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I. Policy Scope

To be considered for reimbursement, all outpatient laboratory claims should be submitted in accordance with:

- AMA CPT and HCPCS coding and ICD-10 diagnosis coding guidelines
- Other laboratory and pathology coding guidelines
- All applicable regulatory guidelines

This policy outlines additional requirements beyond the guidelines listed above that are required for reimbursement. Note that these guidelines are reviewed and updated periodically.

II. Modifier Guidelines/Instructions

Technical, Professional, and Global services (TC, 26 modifiers)

- Before using the 26 or TC modifiers, verify that these modifiers are allowable with the procedure code.
- Do not append these modifiers to the procedure code when performing the global service.

Tests performed by a Reference laboratory

- When laboratory procedures are performed by a party other than the treating or reporting physician
 to other qualified health care professional, the procedure must be identified by adding modifier 90
 to the claim line.
- Only independent clinical laboratories may append modifier 90 to indicate that the service was referred to an outside laboratory.

Repeat Testing

- While treating a patient, it may be necessary to repeat the same laboratory test on the same day
 to obtain subsequent (multiple) test results. Under these circumstances, the laboratory test
 performed can be identified by its usual procedure number and the addition of modifier 91.
- Modifier 91 may not be used when tests are rerun to confirm initial results; due to testing problems
 with specimens or equipment; or for any other reason when a normal, one-time, reportable result
 is all that is required.

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 Modifier 91 may not be used when other code(s) describe a series of test results (e.g., glucose tolerance tests, evocative/suppression testing).

Clinical Laboratory Improvement Amendments (CLIA) Waived Testing

 Laboratory tests which are CLIA-waived must have the QW modifier appended to the procedure code.

III. Place of Service Guidelines

In accordance with S611b of OBRA of 1989, a referring lab can bill for tests performed by a reference lab only if it meets any one of the following exceptions:

- The referring laboratory is in or is part of a rural hospital
- The referring lab and the reference lab are 'subsidiary related.' That is:
 - The referring lab is a wholly owned subsidiary of the reference lab
 - The referring lab wholly owns the reference lab
 - Both the referring lab and reference lab are wholly owned subsidiaries of the same entity.

IV. Genetic Counseling Reimbursement Guidelines

Genetic counseling, when required, **MEETS COVERAGE CRITERIA** ONLY when performed by a provider who is NOT an employee or contractor of the rendering lab. Genetic counseling should be independent of the laboratory rendering the testing to prevent conflict of interest. Genetic counseling documentation consists of written documentation of the counseling elements provided to the member (may include: risks, benefits, care guidance, and follow-up plans). Any genetic counseling provided, whether a covered benefit or not, will be considered during review of health plan laboratory policy where counseling is a required component.

V. Non-Reimbursable CPT/HCPCS Codes

Some procedure codes will not be reimbursed due to their expiration or replacement with more appropriate codes.

- AMA drug assay codes 80320 to 80377 are not accepted and will not be reimbursed. Refer to policy T2015, Opioids Testing in Pain Management and Substance Abuse, for guidelines for submitting G0480 to G0483.
- Proprietary Laboratory Analyses (PLA) codes will not be reimbursed unless a laboratory policy specifically covers the PLA code.



 Unlisted codes (81479, 81599, 84999) will not be accepted if a specific Tier 1, Tier 2, GSP, or MAAA code exists.

VI. Panel Reimbursement

Reimbursement for genetic panel testing is as follows:

- If a procedure code is available for the multi-gene panel test, then this code is to be utilized (i.e., 81442 Noonan spectrum disorders genomic sequence analysis panel).
- If there is not a specific next generation sequencing (NGS) procedure code that represents the requested test, the procedure may be represented by a **maximum of ONE** unit of 81479 [unlisted molecular pathology procedure] (i.e., 81479 X 1 should account for all remaining gene testing) **OR** all genes tested on the panel must be represented by **ALL** appropriate Molecular Pathology Tier 1 or 2 procedure codes (with exception of 81479 x 1 only being listed once if it appropriately represents more than one gene in the panel).
- **ALL** gene tests in the panel must be listed on the request and rationale for the clinical utility for the gene test must come from the ordering provider.
- If ALL codes that represent the testing of the panel are not submitted, the test will be denied as
 not medically necessary due to incorrect coding process, as neither laboratory or clinical
 reviewer should assign meaning to incomplete unspecified panel codes.
- Concurrent ordering of multi-gene panel tests for a specific condition is strictly prohibited; only one multi-gene panel test may be ordered at a time for a specific condition.

VII. Edit Types

Outpatient lab claims are consistently evaluated for reimbursement against several standard edit types using administrative information (e.g., claim information, historical claims). The specific edits are described below.

Additional Tests on the Date of Service

The presence or absence of additional tests on a single date of service (DOS) may trigger a reimbursement denial for a claim line.

The exclusivity edit is based upon:

- A list of tests where Correct Coding Initiative (CCI) and/or AMA coding guidance identify that
 two procedure codes for the test are not permitted for the same patient at the same time because
 it is only appropriate to charge for one of those procedures.
- Clinical guidelines for testing preclude the simultaneous performing of two tests. For example, individual components of panel procedures codes will not be separately reimbursed when billed with the panel procedure code.

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 Technically complex procedures which incorporate simple procedures will not be reimbursed for the same patient on the same DOS. For example, billing for multiple testing methodologies (e.g., direct, amplification, and quantitative testing) for the same microorganism codes is not

reimbursed.

Thus, a denial based upon this edit is one that is based upon evaluation of universal, objective criteria related to how the test is being billed, not an assessment of a patient's condition to determine whether both codes were appropriate.

Incorrect Diagnosis Code

Select diagnosis and procedure code combinations are permitted or precluded depending on the nature

of the policy.

The edit functions to identify those tests that are never appropriate unless the physician has first concluded that the patient presents with the indicated diagnosis. Although the edit is contingent upon the diagnosis of the individual patient, it is not conducting any clinical evaluation of whether the condition, in fact, exists. Rather, the inherent nature of the test (only being indicated for patients with the condition or contraindicated for the condition) and the question of whether the pre-requisite condition is present are the conditions for reimbursement.

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Incorrect Patient Age

This edit addresses medical policies with coverage criteria, CPT/HCPCS codes, and diagnosis codes that not are reimbursable based on the patient's age on the DOS.

For example, testing on newborns must be associated with a member who is 28 days of age or younger.

Incorrect Place of Service

This edit is invoked when the Place of Service is identified as inappropriate with the laboratory test/service performed submitted on the claim.

Once per Lifetime Tests

This edit limits the frequency of applicable laboratory services/procedure codes to once in the patient's lifetime.

Certain laboratory services should only be performed once in a patient's lifetime as outlined in medical policy. If a once-per-lifetime test is submitted for reimbursement more than once, the subsequent submissions will not be reimbursed.



Unit Threshold Met (Daily and Historical)

These edits are invoked when the number of units billed for the procedure on a single DOS or over a period of time exceed an allowed reimbursement quantity without considering any aspect of an individual's specific condition. Maximum units of service are determined by one or more of the following:

- The CPT or HCPCS code description defines the number of units per patient per DOS for a unique billing event.
- Laboratory Coverage Guidelines outlined in medical policy establish the number of units for a laboratory service.
- The service is anatomically or clinically limited to the number of procedures that may be performed and therefore units billed.
- Scientific or statistical analyses demonstrate a reasonable limitation of the number of units that should be performed within a period of time.
- Third-parties such as Correct Coding Initiative or Centers for Medicare and Medicaid Services limit reimbursement to a specified number of units.

If a procedure code that is assigned a maximum unit value is reported with a greater unit count, the claim line will be reimbursed only for the number of units up to but not exceeding the allowed maximum.

VIII. References

- Centers for Medicare and Medicaid Services, "Medically Unlikely Edits" https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/MUE.html
- 2. American Medical Association, Current Procedural Terminology (CPT ®), Professional Edition
- 3. https://www.cms.gov/Regulations-and- Guidance/Guidance/Manuals/downloads/clm104c16.pdf
- 4. CMS Pub. 100-04, chapter 16, section 40.1.1 external link (PDF, 497 KB)

Approval History

Туре	Date	Action
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Revision Date		