

CHAPTER 529.1 LABORATORY AND PATHOLOGY SERVICES

TABLE OF CONTENTS

SECTION	PAGE NUMBER
Background .....	2
Policy .....	2
529.1.1 Laboratory Services .....	2
529.1.2 Pathology Services .....	2
529.1.3 Specimen Collection .....	3
529.1.4 Genetic Testing .....	3
529.1.5 Provider Participation Requirements .....	4
529.1.6 Documentation Requirements .....	4
529.1.7 Prior Authorization .....	4
529.1.8 Reimbursement Methodology .....	5
529.1.9 Non-Covered Services .....	5
Glossary .....	6
References .....	7
Change Log .....	8

## CHAPTER 529.1 LABORATORY AND PATHOLOGY SERVICES

### BACKGROUND

Covered laboratory services include, but are not limited to, diagnostic and therapeutic and pathology procedures. West Virginia Medicaid covers various pathology services for Medicaid members. Services may be subject to medical necessity review, appropriateness criteria, and any prior authorization requirements.

### POLICY

#### 529.1.1 Laboratory Services

West Virginia Medicaid covers the collection of specimens either through routine venipuncture, finger, heel or ear stick, and catheterization (urine collection), etc.

Laboratory services may be provided in an office, clinic, hospital setting, or an independent clinical laboratory. Laboratory services are limited to those tests identified by the Centers for Medicare and Medicaid Services (CMS) which the individual provider or laboratory is Clinical Laboratory Improvement Amendments- (CLIA) certified to provide, bill and for which it can receive Medicaid payment.

Practitioners billing CLIA regulated laboratory tests must submit the CLIA certification or registration certification to the Bureau for Medical Services (BMS) fiscal agent for inclusion into the respective practitioner's enrollment record. CLIA certifications must be kept current.

Laboratory services require a written practitioner's order which includes the original signature of the member's treating provider, date ordered, member's diagnosis, and the specific test or procedure requested. Use of non-specific diagnosis code does not satisfy this requirement.

When specific, covered laboratory services require prior authorization review for medical necessity, the required medical documentation must be submitted to BMS utilization management contractor (UMC) by the referring practitioner. When services require prior authorization, a prior authorization must be obtained regardless of place of service.

Categorizations of tests can be found on the [CMS website](#).

#### 529.1.2 Pathology Services

Pathology services must be requested by a treating provider regarding an abnormal condition and must result in a written report by a pathologist. A pathologist will be reimbursed for the professional component of pathology services. The professional component is paid according to the Resource-Based Relative Value Scale (RBRVS) fee schedule, and appropriate modifiers must be billed. The total component is eligible for reimbursement to a laboratory which employs the pathologist.

These services may be subject to medical necessity review, appropriateness criteria, and prior authorization requirements.

## CHAPTER 529.1 LABORATORY AND PATHOLOGY SERVICES

### 529.1.3 Specimen Collection

A specimen collection fee is not separately reimbursable when the same provider is collecting the specimen and processing the specimen. The collection of the specimen is considered an inherent part of processing the specimen. A specimen collection fee is separately reimbursable to the collecting provider when the specimen is collected in one place of service but is processed elsewhere.

When a specimen is drawn and sent to a reference lab for processing, West Virginia Medicaid will reimburse the referring provider for the specimen collection and the reference lab processing the specimen. The reference lab must enroll for reimbursement for services rendered.

Only one collection fee is allowed for each type of specimen (e.g., blood, urine) for each member encounter, regardless of the number of specimens drawn. When a series of specimens is required to complete a single test (e.g., glucose tolerance test), the series is treated as a single encounter.

Medicaid defines the date of service for clinical laboratory providers as the date on which the specimen was collected. For specimen collections that span more than one calendar day, the date of service is the date the collection began.

### 529.1.4 Genetic Testing

Genetic and molecular pathology procedures are medical laboratory procedures that identify changes in genes, chromosomes, or proteins. Genetic testing can be done to confirm a suspected diagnosis, predict illness, detect individuals carrying a specific gene and predict response to therapy. West Virginia Medicaid considers providing genetic testing when *all* of the following criteria are met:

- The member displays clinical features, or current signs and symptoms, of a genetic condition or is at high risk of inheriting the mutation in question (pre-symptomatic); and
- Clinical studies published in peer-reviewed literature have established strong evidence that the result of the test will directly impact the medical management of the member; and
- The testing method is proven to be scientifically valid and, if testing guidelines exist, the clinical scenario falls within those recommendations; and
- After a history, physical examination, pedigree analysis, genetic counseling (provided from a practitioner with genetic expertise), and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain; and
- Disease-specific criteria are met; and
- Prior authorization from the UMC (if applicable) is obtained.

Genetic testing is a rapidly evolving science. Evidence of clinical utility for many tests is still being established. Certain genetic tests require prior authorization. In order to determine medical necessity, all of the following information must be submitted for review to our UMC in addition to any specific criteria requirements.

1. Name of genetic test(s)
2. Name of the performing laboratory.
3. The exact genes(s) and/or variants being tested
4. Relevant billing codes

## CHAPTER 529.1 LABORATORY AND PATHOLOGY SERVICES

5. Brief description of how the genetic test results will guide clinical decisions that would not otherwise be made in the absence of testing
6. Medical records related to the genetic test
  - a. History and physical exam
  - b. Conventional testing and outcomes
  - c. Conservative treatment provided, if any

Please refer to the West Virginia Medicaid's [UMC webpage](#) for specific requirements.

### 529.1.5 Provider Participation Requirements

In order to be eligible for payment for laboratory services, a clinical laboratory must be certified by CMS to perform the specialties or subspecialties of tests billed to Medicaid as of the date the tests are performed. Reimbursement for clinical laboratory services are paid to various providers such as laboratories, outpatient hospitals, and practitioners certified under CLIA. Providers billing CLIA-regulated laboratory tests must have CLIA certification or CLIA certification of registration. A copy of any current certifications must be on file with the West Virginia Medicaid Enrollment Unit.

Refer to [Chapter 300, Provider Participation Requirements](#) for additional information.

### 529.1.6 Documentation Requirements

Laboratory services require a written order which includes the original signature of the member's treating provider, date test was ordered, member's diagnosis, and the specific test or procedure requested. Use of a non-specific diagnosis code does not satisfy this requirement. The laboratory order and the results of the lab test must be kept on file with the member's medical record.

### 529.1.7 Prior Authorization

All requests for covered services requiring prior authorization must be submitted to the UMC for medical necessity determination. Nationally accredited, evidence-based, medically-appropriate criteria, such as InterQual, or other medical-appropriateness criteria approved by BMS, are utilized for reviewing medical necessity of services requested.

It is the responsibility of the enrolled treating, prescribing, ordering, or referring practitioner to submit a request to the UMC with relevant medical documentation that justifies the medical necessity of the proposed procedure/service. Clinical documentation submitted for prior authorization review must not be more than six months old.

If the covered services are provided before the prior authorization is confirmed, the service will be denied and cannot be reimbursed by BMS. Request for or receipt of prior authorization does not guarantee approval or payment

It is recommended that the [UMC web portal](#) be utilized for submitting any request for services requiring prior authorization. Providers using the UMC password-protected web portal to submit prior authorization requests may also use the password -protected web portal to obtain the approval(s) and their assigned prior authorization number(s), or the denial(s) and the reason(s) for the denial(s) within two business days after submitting the request and clinical documentation.

## CHAPTER 529.1 LABORATORY AND PATHOLOGY SERVICES

When the request for service is denied based on medical necessity, the denial is communicated to the provider of service via the UMC's password-protected web portal with the reason(s) of denial and notification of their right for reconsideration of the denial. The member or their legal representative is notified of the denial with information related to their right of a Fair Hearing with a copy of the Request for Fair Hearing form for the submission to BMS.

Retrospective authorization is available by the UMC in the following circumstances:

A procedure/service denied by the member's primary payer, providing all requirements for the primary/payer have been followed, including appeal processes; or  
Retroactive West Virginia Medicaid eligibility.

Refer to [Chapter 100, General Administration and Information](#) for additional information.

### 529.1.8 Reimbursement Methodology

West Virginia Medicaid pays the lesser of 90 percent of the Medicare Clinical Laboratory Fee Schedule or the provider's usual and customary fee for laboratory services. The BMS Clinical Laboratory Fee Schedule is located on the [BMS website](#). Refer to [Chapter 600, Reimbursement Methodologies](#) for further information. A pathologist, when billing separately, will be reimbursed for the professional component of pathology services. The professional component is paid according to the RBRVS fee schedule and appropriate modifier must be billed.

### 529.1.9 Non-Covered Services

West Virginia Medicaid shall not reimburse an independent laboratory for a test ordered by a provider who has, or whose family has, an ownership or financial interest in the facility or who receives any form of compensation, fee, or gratuity for requesting laboratory services from that facility.

Non-covered laboratory services are not eligible for fair hearings or desk/document reviews. These services include, but are not limited to:

- Blood tests required for marriage, employment, paternity determination, etc.
- Fertility services such as embryo/sperm collections, and banking, infertility studies, any tests or services related to charges for surrogate motherhood
- Experimental/research/investigational examinations, testing, or screening
- Services not ordered by the member's treating provider, including direct-to-customer testing (mail order, online ordering)
- Services that are provided to members who are not eligible to receive them on the date provided.
- Reports to providers of services
- Reports requested by BMS or its authorized representative
- Mass screenings or examinations of members at nursing facilities, schools, or other institutional or public settings
- Lab tests performed for quality assurance/confirmation
- Repeated tests due to provider error

## CHAPTER 529.1 LABORATORY AND PATHOLOGY SERVICES

- Routine reflex testing. (Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test is medically appropriate. This is covered only when specifically ordered by the provider as a medical necessary)
- Specimen collection when same provider provides specimen analysis
- More than one specimen collection for each member per encounter  
Specimen collection for throat cultures or pap smear, as these services are included in the evaluation and management visit
- Autopsies and/or supervisory pathology services and all associated services relating to postmortem examination
- Handling and/or conveyance of specimens for transfer from one site to another
- Separate payment for validity/adulteration testing of urine drug screens
- Services that are covered by federal, state, or local grants
- Services that are available free of charge to the general public
- Drug screening for pre-employment or employment purposes, medicolegal and/or court ordered drug screenings
- Any lab service the facility is not CLIA certified to provide
- Duplicate lab services by the same or different providers
- Crime scene lab services
- Any lab service that is considered bundled into an all-inclusive rate
- Tests billed separately when tests are lesser charge when part of a panel
- Genetic testing for the sole convenience of information for the member without impacting treatment; and
- Genetic testing or the medical management of other family members done to benefit the family member(s) rather than benefit the member, unless otherwise specified in policy.

Non-covered services are not eligible for a West Virginia Department of Health and Human Resources (DHHR) fair hearing or desk/document review.

## GLOSSARY

Definitions in [Chapter 200, Definitions and Acronyms](#) apply to all West Virginia Medicaid services, including those covered by this chapter. Definitions in this glossary are specific to this chapter.

**CLIA Certificate:** Any of the following types of certificates issued by Centers for Medicare and Medicaid Services (CMS):

- **Certificate of Accreditation (COA):** A certificate issued to a laboratory that is CLIA approved to perform tests categorized as waived, Provider Performed Microscopy Procedures (PPMP), and moderate and/or high complexity testing. These labs must meet the standards of a private non-profit accreditation program approved by CMS.
- **Certificate of Compliance (COC):** A certificate issued to a laboratory that is proven to be in compliance with applicable CLIA requirements. Laboratories with a COC can perform tests categorized as waived, PPMP and moderate and/or high complexity tests.
- **Certificate of Provider Performed Microscopy Procedures (PPMP):** A certificate issued to a laboratory in which a physician or midlevel practitioner performs no tests other than PPMP procedures, and if desired, waived tests.

## CHAPTER 529.1 LABORATORY AND PATHOLOGY SERVICES

- **Certificate of Registration (COR):** A certificate issued to a laboratory that applies for a COC or a COA. This enables the laboratory to conduct waived, PPMP and moderate and/or high complexity testing while achieving their CLIA certification.
- **Certificate of Waiver (COW):** A certificate that permits a laboratory to perform only waived tests.

**Clinical Laboratory:** Any facility or place, however named, for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings.

**Clinical Laboratory Improvement Amendments (CLIA):** An established standard for laboratories to ensure the accuracy, reliability, and timeliness of patients' test results regardless of where the test is performed. Congress passed CLIA in 1988 establishing quality standards for all laboratory testing performed on humans (clinical) to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The regulations are based on the complexity of the test method.

**Exempt Tests:** Laboratory testing that is not regulated by nor certified by CLIA.

**Genetic Testing:** Involves the analysis of chromosomes, DNA (deoxyribonucleic acid), RNA (ribonucleic acid), genes or gene products to detect inherited or non-inherited genetic variants related to disease or health.

**Laboratory Services:** Services ordered by or under the direction of a licensed practitioner of the healing arts within the scope of his or her practice as defined by state law, performed in compliance with the rules implementing CLIA.

**Moderate/High Complexity Testing:** Testing subject to regulations setting minimum qualifications for all persons performing or supervising these tests, along with corresponding responsibilities for each position in the lab. These laboratories must also participate successfully in approved proficiency testing programs, which provide an external evaluation of the accuracy of the laboratory's test results. Moderate and high complexity laboratories must have systems and processes for monitoring testing equipment, procedures to ensure proper test performance and accurate results and an overall plan to monitor the quality of all aspects of the laboratory's operation ongoing.

**Referring Lab:** A laboratory that receives a specimen to be tested and then refers the specimen to another laboratory for the performance of the laboratory test.

**Reference Lab:** Any lab performing clinical laboratory diagnostic tests (or the interpretation/report of such tests, or both) without a face-to-face encounter between the member and the lab billing for the test and/or interpretation/report.

## REFERENCES

West Virginia State Plan references laboratory services at sections [3.1-A\(3\)](#) and [3.1-B\(3\)](#).

**CHAPTER 529.1 LABORATORY AND PATHOLOGY SERVICES**

Add other references for policy if applicable.

**CHANGE LOG**

REPLACE	TITLE	EFFECTIVE DATE
Entire Chapter 529 Laboratory Services	Policy 529.1 Laboratory and Pathology Services	October 2, 2015
Entire Manual	<ul style="list-style-type: none"> <li>529.1.3 - Added date of service definition</li> <li>529.1.4 Genetic Testing -Replaced entire section</li> <li>529.1.9 Non-Covered Services - Updated bullets</li> <li>Glossary - Updated definitions</li> <li>Entire manual - Updated hyperlinks and grammar</li> </ul>	April 1, 2022

DRAFT