecular Diagnostic Tests (MDT)

UnitedHealthcare Medicare Advantage requires providers to submit the appropriate unique test identifier (DEX Z-Code™) for molecular diagnostic tests and other molecular pathology services administered through the DEX Program. When reported in conjunction with the appropriate CPT/HCPCS code, the identifier allows UnitedHealthcare Medicare Advantage to determine the exact test that has been performed, facilitating the process of making reimbursement determinations.

Unique Test Identifier

Providers must report Molecular Pathology (MoPath) Laboratory Developed Tests (LDT) and Molecular Diagnostic Tests (MDT) with the CPT and/or HCPCS code(s) that most accurately describes the specific test performed. Tests that are not described by a specific code require the use of an unlisted code. Although many of the MoPath codes were assigned descriptions, these descriptions do NOT identify a specific test. For this reason, the DEX Program requires laboratories to obtain a test-specific identifier — a DEX Z-Code – that is unique to the laboratory's specific test (i.e., the unique test identifier establishes a link to the specific test performed).

Unique Test Identifier Registration:

To submit claims for tests reported with Molecular Pathology CPT/HCPCS codes, laboratories must register and receive a test ID. To access the online DEX registry, laboratories should follow the following steps:

- Go to the DEX ™ Diagnostics Exchange: https://app.dexzcodes.com.
- Select 'Register My Organization' and follow the prompts to register your organization. Palmetto will leverage the DEX™ Diagnostics Exchange, a web-based service designed to identify tests and help establish transparency in the evidence-based coverage of them. This tool enables labs to confidentially share test information with DEX online.

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Claim Submission Requirements:

To report a Molecular Diagnostic Test service, please submit the following claim information:

- Select appropriate Molecular Pathology CPT® code
- Enter 1 unit of service (UOS)

- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT® code in the comment/narrative field for the following professional claim field/types:
  - Loop 2400 or SV101-7 for the 5010A1 837P
  - Box 19 for paper claim
- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT® code in the comment/narrative field for the following Facility claim field/types:
  - Line SV202-7 for 837I electronic claim
  - Block 80 for the UB04 claim form

Edit Sources:
UnitedHealthcare Medicare Advantage utilizes the Optum Genomics Payment Manager to evaluate MDT claims to confirm the reported services include a valid DEX Z- Code™ and/or a valid Z-Code/Molecular Pathology CPT/HCPCS code combination.

Multiple Molecular Pathology Procedures:
Labs should use one CPT code to describe each clinical test. A DEX Z-Code™ identifier application is required for a single assay that may involve multiple tests in order to produce a single result. UnitedHealthcare Medicare Advantage will deny duplicate or multiple molecular pathology CPT codes reported with the same DEX Z-Code™ for the same patient on the same date of service.

Definitions	
DEX Z-Code™ Identifiers	Palmetto GBA's unique and proprietary 5-character alpha-numeric codes assigned within the DEX Diagnostics Exchange.
Laboratory Developed Test (LDT):	A test developed by a laboratory for the use of its own clients. Typically, LDTs are not approved or cleared by the FDA.
Molecular Diagnostic Test (MDT):	A test that involves the detection or identification of nucleic acids (DNA/RNA), proteins, chromosomes, enzymes, cancer chemotherapy sensitivity and/or other metabolites. The test may or may not include multiple components. An MDT may consist of a single mutation analysis/identification, and/or may or may not rely upon an algorithm or other form of data evaluation/derivation.
Molecular Diagnostic Services Program (MolDX)	A program designed and operated by Palmetto GBA to identify and establish coverage on existing tests, newly developed LDTs, tests using pathology NOC codes, and other molecular diagnostic tests that fall within the scope of the Molecular Diagnostic Test (MDT) LCD A56853.
Molecular Pathology Codes (MoPath)	A series of CPT codes published by the AMA describing molecular diagnostic tests. MoPath codes are found in the 80000 series of CPT codes.
Not Otherwise Classified (NOC) Codes	Codes used to report an item or service for which no specific code exists. Sometimes referred to as "unlisted" or "miscellaneous" codes.

Questions and Answers	
1	**Q:** How long does it take to receive a DEX Z-Code™ when registering a test with the Diagnostics Exchange™ (DEX)? **A:** Each laboratory must register their organization first. Next the laboratory must register each unique test in the DEX system. After DEX assigns a Z-code to a lab for a specific test, the DEX team will review the test application and will assign a CPT® code to the test. Receiving a Z-code for a test will occur within

	approximately 2 weeks from adding your test into the DEX system. For further guidance on the timeline for the registration of your tests, refer to DEX - DEX Diagnostics Exchange Test Registration (dexzcodes.com)
2	**Q:** How do we register DEX Z-Code™ for custom panels? **A:** Labs must register all components of a panel, whether in-scope or out-of-scope of the program. DEX will map only the test(s) that are in scope for this program. (i.e., EGFR by molecular methodology and ROS1 and ALK by IHC). For detailed submission instructions, go to https://app.DEXzcodes.com/login or contact DEX.customer.service@palmettogba.com.
3	**Q**: If we use a reference lab for a particular test, how do we register our DEX Z-Code™ identifier? **A**: Both labs must register as an organization in DEX. The performing lab submits the test details to receive the Z-code. If you send your test to a reference lab to be performed, you will need to request "sharing" in DEX to obtain access to the Z-code. The billing lab uses the Z-code of the performing lab. The two labs link up in DEX with a Sharing Request. Labs will only request Z-codes for tests that are performed in house.
4	**Q**: How do I register a test that's performed at two different locations in the Diagnostics Exchange™ (DEX)? **A**: If the test process is standardized and the same method is used to acquire the results in both locations, labs will only have to submit one application for the test. However, if there is a difference in the method, an application will be required from both locations.
5	**Q**: Is the DEX Z-Code™ identifier the same as the GTR from the National Institute of Health (NIH) GTR ID? **A**: No. The GTR ID is created when labs register tests with the NIH GTR. For detailed submission instructions, see ncbi.nlm.nih.gov/gtr/docs/submit/#submission or contact gtr@ncbi.nlm.nih.gov.

Resources

- American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
- Medicare Claims Processing Manual - Chapter 16 - Laboratory Services and Chapter 23, Section 40 Clinical Diagnostic Laboratory Fee Schedule
- Medicare Benefit Policy Manual, Chapter 15, Section 80.1 Clinical Laboratory Services
- NCCI Policy Manual for Medicare Services, Chapter 10, Pathology/Laboratory Services
- Title XVIII of the Social Security Act (SSA) §1833(e), prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.
- Local Coverage Article A56853 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)

History

02/01/2022	• Revised the Overview section with additional details regarding the MolDX Program. • Updated the Reimbursement Guidelines section with additional details relative to obtaining and reporting unique identifiers for molecular diagnostic tests. • Added Definitions and Questions and Answer sections.
10/1/2021	Policy implemented by UnitedHealthcare Medicare Advantage
3/3/2021	Policy approved by the UnitedHealthcare Medicare Advantage Stakeholders