### Laboratory Claim Reimbursement

#### 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.

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

eviCore manages claims payment for our subscribing Health Plans. Procedure codes (CPT, HCPCS) are adjudicated against claims review and payment rules. Payment and coverage adjustments may be made in addition to those outlined in this policy.

The following claim reimbursement policies provide general guidance on what forms of review may be employed. They are intended to augment other clinical and administrative policies and do not represent all possible claim treatments.

Criteria: Claims Reimbursement

Introduction

All procedure codes included in the Molecular and Genomic Testing Laboratory Program (as outlined in the table at the top of this document) may be subject to claims review and payment policies. The following policies define many, but not all, of the most commonly applied claim edits performed under this program.

Authorization Check

Required Authorization

Procedure codes that require medical necessity authorization are defined in published Plan procedure code management lists, which are generally available on the Health Plan’s website. All claims will be reviewed for the presence of any procedure code that requires authorization. When required, the following process is employed:

- The procedure code(s) requiring authorization will be checked against an authorization database.
- The procedure code will be released for further adjudication if an authorization is on file for all units of that procedure code and the code is billed with any stipulated additional information (e.g., modifier, unique test identifier).
- If any of the following are true, the Plan’s authorization requirements will be enforced. This may include denial for failure to comply with prior authorization requirement or post-service medical necessity review.
  - An authorization is not on file for all units of that CPT/HCPCS, or
  - The stipulated modifier is not appended to the code, or
  - The authorization is not valid for the date of service.
Voluntary Prior Authorization

Providers may choose to seek prior authorization for one or more procedure codes that are in scope for the Molecular and Genomic Lab Management Program but do not routinely require pre-service review. This is termed voluntary prior authorization. A voluntary prior authorization will also be performed for all codes that do not require prior authorization when they are being billed as part of a test panel with any codes that do require authorization.

- If a voluntary authorization is on file for any procedure code, and the procedure code is billed with all stipulated information, the procedure will be released for further adjudication.
- If an authorization is not on file for all units of that procedure code, the stipulated information is not included on the claim, or the date of service is not valid, all or some of the units for that procedure may undergo any post-service medical necessity review processes in place for that procedure but will not be denied for failure to obtain authorization.

Substitutable Codes

Note that an authorization for a procedure code may be used to approve coverage for a DIFFERENT billed procedure code that is substantially similar in clinical intent to the authorized code (e.g., an authorization to perform CPT 81228 is substitutable if CPT 81229 is billed). Clinically reasonable substitution rules are automatically applied through the claims adjudication process. When substitution rules are invoked, the billed procedure code is the paid procedure code. The companion Procedure Code Substitution table includes additional details. (See the Supporting Documents section at the end of this guideline.)

Post-Service Medical Necessity Determination

Many lab tests that are in scope for the Molecular and Genomic Lab Management Program are not managed through mandatory authorization requirements. Appropriate billing or medical necessity may be assessed upon claim submission (post-service) prior to payment as follows:

- All procedure codes managed under this program may be subject to post-service medical necessity review.
- Any and all available claims data (e.g., ICD code, age, gender, historical or co-existing procedures, etc.) may be used to determine medical necessity or identify cases requiring further review.
  - Claims data may be sufficient to determine medical necessity without additional clinical information. When medical necessity is determined based on claims data alone, the claims information that will either support or refute medical necessity is defined in the clinical policy (e.g., submitted ICD codes do not support medical necessity for a procedure).
When a case is identified for additional post-service medical necessity review, communication is sent to at least the rendering provider requesting additional information with the following possible outcomes:

- If the required clinical information is provided and fulfills criteria, the procedure is approved and the claim is released for further adjudication.
- If the required clinical information is provided and does not fulfill criteria, the procedure is denied for lack of medical necessity.
- If the required clinical information is not provided within the specified timeframe, the procedure is denied for failure to comply with the post-service review process.

The factors that may prompt post-service medical necessity review include, but are not limited to:

- ICD codes that support clinical criteria are not reported on the claim.
- A billed amount threshold is exceeded.
- A particular procedure code is billed with other procedure codes (bundled testing whether defined by the laboratory as a panel or not).
- The claim is submitted by a provider (participating and non-participating) selected for focused review.
- Billing portrait demonstrates billing patterns selected for focused review.

There are multiple sources of the rules established by this policy including CMS documents, published code definitions, specialty guidelines, peer reviewed literature, expert opinion, and claims experience with codes or providers.

**Gender Nondiscrimination**

Gender reported on a claim is one element used to determine medical necessity. In situations where the reported gender may not be consistent with the medical needs based on biological sex (e.g., transgender, transsexual, intersex individuals), the KX modifier should be appended to each billed procedure code that may have gender-related policy. The KX modifier will allow automated gender-specific edits to be bypassed.

**Lifetime Maximums**

In general, the same or similar tests performed on heritable DNA should not need to be performed more than once on the same person in that person's lifetime (e.g., gene sequencing or a similar mutation panel on a gene should not need to be repeated). Rarely, a procedure code may be billed twice for the same female member when subsequent instances represent testing on the female member's fetus. It is the provider's responsibility to determine if any contemplated genetic testing has already been performed for the member and to avoid unnecessary repeat testing.
Lifetime maximum rules will be applied for procedure codes that involve genetic testing of heritable DNA in the following manner:

- The companion *Lifetime Maximums* table includes a list of procedure codes subject to the lifetime maximum policy. (See the Supporting Documents section at the end of this guideline.)
  
  - Only a single date of service will be reimbursed for any procedure code with a lifetime maximum for a single individual.
  
  - While most procedure codes have a lifetime maximum of one unit, some have a limit of 2 (e.g. known familial mutations for recessive conditions).
  
  - Procedure codes representing tests that may reasonably be performed on a fetus through prenatal diagnosis are covered services more than once per lifetime. When applicable, claims should include the following ICD code to indicate prenatal diagnosis: O35.2X.

- All claims submitted for procedure codes subject to lifetime maximums will be checked for previous payment in historical claims data.

- Testing more than once per lifetime is not medically necessary and such claims will be denied for reimbursement if:
  
  - The procedure code is known to have already been paid for that member, and
    - The member is a male, or
    - The member is a female, and
      - The code does not allow a prenatal diagnosis override, or
      - No ICD code suggesting prenatal diagnosis is submitted for a code that does allow a prenatal diagnosis override

**Frequency Rules**

Tests that do not involve unchanging, inherited DNA may be repeated for medically necessary reasons. Any limits to the frequency at which such tests should be repeated is defined in the applicable clinical policy. These frequency limits will be assessed at claim submission based on available historical claims data.

**Maximum Units per Date of Service**

Most procedure codes have a reasonable maximum number of expected units that should be billed on a single date of service. Maximum expected units are coded into claims systems to prevent billing, data entry, and payment errors.

The CMS National Correct Coding Initiative provides guidance on maximum units for many procedure codes through their Medically Unlikely Edits. When not provided by
CMS, maximum units are established based on code definitions, specialty guidelines, peer reviewed literature, expert opinion and claims experience with those codes.

Maximum units per date of service rules are administered as follows:

- The *Maximum Units* table includes all procedure codes that have established maximum units. (See the Supporting Documents section at the end of this guideline.)

- The allowable daily maximum units for a procedure code are not reliant on medical necessity policy. They may only be addressed in this table and nowhere else in any other policy.

- Total billed units are calculated based on the combined number of times a procedure code is billed on a single date of service. This applies to codes billed with multiple units on a single claim line, units reported on separate claims lines on the same claim, or multiple units reported on separate claims for that date of service. All maximum unit rules are applied per date of service and do not allow additional units simply because they are billed on separate claim lines.

- When multiple units are billed, only the number of units up to the allowable daily maximum will be reimbursed.

- Some unusual circumstances justify exceeding the established maximum units per date of service.
  
  - When such exceptions are recognized in eviCore clinical policy, instructions for submitting claims with additional units are provided.
  
  - When exceptions are not specifically addressed in policy, reimbursement of additional units will be considered if supporting documentation is provided.

**NCCI PTP Coding Edits**

When two or more procedure codes are billed for the same member, on the same date of service, by the same provider, those codes must be compared to ensure the procedures are distinct from each other, should commonly be billed together, and are not mutually exclusive. The CMS National Correct Coding Initiative provides guidance through their Procedure to Procedure (PTP) coding edits.

NCCI PTP coding edits are administered as follows:

- Providers should bill only the most comprehensive procedure code(s) that represent the performed procedures with the fewest number of codes possible.

- The *NCCI Code Pair Edits* table includes all code pairs considered to be components of one another or mutually exclusive. When two codes are billed together that appear in columns 1 and 2 of this table, the code in column 1 is paid, while the code in column 2 is denied as inclusive. (See the Supporting Documents section at the end of this guideline.)
• Some unusual circumstances justify billing both codes in a pair for separate, reasonable indications. In such cases, an appropriate modifier may be used to override the CCI edit as outlined in the provided table. Additional supporting documentation to explain the necessity of both procedures may be required.

**Professional and Technical Component Modifiers**

Modifiers may be used to convey when only the professional or technical components of a test have been performed separately by the billing provider.

• Modifier 26 represents the professional component, such as the clinical interpretation of a test.
• Modifier TC represents the technical component, such as the equipment, supplies, and technical work.

The CMS Professional Component/Technical Component (PC/TC) indicators in the National Physician Fee Schedule Relative Value File are used to determine whether a procedure code is eligible for separate reimbursement for professional and technical components. The file is available at: [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files.html). In some instances, professional services are billed separately from technical services even when the billing code does not have a modifier 26 or TC designation. This policy applies to all instances of services where there are separate professional and technical charges.

Professional and technical modifiers are administered as follows:

• The *PC&TC Modifiers* table for all codes subject to the following modifier claims rules. (See the Supporting Documents section at the end of this guideline.)
• If a procedure code is eligible for separate PC/TC reimbursement (PC/TC indicator 1), that code may be billed with no modifier to represent a global service (both PC and TC components) or the modifiers 26 or TC, but not both.
• Procedure codes that are designated as only global without being eligible for separate PC/TC component reimbursement should not be billed with modifier 26 or TC, and will be subject to denial if inappropriately billed.
• Physician specialty and CMS place of service codes are used to determine eligibility to bill professional or technical components.

**Add-on Codes**

Some procedure codes are defined as “add-on” codes that should always be supplemental to a separate primary code. The CMS National Correct Coding Initiative provides guidance through their Add-on Code Edits. Language in the code description or knowledge of testing practices may also be used.

Add-on code edits are administered as follows:
• The Add-on Codes table includes all codes subject to the add-on claims rules. (See the Supporting Documents section at the end of this guideline.)

• Add-on codes will not be reimbursed when not billed with their appropriate primary code(s) on the same date of service by the same provider.

**Laboratory Certification Check**

The Clinical Laboratory Improvement Amendments (CLIA) was established to ensure the accuracy and reliability of laboratory testing.

All laboratories that perform any clinical (not research) testing on humans in the United States – including hospital, doctor's office, and independent labs – are subject to CLIA regulations and must have a CLIA certificate.

Several organizations are approved to accredit laboratories under CLIA (e.g., College of American Pathologists, COLA, Joint Commission, etc.). Laboratories in two states, Washington and New York, are subject to State CMS-approved laboratory programs but not a separate CLIA certification process. Laboratories located in New York must hold a New York State Clinical Laboratory permit, which meets CLIA requirements and a CLIA certificate is provided. Laboratories in Washington State are subject to the Medical Test Site (MTS) Licensing process, and when successful, an MTS license and a CLIA certificate number are both issued without a separate CLIA application process.

Lab tests are categorized by the Food and Drug Administration (FDA) based on complexity: waived, moderate (which includes the provider-performed microscopy procedures sub-category) and high complexity. Clinical laboratories must obtain a certificate that corresponds with the highest complexity of tests performed at a particular location.


Any laboratory that submits a claim that includes any procedure code under the management of the Molecular and Genomic Testing Laboratory Program is subject to quality assessment based on the following principles.

• CLIA edits will be applied to all applicable procedure codes (as defined by CMS) that are under the Molecular and Genomic Testing Lab Program management.

• Laboratories billing procedure codes subject to CLIA edits must:
  - Hold a valid, current CLIA certificate of a type that supports the billed test complexity, and
  - Include the 10-digit CLIA certification number for the specific site where the test was performed on the submitted claim (Item 23 of the HCFA 1500 form or loop 2300 or 2400, REF/X4, 02 for electronic claims)
• Provider claims data will be cross-checked with the procedure code and CLIA certificate data from the CMS Provider of Services file to determine certification to provide the service.

• If the billing provider does not have an appropriate CLIA certificate, the service will not be eligible for reimbursement.

Supporting Documents

Supporting documents for this Laboratory Claim Reimbursement guideline are available on request.

References


9. U.S. Food and Drug Administration. IVD Regulatory Assistance: Clinical Laboratory Improvement Amendments (CLIA). Available at: