Policy Number 2024R0111C

# Molecular Pathology Policy, Professional and Facility

# IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

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 reimbursement policies may 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 CMS 1500 forms and, when specified, to those billed on UB04 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 reference resource regarding UnitedHealthcare's reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare 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 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 physician 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 due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations. UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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# **Application**

This reimbursement policy applies to services reported using the 1500 Health Insurance Claim Form (a/k/a CMS-1500), UB04 claim form or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians and other qualified health care professionals, outpatient facility claims, Ambulatory Surgical Centers (ASC), Outpatient Surgical Centers (OSC), including, but not limited to, non-network authorized and percent of charge contract physicians, other qualified health care professionals or facilities.

#### **Policy**

#### Overview

UnitedHealthcare requires providers to submit a DEX Z-Code® with every Molecular Pathology Code submitted for these services to be considered for reimbursement.

All services described in this policy may be subject to additional UnitedHealthcare reimbursement policies including, but not limited to, the Clinical Laboratory Improvement Amendments (CLIA) ID Requirement Policy, the Laboratory Services Policy, the Add-On Policy, the Maximum Frequency Per Day Policy, the Rebundling Policy and the CCI Editing Policy.

### **Reimbursement Guidelines**

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### Molecular Diagnostic Tests (MDT)

UnitedHealthcare requires providers to submit the appropriate unique test identifier (DEX Z-Code®) and appropriate CPT code for Molecular Diagnostic Tests (MDT) and other molecular pathology services for such claims to be considered for reimbursement. When reported in conjunction with the appropriate CPT/HCPCS code, the identifier helps UnitedHealthcare determine the exact test that has been performed, facilitating reimbursement determinations. More information about Palmetto DEX Z-Code® and how to obtain one can be found at https://app.dexzcodes.com.

Providers must report Molecular Pathology and Molecular Diagnostic Tests (MDT) with the CPT and/or HCPCS code(s) that most accurately describes the specific test performed, as assigned through the Palmetto DEX Z-Code® registry. -

# **Claim Submission Requirements:**

To report a Molecular Diagnostic Test (MDT) 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:
  - o Loop 2400 or SV-101-7 for the 5010A1 837P
  - o 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:
  - o Line SV-202-7 for 837I electronic claim
  - o Block 80 for the UB04 claim form

# **Multiple Molecular Pathology Procedures:**

You should submit one CPT code and a DEX Z-Code® for tests that may involve multiple genes that produce a single result. UnitedHealthcare 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                      |                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Molecular Pathology              | Molecular pathology procedures are medical laboratory procedures involving the analyses of nucleic acid (i.e., DNA, RNA) to detect variants in genes that may be indicative of germline (e.g., constitutional disorders) or somatic (e.g., neoplasia) conditions, or to test for histocompatibility antigens (e.g., HLA).                                                                  |
| DEX Z-Code® Identifiers          | Unique and proprietary 5-character alpha-numeric codes assigned within the DEX® Diagnostics Exchange.                                                                                                                                                                                                                                                                                      |
| 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. |
| DEX® Diagnostic Exchange (DEX®)  | A registry designed and administered by Palmetto GBA to identify new and existing tests that fall within the scope of the Molecular Diagnostic Test (MDT) Billing and Coding Article ID# A56853.                                                                                                                                                                                           |
| Molecular Pathology Codes        | A series of CPT codes published by the AMA describing Molecular Diagnostic Tests (MDT) found in the 80000 series of CPT codes.                                                                                                                                                                                                                                                             |



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| <b>Not Otherwise</b> | Classified | (NOC) |
|----------------------|------------|-------|
| Codes                |            |       |

Codes are used to report an item or service for which no specific code exists. Sometimes referred to as "unlisted" or "miscellaneous" codes.

| Que | Questions and Answers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |  |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|
|     | Q: How do I register for a Unique Test Identifier?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |  |
| 1   | <ul> <li>A: To access the online Palmetto DEX® registry, laboratories should follow the following steps:</li> <li>Go to the Palmetto DEX® Diagnostic Exchange (DEX®): <a href="https://www.dexzcodes.com">https://www.dexzcodes.com</a>.</li> <li>Select DEX® Registry.</li> <li>Select 'Register My Organization' and follow the prompts to register your organization.</li> <li>The Palmetto DEX® Diagnostic Exchange (DEX®), a web-based service, is designed to identify.</li> <li>tests and help establish transparency. This tool enables providers to confidentially share test information with DEX online.</li> </ul> |  |  |
|     | During registration, your test will be assigned a CPT code to bill with in addition to the Z-Code identifier which will be submitted in field 2400 SV-101-7 (Professional), SV-202-7 (Institutional) on the electronic claim form or in the shaded area of the service line in section 24 on a paper claim form.                                                                                                                                                                                                                                                                                                               |  |  |
| 2   | Q: Where can I find a list of CPT codes subject to the Palmetto DEX Z-Code® registry?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |  |
|     | A: The most current list and any updates will be available at <a href="https://www.dexcodes.com">www.dexcodes.com</a> .                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  |  |
| 3   | <ul> <li>Q: How do we register Palmetto DEX Z-Code® for custom panels?</li> <li>A: All components of a panel should be registered, whether in-scope or out-of-scope of the policy. DEX® will map only the test(s) that are in scope for this policy (i.e., EGFR by molecular methodology and ROS1 and ALK by IHC). For detailed submission instructions, go to <a href="https://www.dexzcodes.com">https://www.dexzcodes.com</a> or contact <a href="DEX.customer.service@palmettogba.com">DEX.customer.service@palmettogba.com</a>.</li> </ul>                                                                                |  |  |
| 4   | Q: If we use a reference lab for a particular test, how do we register our Palmetto DEX Z-Code® Identifiers?  A: Both providers would 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 provider uses the Z-Code of the performing provider. The two providers link up in DEX® with a Sharing Request. Providers will only request Z-Codes for tests that are performed in house.                                       |  |  |
| 5   | Q: How do I register a test that's performed at two different locations in the Palmetto Diagnostics Exchange® (DEX®)?  A: If the test process is standardized and the same method is used to acquire the results in both locations, providers will only submit one application for the test. However, if there is a difference in the method, an application will be required from both locations.                                                                                                                                                                                                                             |  |  |
| 6   | Q: Is the DEX Z-Code® Identifiers the same as the GTR from the National Institute of Health (NIH) GTR ID?  A: No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |  |
| 7   | <ul> <li>Q: Is it appropriate to report multiple codes using a modifier 59 when different methodologies and genes are tested on a single specimen?</li> <li>A: Testing on a single specimen should be reported with a single code (Tier 1, Tier 2, PLA, GSP, or when no other code is applicable, the unlimbed code (24.470). The code reported for the testing on the circle code is applicable.</li> </ul>                                                                                                                                                                                                                   |  |  |
|     | code is applicable, the unlisted code 81479). The code reported for the testing on the single specimen includes testing by all methodologies, all genes and analytes, all components (specimen preparation, DNA/RNA quantification, etc.) and all analytical services performed for the test. In the rare situation that separate specimen(s) are tested on the same patient on the same date of service for distinctly separate indications, the Proprietary information of UnitedHealthcare, Copyright 2024 United HealthCare Services, Inc.                                                                                 |  |  |

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initial specimen is reported without a modifier and an additional code may be reported with an appropriate modifier for the additional specimen tested. The use of a modifier to identify a different indication on the same date of service must be supported by the test requisition form and documentation. Per the CMS National Correct Coding policy if the single procedure is performed, only one unit of service may be reported. Modifiers should not be used to report multiple codes when a single specimen is tested.

#### Resources

American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services

Centers for Medicare and Medicaid Services, CMS Manual System or other CMS publications and services

| History   |                                                                                                                                                             |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4/14/2024 | Policy Version Change Table of contents Removed. Updated application language                                                                               |
| 4/1/2024  | Policy Version Change Updated application language Enforcement of the policy is temporarily delayed. See April 1, 2024, Network News Bulletin announcement. |
| 9/1/2023  | Policy Version Change Enforcement of the policy is temporarily delayed. See September 1, 2023, Network News Bulletin announcement.                          |
| 8/1/2023  | Policy Version Change Reimbursement Guidelines Section, Definitions Section, Question and Answers Section Updated. List tables archived.                    |
| 7/1/2022  | Policy Version Change Reimbursement Guidelines Section: Updated Proprietary Laboratory Analysis (PLA) Codes List Table. Entries prior to 7/1/2020 archived  |
| 4/1/2022  | Policy Version Change Reimbursement Guidelines Section: Updated Proprietary Laboratory Analysis (PLA) Codes List Table.                                     |
| 11/1/2019 | Policy implemented by UnitedHealthcare Employer & Individual                                                                                                |
| 4/26/2019 | Policy approved by the Reimbursement Policy Oversite Committee                                                                                              |