# Laboratory Billing and Reimbursement

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### Procedures addressed

The inclusion of any procedure code in this table does not imply that the code is under management or requires prior authorization. Refer to the specific Health Plan's procedure code list for management requirements.

| Procedures addressed by this guideline | Procedure codes |
|---|---|
| Molecular Pathology | 81105 - 81479 |
| Molecular Multianalyte Assays with Algorithmic Analyses (MAAA) | 81490 - 81599; Molecular* administrative MAAA codes (ending in M) |
| Molecular Proprietary Laboratory Analyses (PLA) | Molecular* PLA codes (ending in U) |
| Molecular Infectious Testing | Molecular tests* within range 87149 – 87912<br>G0476 |
| Molecular HCPCS Codes | S3800 - S3870<br>G0452, G0327, G9143<br>U0001-U0002 |
| Molecular Cytopathology Procedures (Flow Cytometry, In Situ Hybridization) | 88120 - 88121<br>88182 - 88199 |
| Cytogenetics | 88230 - 88299 |
| Molecular Surgical Pathology Procedures (Immunohistochemistry, In Situ Hybridization) | 88341 - 88344<br>88360 - 88361<br>88364 –88377<br>88380 - 88387 |





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| Procedures addressed by this guideline | Procedure codes |
|---|---|
| Other Molecular Codes | 86152<br>86153 |

**Note:**

*Generally defined as codes that include "DNA", "RNA", "nucleic acid", "genotype", "phenotype" or related language in the code description.

### Description

The administrative handling of procedure codes by the EviCore Laboratory Management Program is addressed by this guideline. This guideline provides general guidance on what forms of review may be employed. It is intended to augment other clinical and administrative guidelines and should not be considered all-inclusive. The assessment of medical necessity of tests requested with these codes is addressed separately.

## What Are Laboratory Procedure Codes

Common Procedural Terminology (CPT) codes are five-digit codes developed by the American Medical Association (AMA), and intended to report a wide range of tests and procedures.

The AMA issues guidance regarding the appropriate use of CPT codes in annual publications of the AMA CPT Professional manual. CPT codes that represent lab testing are generally published in the Pathology and Laboratory section and/or Appendix O of the CPT manual.[1]

The Healthcare Common Procedure Coding System (HCPCS) is the system used by the Centers for Medicare & Medicaid Services (CMS) to ensure consistent coding of claims for Medicare and other health insurance programs. Level I of the HCPCS simply utilizes the CPT coding system. In contrast, level II of the HCPCS includes alpha-numeric codes that describe drugs, supplies, and services that are not addressed by the CPT codes. These level II codes are developed and maintained by CMS. Various HCPCS codes beginning with "G", "P", "Q", "S", and "U" may apply to laboratory procedures. These codes are allowed to be used by non-Medicare insurers.[2]

## Guidelines and Evidence

### The National Correct Coding Initiative (NCCI)

CMS provides Pathology/Laboratory Services coding guidance in chapter 10 of the NCCI Policy Manual, which is often broadly adopted by other non-CMS payers.[3]

The NCCI Policy Manual's general guidance for laboratory procedure codes included, but was not limited to, the following statements:[3]

- "Providers/suppliers shall report the HCPCS/CPT code that describes the procedure performed to the greatest specificity possible. A Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) code shall be reported only if all services described by the code are performed. A provider/supplier shall not report multiple HCPCS/CPT codes if a single HCPCS/CPT code exists that describes the services. This type of unbundling is incorrect coding."
- "HCPCS/CPT codes include all services usually performed as part of the procedure as a standard of medical/surgical practice. A provider/supplier shall not separately report these services simply because HCPCS/CPT codes exist for them."
- "The "CPT Professional" also includes coding instructions which may be found in the "Introduction", individual chapters, and appendices. In individual chapters, the instructions may appear at the beginning of a chapter, at the beginning of a subsection of the chapter, or after specific CPT codes. Providers/suppliers should follow "CPT Professional" instructions unless CMS has provided different coding or reporting instructions."
- "Medicare does not pay for duplicate testing. Multiple tests to identify the same analyte, marker, or infectious agent shall not be reported separately. For example, it would not be appropriate to report both direct probe and amplified probe technique tests for the same infectious agent."
- "If a laboratory procedure produces multiple reportable test results, only a single HCPCS/CPT code shall be reported for the procedure. If there is no HCPCS/CPT code that describes the procedure, the laboratory shall report a miscellaneous or unlisted procedure code with a single unit of service."

NCCI also maintains lists of procedure code standards (i.e. "edits") that are used to promote national correct coding of Medicare Part B claims.[4-6] These edits have been adopted by some non-CMS payers as well.

### Procedure Coding Guidelines by Category

The AMA organizes their laboratory CPT codes into the categories listed below.[1]

- CPT Codes 80047-80081: Organ or Disease Oriented Panels
- CPT Codes 80143-80299: Drug Assay
- CPT Codes 80305-83992: Therapeutic Drug Assays

- CPT Codes 80400-80439: Evocative/Suppression Testing Procedures
- CPT Codes 80503-80506: Pathology Clinical Consultations
- CPT Codes 81000-81099: Urinalysis Procedures
- CPT Codes 81105-81408; 81479: Molecular Pathology
- CPT Codes 81410-81471: Genomic Sequencing Procedures (GSP) and Other Molecular Multianalyte Assays
- CPT Codes 0002M-81599: Multianalyte Assays with Algorithmic Analyses (MAAA)
- CPT Codes 82009-84999: Chemistry Procedures
- CPT Codes 85002-85999: Hematology and Coagulation Procedures
- CPT Codes 86000-86849: Immunology Procedures
- CPT Codes 86850-86999: Transfusion Medicine Procedures
- CPT Codes 87003-87999: Microbiology Procedures
- CPT Codes 88000-88099: Anatomic Pathology Procedures
- CPT Codes 88104-88199: Cytopathology Procedures
- CPT Codes 88230-88299: Cytogenetic Studies
- CPT Codes 88300-88399: Surgical Pathology Procedures
- CPT Codes 88720-88749: In Vivo [eg, Transcutaneous] Laboratory Procedures
- CPT Codes 89049-89240: Other Pathology and Laboratory Procedures
- CPT Codes 89250-89398: Reproductive Medicine Procedures
- CPT Codes ending in "U": Proprietary Laboratory Analyses (PLA) Codes

A comprehensive review of all laboratory and pathology procedure coding guidelines is beyond the scope of this guideline. A discussion of coding guidelines that have particular relevance for EviCore's management of these procedure code categories can be found below.

**Molecular Pathology Procedures (81105-81408; 81479)**

Tier 1 Molecular Pathology Codes (81105-81383) represent gene-specific and genomic procedures.[1] Only one specific molecular pathology procedure is associated with each code.

Tier 2 Molecular Pathology CPT Codes (81400-81408) are a set of CPT codes designed to represent the level of technical and interpretive effort required for a large number of molecular and genomic tests that have not been assigned a unique CPT code (i.e., are not addressed by Tier 1, GSP, MAAA, or PLA codes). Specific tests, or analytes, are assigned to these Tier 2 codes by the AMA and cannot be self-assigned by the laboratory.

The AMA codebook stated that 81403 may be used to represent known familial mutation analysis when a Tier 1 code is not available; see the guideline *Genetic Testing for Known Familial Mutations* for more details on this type of test.

Unlisted Molecular Pathology Code 81479 is assigned to molecular and genomic test procedures that are not addressed by a Tier 1, Tier 2, or Genomic Sequencing Procedure (GSP) code.

The AMA codebook stated the following regarding the use of these codes:[1]

- "The molecular pathology codes include all analytical services performed in the test (eg, cell lysis, nucleic acid stabilization, extraction, digestion, amplification, and detection). Any procedures required prior to cell lysis (eg, microdissection, codes 88380 and 88381) should be reported separately."
- For Tier 2 codes in particular: "Use the appropriate molecular pathology procedure level code that includes the specific analyte listed after the code descriptor. If the analyte tested is not listed under one of the Tier 2 codes or is not represented by a Tier 1 code, use the unlisted molecular pathology procedure code, 81479."

The NCCI Manual stated the following regarding the use of these codes:[3]

- "Molecular pathology procedures (e.g., CPT codes 81161-81408) include all aspects of sample preparation, cell lysis, internal measures to assure adequate quantity of DNA or RNA, and performance of the assay. These procedures include DNA analysis and/or RNA analysis."
- "A Tier 1 or Tier 2 molecular pathology procedure CPT code should not, in general, be reported with a genomic sequencing procedure, molecular multianalyte assay, multianalyte assay with algorithmic analysis, or proprietary laboratory analysis CPT code where the CPT code descriptor includes testing for the analyte described by the Tier 1 or Tier 2 molecular pathology code."

When multiple Tier 1, Tier 2, and/or unlisted codes are billed together, this is considered a panel (see "Multigene Panel Coding").

**Genomic Sequencing Procedures (GSP) (81410-81471)**

GSP codes represent DNA or RNA sequence analysis methods that simultaneously assay multiple genes or genetic regions relevant to a specific clinical situation (e.g., multi-gene panels), typically via next generation sequencing (NGS) or massively parallel sequencing (MPS).[1]

The AMA codebook stated the following regarding the use of GSP codes:[1]

- "The analyses listed below are often performed using NGS/MPS technology; however, the analyses may also be performed by other molecular techniques (polymerase chain reaction [PCR] methods and microarrays). These 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 all of the components of the descriptor are not performed, use individual Tier 1 codes, Tier 2 codes, or 81479 (Unlisted molecular pathology procedure)."

### Multianalyte Assays with Algorithmic Analyses (MAAA) (0002M-81599)

MAAA codes represent procedures that incorporate different types of assays, in combination with an algorithmic analysis and other patient information (if applicable), to generate a numeric score or probability. The AMA maintains a list of all MAAA codes, along with the associated proprietary name (if applicable) in Appendix O of the CPT Professional manual. These tests are typically unique to a single laboratory.[1]

The AMA codebook stated the following regarding the use of MAAA codes:[1]

- "The results of individual component procedure(s) that are inputs to the MAAAs may be provided on the associated laboratory report, however these assays are not reported separately using additional codes."
- "In order to report a MAAA code, the analysis performed must fulfill the code descriptor and, if proprietary, must be the test represented by the proprietary name listed in Appendix O. When a specific MAAA procedure is not listed below or in Appendix O, the procedure must be reported using the Category I MAAA unlisted code (81599)."
- "These codes encompass all analytical services required (eg, cell lysis, nucleic acid stabilization, extraction, digestion, amplification, hybridization and detection) in addition to the algorithmic analysis itself. Procedures that are required prior to cell lysis (eg, microdissection, codes 88380 and 88381) should be reported separately."

### Microbiology Procedures (87003-87999)

These codes are used to identify microorganisms such as viruses, bacteria, and other infectious agents. Some of these procedures involve the use of molecular diagnostic testing with nucleic acid probes.[1]

The NCCI manual stated the following regarding the use of these codes:[3]

- "With one exception, CMS policy prohibits separate payment for testing for a single microorganism from an anatomic site by more than one methodology. For example, if a physician performs tests for cytomegalovirus antigen at an anatomic site by immunoassay (CPT code 87332) and by nucleic acid direct probe (CPT code 87495), only one of these codes may be reported for the testing. If a culture independent diagnostic testing method is positive for a microorganism, it may be medically reasonable and necessary to additionally culture the microorganism for drug sensitivity testing or (rarely) for community surveillance identification."

### Proprietary Laboratory Analyses (PLA) (CPT Codes ending in "U")

PLA codes are used to describe proprietary clinical laboratory analyses that can only be provided by a single laboratory or set of providing laboratories. A list of these codes is included in Appendix O of the CPT Professional manual, along with the test's proprietary

name. Unlike other categories of CPT codes, new PLA codes are typically released on a quarterly basis.[1]

The AMA CPT Professional codebook stated the following regarding PLA codes:[1]

- "When a PLA code is available to report a given proprietary laboratory service, that PLA code takes precedence. 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 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). For molecular analyses, additional procedures that are required prior to cell lysis (eg, microdissection [codes 88380 and 88381]) may be reported separately."
- "In order to report a PLA code, the analysis performed must fulfill the code descriptor and must be the test represented by the listed proprietary name in Appendix O."

**Multigene Panel Coding**

For laboratory procedures that include multiple molecular/genomic components, the NCCI Manual provided the following coding guidance:[3]

- "If one laboratory procedure evaluates multiple genes using a next generation sequencing procedure, the laboratory shall report only one unit of service of one genomic sequencing procedure, molecular multianalyte assay, multianalyte assay with algorithmic analysis, or proprietary laboratory analysis CPT code. If no CPT code accurately describes the procedure performed, the laboratory may report CPT code 81479 (Unlisted molecular pathology procedure) with one unit of service or may report multiple individual CPT codes describing the component test results when medically reasonable and necessary. Procedures reported together must be both medically reasonable and necessary (e.g., sequencing of procedures) and ordered by the physician who is treating the beneficiary and using the results in the management of the beneficiary's specific medical problem."
- "All genomic sequencing procedures and molecular multianalyte assays (e.g., CPT codes 81410-81471), many multianalyte assays with algorithmic analyses (e.g., CPT codes 81490-81599, 0004M-XXXXM), and many Proprietary Laboratory Analyses (PLA) (e.g., CPT codes 0001U-XXXXU) are DNA or RNA analytic methods that simultaneously assay genes or genetic regions. A provider/supplier shall not additionally separately report testing for the same gene or genetic region by a different methodology (e.g., CPT codes 81105-81408, 81479, 88364-88377). CMS payment policy does not allow separate payment for multiple methods to test for the same analyte."

**Note:**

This benefit/harm statement only applies to those jurisdictions that do not have Medicare guidance. Based upon the clinical policy, following EviCore's Laboratory Billing and

Reimbursement guideline will ensure adherence to appropriate billing, coding, and reimbursement processes. However, it is possible that there will be a delay in care until the outlined procedures in the guideline are followed.

## Criteria: Manual Procedure Code Review

All procedure codes included in the Laboratory Management Program may be subject to specific coding requirements. The following define many, but not all, of the most commonly applied coding requirements under this program. Any procedure codes that do not meet these criteria will not be reimbursable, even if medical necessity criteria for the associated test(s) are met. Exceptions to these requirements will be handled on a case-by-case basis.

### Correct Coding Requirements

Any procedure codes managed by the program will be subject to the requirements outlined below.

- Any test-specific coding requirements, which are generally addressed in the Billing and Reimbursement Considerations section of applicable clinical guidelines, must be met.
- NCCI coding guidance is generally adopted by EviCore in the absence of coding requirements addressed in test-specific guidelines.
- All procedure code(s) must be an accurate representation of the associated test(s). This includes:
  - The procedure code(s) must be in effect on the date of service associated with the case review or claim (please refer to the *Date of Service and Authorization Period Effective Date* guideline for details about how this date is determined for prior authorizations).
  - The test must fulfill all of the minimum requirements of the AMA/CMS code description. This includes, but is not limited to, specimen type, test content, and test methodology (e.g. sequencing, deletion/duplication analysis, targeted mutation analysis, etc.).
  - Proprietary codes (e.g., PLA codes and proprietary MAAA codes) will only be accepted when used by the single laboratory or set of providing laboratories to which the AMA has assigned the code. The code will not be accepted for use by a different laboratory, even if their test is similar in nature.
  - Tier 2 Codes (81400-81408) will only be accepted when the AMA has specifically assigned the test to the Tier 2 code. Laboratories may not self-assign tests to Tier 2 codes that are not specifically listed as analytes by the AMA.
  - GSP codes (81410-81471) will only be accepted for panels that include the minimum gene content required per the AMA descriptor. When this gene list

is directly preceded by the word "including", all of the specified genes must be included on the associated panel. When the gene list is directly preceded by the abbreviation "e.g.", these genes are considered examples, and do not need to be included on the panel.
    - When a specific code that accurately describes the test is not available, the appropriate unlisted/miscellaneous procedure code should be used (e.g., 81479, 81599, etc.).
- Add-on codes (e.g. 81266, 88185, etc.) will be addressed as follows:
    - The add-on code(s) will only be reimbursed when billed with the appropriate primary code(s) on the same date of service by the same provider.
    - If none of the primary code(s) meet medical necessity criteria, any accompanying add-on code(s) will not be separately reimbursable.
- Panel coding and billing should reflect the efficiency gains for the laboratory in testing multiple candidate genes simultaneously. Currently, laboratories are billing for panels in a variety of ways. When a panel approach to testing is determined to be medically necessary, the following billing guidelines will apply:
    - If a panel is billed with multiple procedure codes representing individual genes analyzed, the panel will be redirected to an appropriate panel code. If the laboratory will not accept redirection to a single code, the medical necessity of each billed component procedure will be assessed independently. Only the individual panel components that meet medical necessity criteria as a first tier of testing will be reimbursed. The remaining individual components will not be reimbursable.
    - Examples of appropriate panel codes include:
        - An appropriate proprietary laboratory analyses (PLA) code, or
        - An appropriate genomic sequencing procedure (GSP) code (if there are two different GSP codes to describe the sequencing and deletion/duplication analysis components of the test, both codes will be reimbursable as long as medical necessity is established for both methodologies), or
        - If no more specific code exists, the panel will be redirected to a single unit of the unlisted molecular pathology code 81479, which can be used to represent a panel in total.
    - If the member meets medical necessity, billing of the deletion/duplication portion of the panel with a microarray code (typically billed with 81228 or 81229) is allowed when at least 3 genes are included on the panel. Panels with less than 3 genes are more appropriately billed with individual CPT codes.
    - If a panel was previously performed and an updated, larger panel is being requested, only testing for the medically necessary, previously untested genes will be reimbursable. Therefore, only the most appropriate procedure codes for those additional genes will be considered for reimbursement.

- When multiple codes are submitted that address the same test content for the same date of service, only the most appropriate code(s) will be eligible for reimbursement, and the redundant/overlapping code(s) will not be reimbursable. Codes meeting medical necessity requirements will be prioritized for approval in the following manner:
  - Any guidance provided in the applicable clinical guideline will be followed, when available.
  - A proprietary code (e.g. PLA code or proprietary MAAA code) will be prioritized over non-proprietary codes when available for the providing laboratory.
  - An appropriate test-specific code will be prioritized over a non-specific code for a single gene/analyte test (e.g., a tier 1 code is prioritized over an unlisted code).
  - For procedures with multiple components, a single code will be prioritized over a combination of codes.
- When a prior authorization request is submitted for a group of procedure codes and at least one procedure code requires prior authorization, all submitted procedure codes that are under management by the Program (in any form) will be reviewed regardless of the authorization requirements for each code.

## References


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