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Corporate Medical Policy

Laboratory Procedures Medical Policy AHS - R2162

File Name: laboratory procedures medical policy

Origination: 01/01/2019 **Last Review:** 07/2024

Description of Procedure or Service

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.

Policy

BCBSNC will provide reimbursement for laboratory procedures based on the guidelines listed below.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore, member benefit language should be reviewed before applying the terms of this medical policy.

Policy Guidelines

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 physician, reporting physician or other qualified health care professional, the laboratory 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.
- When a normal, one-time, reportable result is all that is required, modifier -91 may not be used if tests are rerun to confirm initial results, due to testing problems with specimens or equipment, or for any other reason.
- When other code(s) describe a series of test results (e.g., glucose tolerance tests, evocative/suppression testing), modifier -91 may not be used.

Clinical Laboratory Improvement Amendments (CLIA) Waived Testing

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

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 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.
 - o The referring lab wholly owns the reference lab.
 - Both the referring lab and reference lab are wholly owned subsidiaries of the same entity.

Genetic Counseling Considerations

Reimbursement of genetic counseling is outside the scope of BCBSNC lab policies. However, reimbursement of some genetic testing may be dependent on genetic counseling having been performed: any genetic counseling provided will be considered during review of a health plan laboratory policy where genetic counseling is a required component. Genetic counseling documentation consists of written documentation of the counseling elements provided to the member.

General expectations that should be documented with genetic counseling include explanation of the following: the testing process, what the tests can and cannot do, and how well the tests work. Furthermore, discussion should include what different results mean to the tested individual, including discussing how knowing the test results may affect the individual's emotions and mental health, as well as how knowing the results may affect the individual's family. Additionally, diagnostic and treatment options based on results should be discussed. Ideally, when a multigenerational family history is available, this history should be documented and summarized.

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 Prescription Medication and Illicit Drug Testing in the Outpatient Setting AHS-T2015 for guidelines for submitting G0480 to G0483.
- Unlisted codes (81479, 81599, 84999) will not be accepted if a specific Tier 1, Tier 2, GSP, MAAA, or Proprietary Laboratory Analyses (PLA) code exists.
- PLA codes will not be reimbursed unless a laboratory policy specifically covers the PLA code.

Panel Reimbursement

Genes can be assayed serially or in parallel. Parallel sequencing is when all of the requested genes are assayed on the same date of service with no consideration for the results of another gene assayed during the process. When two or more genes are assayed in parallel using next generation sequencing, then those two or more genes are considered part of the same panel (consistent with NCCI manual Chapter 10, Section F, number 8). 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).
- Multi-gene panels must contain the genes specified in the AMA CPT coding description.
- If there is not a specific next generation sequencing (NGS) procedure code that represents the requested test, a **maximum of ONE** unit of 81479 [unlisted molecular pathology procedure] may be billed.
- 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 incorrect codes are submitted to represent panel testing, reimbursement is not allowed for ALL codes submitted due to incorrect coding process.
- 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.

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.
- 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.

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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0331U, 0341U, 0342U, 0351U, 0355U, 0361U, 0372U, 0375U, 0376U, 0378U, 0381U, 0382U, 0383U, 0384U, 0385U, 0389U, 0390U, 0393U, 0394U, 0407U, 0418U, 0421U, 0427U, 0430U, 0431U, 0432U, 0449U, 0450U, 0451U, 0457U, 0458U, 0472U, 0482U, 0483U, 0484U, 0486U, 0510U, 0511U, 0522U, 0524U, 0526U, 0527U.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

<u>Centers for Medicare and Medicaid Services, "Medically Unlikely Edits"</u> https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/MUE.html

American Medical Association, Current Procedural Terminology (CPT ®), Professional Edition

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c16.pdf

CMS Pub. 100-04, chapter 16, section 40.1.1 external link (PDF, 497 KB)

https://www.cms.gov/files/document/medicaid-ncci-policy-manual-2022-chapter-10.pdf Specialty Matched Consultant Advisory Panel review 7/2021

Medical Director review 7/2021

Medical Director review 7/2024

Policy Implementation/Update Information

For policy titled: Laboratory Procedures Reimbursement Policy AHS - R2162

- 1/1/19 New reimbursement policy developed. Reimbursement for laboratory procedures will be based on the guidelines noted in the policy. Medical Director review 1/1/2019. Policy noticed 1/1/2019 for effective date 4/1/2019. (an)
- 1/14/20 Routine policy review. Senior Medical Director approved 12/2019. No changes to policy statement. (an)
- 6/9/20 Revised final statement in the Guidelines section to read: If a procedure code that is assigned a maximum unit value is reported with a greater unit count, the claim line will be denied, and the provider will be responsible for resubmitting the claim only for the number of units up to but not exceeding the allowed maximum. (bb)
- 7/28/20 Reviewed by Avalon 2nd Quarter 2020 CAB. Medical Director review 7/2020. Added Genetic Counseling and Panel Reimbursement sections to Policy Guidelines. (bb)
- 12/31/20 Routine policy review. Medical Director approved 12/2020. No changes to policy statement. (eel)

For policy titled: Laboratory Procedures Medical Policy AHS – R2162

- 5/4/21 Reviewed by Avalon 1st Quarter 2021 CAB. Title changed from Laboratory Procedures Reimbursement Policy to "Laboratory Procedures Medical Policy". Changed "Policy Scope" to "Description". The following statement was added to the section on reimbursement for genetic panel testing: "Concurrent ordering of multigene panel tests for a specific condition is strictly prohibited: only one multigene panel test may be ordered at a time for a specific condition. Medical Director review 4.2021. (jd)
- 9/7/21 Specialty Matched Consultant Advisory Panel review 7/2021. Medical Director review 7/2021. (jd)
- 7/1/22 The following PLA code was added to the Billing/Coding section: 0331U. (jd)
- 9/30/22 Added codes 0341U, 0342U and 0351U to Billing/Coding section. (tm)
- 12/30/22 Updated Billing/Coding section to add 0355U, 0357U, 0361U effective 1/1/2023. (tm)
- 3/31/23 Updated Billing/Coding section to add codes 0372U, 0375U, 0376U, 0378U, 0381U, 0382U, 0383U, 0384U and 0385U effective 4/1/2023. (tm)
- 6/30/23 Codes 0389U, 0390U, 0393U, 0394U added to Billing/Coding section, effective 7/1/23. (tm)
- 12/29/23 Updates to Billing/Coding section: codes 0407U and 0418U added, effective 10/1/23 and codes 0421U, 0427U, 0430U, 0431U and 0432U added, effective 1/1/24. (tm)
- 4/17/24 Code 0449U added to Billing/Coding section, effective 4/1/24. (tm)
- 5/29/24 Annual policy review. Code 0357U removed from Billing/Coding section. Policy Guidelines updated. No updates from lab benefit manager, no change to policy statement. (tm)
- 7/17/24 Codes 0450U, 0451U, 0457U, 0458U and 0472U added to Billing/Coding section, effective 7/1/24. (tm)
- 9/4/24 Reviewed by Avalon 2nd Quarter 2024 CAB. Policy Guidelines and References updated. Genetic Counseling section renamed to Genetic Counseling Considerations and updated to state: "Reimbursement of genetic counseling is outside the scope of BCBSNC lab policies. However, reimbursement of some genetic testing may be dependent on genetic counseling having been performed: any genetic counseling provided will be considered during review of a health plan laboratory policy where genetic counseling is a required component. Genetic counseling documentation consists of written documentation of the counseling elements provided to the member. General expectations that should be documented with genetic counseling include explanation of the following: the testing process, what the tests can and cannot do, and how well the tests work. Furthermore, discussion should include what different results mean to the tested individual, including discussing how knowing the test results may affect the individual's emotions and mental health, as well as how knowing the results may affect the individual's family. Additionally, diagnostic and treatment options based on results should be discussed. Ideally, when a multigenerational family history is available, this history should be documented and summarized." Panel Reimbursement section updated to include definition of a genetic panel and coding considerations were added and/or adjusted. Added new bullet point 2: "Multi-gene panels must contain the genes specified in the AMA CPT coding description." Former bullet 2, now bullet 3, updated. Previously read: "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)." Now reads: "If there is not a specific next generation sequencing (NGS) procedure code that represents the requested test, a **maximum of ONE** unit of 81479 [unlisted molecular pathology procedure] may be billed." Former bullet 4, now bullet 5, updated. Previously read: "If ALL codes that represent the testing of the panel are not submitted, reimbursement is not allowed due to incorrect coding process, as neither laboratory nor clinical reviewer should assign meaning to incomplete unspecified panel codes." Now reads: "If incorrect codes are submitted to represent panel testing, reimbursement is not allowed for **ALL** codes submitted due to incorrect coding process." Medical Director review 7/2024. (tm)

- 10/1/24 Codes 0482U, 0483U, 0484U, 0486U, 0510U, and 0511U added to the Billing/Coding section, effective 10/1/24. (tm)
- 12/31/24 Codes 0522U, 0524U, 0526U and 0527U added to Billing/Coding section, effective 1/1/2025. (tm)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.