Molecular Pathology Policy, Professional

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) 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, including, but not limited to, non-network authorized and percent of charge contract physicians and other qualified health care professionals.

This policy does not apply to UnitedHealthcare® Oxford.

Policy

Overview

This policy describes the information required when claims are submitted for Molecular Pathology services utilizing Tier 1 and Tier 2 Molecular Pathology codes, Genomic Sequencing Procedures (GSP) and other Molecular Multianalyte Assay codes, Proprietary Laboratory Analysis (PLA) codes and unlisted code 81479.

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, and the CCI Editing Policy.

Reimbursement Guidelines

According to the American Medical Association (AMA) molecular pathology procedure code selection is typically based on the specific gene(s) that is being analyzed. Genes are described using Human Genome Organization (HUGO) approved gene names and are italicized in the code descriptors. Gene names were taken from tables of the HUGO Gene Nomenclature Committee (HGNC) at the time the CPT codes were developed. The AMA has provided Claim Designations using these abbreviated gene names and/or analytes. These Claim Designations are crosswalked to the appropriate codes to report on the Molecular Pathology Gene Table provided in the Pathology and Laboratory section of the AMA CPT codebook.

Codes that describe tests to assess for the presence of gene variants use common gene variant names. Typically, all of the listed variants would be tested. However, these lists are not exclusive. If other variants are also tested in the analysis, they would be included in the procedure and not reported separately. The molecular pathology codes include all analytical services performed in the test (eg, cell lysis, nucleic acid stabilization, extraction, digestion, amplification, and detection).

Tier 1 molecular pathology codes represent gene-specific and genomic procedures. Molecular pathology procedures that are not specified in a Tier 1 code should be reported using either the appropriate Tier 2 code or the unlisted molecular pathology procedure code, 81479.
Please refer to the list located in the Attachments section.

Tier 2 molecular pathology codes are used to report procedures not listed in Tier 1 molecular pathology codes. They are arranged by level of technical resources and interpretive work by the physician or other qualified health care professional. Each Tier 2 code lists the specific analytes associated with the procedure code level. The Tier 2 code reported must have the specific analyte listed under the code or is a code match to the Claim Designation on the AMA Molecular Pathology Gene Table. In order to identify the analyte being tested under the code submitted, an appropriate Claim Designation code or Abbreviated Gene Name must be submitted on the claim. This information should be submitted in field 2400 SV101-7 in the electronic claim form or in the shaded area of the service line in section 24 on a paper claim form. In order to identify the information, a ZZ qualifier is required to be placed without a space or hyphen in front of the Claim Designation code or Abbreviated Gene Name (example: ZZCLRN1).

Tier 2 Molecular Pathology Codes

81400	81401	81402	81403	81404	81405	81406	81407	81408	

Genomic sequencing procedures (GSPs) and other molecular multianalyte assays codes should be used when the components of the descriptor(s) are fulfilled regardless of the technique used to provide the analysis, unless specifically noted in the code descriptor. When a GSP assay includes gene(s) that is listed in more than one code descriptor, the code for the most specific test for the primary disorder sought should be reported, rather than reporting multiple codes for the same gene(s).

Genomic Sequencing Procedures (GSP) and Other Molecular Multianalyte Assay (MAA) Codes

81410	81411	81412	81413	81414	81415	81416	81417	81418	81419	81420	81422
81425	81426	81427	81430	81431	81432	81433	81434	81435	81436	81437	81438
81439	81440	81441	81442	81443	81445	81448	81449	81450	81451	81455	81456
81460	81465	81470	81471								

In addition to Tier 1, Tier 2 and GSP procedure codes, the AMA created Proprietary Laboratory Analysis (PLA) codes. Other CPT code(s), including unlisted codes, should not be used to report single or multianalyte services that may be reported with that specific PLA code. These codes encompass all analytical services required for the analysis (eg, cell lysis, nucleic acid stabilization, extraction, digestion, amplification, hybridization and detection).
Please refer to the list located in the Attachments section.

Individual Tier 1 or Tier 2 codes are considered components to GSP, PLA, or unlisted codes reported for Multianalyte testing on the same specimen. Individual Tier 1 or Tier 2 codes submitted in addition to a GSP, PLA or unlisted code 81479 will be denied.

According to the AMA, code 81479, unlisted molecular pathology procedure, should only be used for a unique procedure that is not adequately addressed by any other CPT code. It should be reported only once per patient, per specimen and date of service to identify the services provided.
In order to identify the molecular pathology procedure performed the provider must submit the unique test ID provided through the National Institutes of Health (NIH) Genetic Testing Registry (GTR). The GTR unique test ID proceeding the decimal should be submitted in field 2400 SV101-7 on the electronic claim form or in the shaded of the service line in section 24 on a paper claim form (example: GTR123456789). The units for CPT code 81479 will be limited by the number of separate specimen types processed on a single patient and each unit of 81479 should be reported on a separate line with a unique GTR test ID for each unit reported (example: testing performed on bone marrow and a blood specimen for different genetic scenarios would be reported on separate lines with the specific GTR test ID listed on each line). Additional information regarding the NIH GTR can be found at: https://www.ncbi.nlm.nih.gov/gtr/

When multiple molecular biomarkers are tested on the same date of service it is considered to be a multianalyte panel and requires reporting with a single CPT code. The appropriate genomic sequencing procedure (GSP) code or Proprietary Laboratory Analysis (PLA) code should be submitted when multi-gene testing is performed instead of submitting the individual Tier 1 and Tier 2 codes. When a GSP or PLA does not describe the multianalyte testing performed, the unlisted CPT code 81479 may be reported to encompass all testing performed. When an unlisted CPT code is reported on the same date of service that a GSP or PLA code is reported for multianalyte testing, only one multianalyte testing code is allowed to encompass all testing performed and the GSP or PLA code will take precedence.

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 (eg, constitutional disorders) or somatic (eg, neoplasia) conditions, or to test for histocompatibility antigens (eg, HLA).
Genomic Sequencing Procedures and Other Molecular Multianalyte Assays	Genomic sequencing procedures (GSPs) and other molecular Multianalyte assays GSPs are DNA or RNA sequence analysis methods that simultaneously assay multiple genes or genetic regions relevant to a clinical situation. They may target specific combinations of genes or genetic material, or assay the exome or genome.

Proprietary Laboratory Analysis (PLA) Codes	These codes describe proprietary clinical laboratory analyses and can be either provided by a single ("sole-source") laboratory or licensed or marketed to multiple providing laboratories (eg, cleared or approved by the Food and Drug Administration [FDA]). These codes include advanced diagnostic laboratory tests (ADLTs) and clinical diagnostic laboratory tests (CDLTs) as defined under the Protecting Access to Medicare Act (PAMA) of 2014.

Questions and Answers	
1	**Q:** Can I report separate molecular pathology CPT codes in instead of a PLA CPT code? **A:** Per the AMA, when a PLA code is available to report a given proprietary laboratory service the service should not be reported with any other CPT code(s) and other CPT code(s) should not be used to report services that may be reported with the specific PLA code.
2	**Q:** The testing for HPA1, HPA2, HPA3, and HPA4 was performed to rule out neonatal alloimmune thrombocytopenia. Would it be correct to report CPT codes 81105, 81106, 81107, and 81108 for this testing? **A:** No, multiple molecular variants tested on the same date of service are considered a multianalyte panel and requires reporting with a single CPT code. The test panel provided should be reported with the PLA (when applicable for the provider), GSP, or other MAA multiple analyte code. In the absence of an existing code, the panel of tests provided may be registered on the NIH GTR and submitted with the unlisted CPT code 81479.
3	**Q:** The testing provided overlapped two different GSP codes. Should I report both GSP codes? **A:** Only one GSP CPT code may be reported for the testing provided. The CPT guidelines for use of the GSP codes indicate when a GSP assay includes gene(s) that are listed in more than on code descriptor, the code for the most specific test for the primary disorder sought should be reported.
4	**Q:** Laboratory XYZ performed testing that fits the PLA code descriptor; however the PLA test was not marketed to Laboratory XYZ by the proprietary clinical laboratory or manufacturer. May the PLA test code be reported? **A:** No, the proprietary clinical laboratory or manufacturer may market the right to use their tests to multiple laboratories. These codes may only be reported by registered proprietary laboratory or laboratories that have the proprietary relationship with the proprietary clinical laboratory or manufacturer.
5	**Q:** When would it be appropriate to report 81479? **A:** It would be appropriate in the following scenarios: • The single gene or analyte analyzed is not represented by an existing Tier 1 or Tier 2 code. If the analyte is not listed in the Tier 1 descriptor or under one of the Tier 2 codes, 81479 should be used. • Multiple gene variants were analyzed in a single test panel and there is not an appropriate PLA, GSP, or other MAA test code to report
6	**Q:** When would it be appropriate to report more than one CPT code 81479 on a single date of service? **A:** From a CPT coding perspective, code 81479, unlisted molecular pathology procedure, should only be reported once per patient, per specimen and date of service to identify the services provided because it does not identify a specific service. When registering more than one CPT code 81479 on the NIH GTR, the appropriate specimen type may be selected (i.e. amniotic fluid, bone marrow, fresh tissue, saliva, urine, etc.) Each CPT code 81479 reported should be listed on separate claim lines with their respective GTR ID. In addition, if requested, the patient records should support that different specimens were tested.
7	**Q:** A test was performed on the anginine vasopressin receptor 2 gene. How should this be reported? **A:** Report Tier 2 code 81404 with ZZAVPR2 in field 2400 Sv101-7 on the electronic claim form or in the shaded area of the service line in section 24 on a paper claim form.
8	**Q:** How do I register my test in the NIH GTR?

	A: Labs can register tests via the GTR submission user interface after they create a MyNCBI credential and a lab record. This may take 2-3 business days. Once a lab has an active lab record, the lab can begin registering tests. Additional information ca be found at: https://www.ncbi.nlm.nih.gov/gtr/docs/submit/
9	**Q:** What are the benefits of registering tests in the NIH GTR? **A:** In addition to providing information about the current scope of genetic testing technologies, NCBI resources seek to improve access to information about medically important variation.
10	**Q:** Is it appropriate to report multiple codes using a modifier 59 when different methodologies and genes are tested on a single specimen? **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 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 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.

Attachments	
Tier-1-Molecular-Pathology-Codes.pdf	This list contains CPT codes categorized as Tier 1 Molecular Pathology codes.
Proprietary-Laboratory-Analyses-PLA-Codes.pdf	This list contains CPT codes categorized as Proprietary Laboratory Analyses (PLA) codes.

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	
1/1/2023	Policy Version Change Reimbursement Guidelines Section: Updated Proprietary Laboratory Analysis (PLA) Codes List Table. Policy List Change: Tier 1 Molecular Pathology Codes, Genomic Sequencing Procedures GSP Codes and Proprietary Laboratory Analyses PLA Codes updated. Entries prior to 1/1/2021 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.
1/1/2022	Policy Version Change Attachments Section: Updated Proprietary Laboratory Analysis (PLA) Codes and Tier 1 Molecular Pathology Codes
11/3/2021	Policy Version Change Attachments Section: Removed Tier 1 and PLA policy code table(s) and converted to Attachment Section List(s)
10/1/2021	Policy Version Change Reimbursement Guidelines Section: Updated Proprietary Laboratory Analysis (PLA) Codes List Table.
7/1/2021	Policy Version Change Reimbursement Guidelines Section: Updated Proprietary Laboratory Analysis (PLA) Codes List Table.
5/12/2021	Policy Version Change Attachments Section: Removed attachments(s) and converted to tables(s)
4/1/2021	Policy Version Change Code Section: Updated Proprietary Laboratory Analysis (PLA) Policy List Change: Proprietary Laboratory Analyses (PLA) Codes
1/1/2021	Policy Version Change Code Section: Updated Proprietary Laboratory Analysis (PLA) Policy List Change: Tier 1 Molecular Pathology Codes, Genomic Sequencing Procedures GSP Codes and Proprietary Laboratory Analyses PLA Codes updated.
11/1/2019	Policy implemented by UnitedHealthcare Employer & Individual
4/26/2019	Policy approved by the Reimbursement Policy Oversite Committee