CHAPTER– 529 COVERED SERVICES, LIMITATIONS, AND EXCLUSIONS FOR LABORATORY SERVICES

CHANGE LOG

Replace	Title	Change Date	Effective Date
Entire Manual	Entire Manual	December 1, 2009	January 1, 2010

CHAPTER 529-COVERED SERVICES, LIMITATIONS, AND EXCLUSIONS FOR LABORATORY SERVICES

TABLE OF CONTENTS

CHAPTER 529–COVERED SERVICES, LIMITATIONS, AND EXCLUSIONS FOR LABORATORY SERVICES

INTRODUCTION

The West Virginia Medicaid Program is administered pursuant to Title XIX of the Social Security Act and Chapter 9 of West Virginia Code. The Bureau for Medical Services (BMS) in the West Virginia Department of Health and Human Resources (DHHR) is the single State agency responsible for administering the Program. This Program, therefore, must also function within federally define parameters. Any service, procedure, item, or situation not discussed in the manual must be presumed non-covered.

Medicaid offers a comprehensive scope of medically necessary medical and mental health services. All covered and authorized services must be provided by enrolled providers practicing within the scope of their license, utilizing professionally accepted standards of care, and in accordance with all State and Federal requirements. Enrolled providers are subject to review of services provided to Medicaid members by BMS whether or not the services require prior authorization. All providers of services must maintain current, accurate, legible and completed documentation to justify medical necessity of services provided to each Medicaid member and made available to BMS or its designee upon request.

Covered laboratory services available to Medicaid members may be provided in an office, clinic, hospital setting, or clinical laboratory, which is in compliance with Clinical Laboratory Improvement Amendments (CLIA) requirements and state regulations. Certain laboratory services may require prior authorization. Appropriate medical documentation shall be submitted to the Utilization Management Contractor (UMC) or Rational Drug Therapy Program (RDTP), by the referring provider prior to services being rendered. Prior authorization is required regardless of the place of service.

This chapter describes West Virginia Medicaid's coverage policies for laboratory services. See *Chapter 510, Hospital Services Manual*, for information regarding hospital laboratory services.

529.1 DEFINITIONS

Definitions governing the provision of all West Virginia Medicaid services shall apply pursuant to the Provider Manual, *Chapter 200, Definitions*. In addition, the following definitions apply and/or relate to laboratory services.

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.
- **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.

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 and must be 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.

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.

Utilization Management Contractor (UMC) - The BMS Utilization Management Contractor authorized to grant prior authorizations.

Waived Tests - Simple laboratory examinations and procedures that employ methodologies that are as simple and accurate as to render the likelihood of erroneous results negligible and/or pose no reasonable risk of harm to the patient if the test is performed incorrectly.

529.2 PROVIDER ENROLLMENT AND PARTICIPATION REQUIREMENTS

To participate in the West Virginia Medicaid Program and receive reimbursement from BMS, providers must:

- Meet and maintain all applicable licensing as required by the state in which the practice is located: (Note: When the license and/or certification(s) are not current, the provider shall not participate in Medicaid until such time the BMS' Provider Enrollment Unit receives the copy of current license(s) and/or certification(s). When current license and/or certification(s) are not on file, reimbursement cannot be provided.)
- Have a valid signed provider enrollment application/agreement on file
- Meet and maintain all BMS provider enrollment requirements.

Refer to *Chapter 300, Provider Participation Requirements*, for additional information related to West Virginia Medicaid Provider enrollment.

In addition to the above, 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 is paid only to laboratories certified under CLIA or as amended. Providers billing CLIA regulated laboratory tests must have CLIA certification or registration certification. A copy of any current certifications must be on file with the West Virginia Medicaid enrollment department.

529.3 COVERED SERVICES

Laboratory services provided by Medicaid enrolled providers are considered for reimbursement by West Virginia Medicaid when the services are determined medically necessary to meet the specific healthcare needs of the member. Covered laboratory services include, but are not limited to, diagnostic and therapeutic laboratory and

pathology procedures. Laboratory services are limited to those tests identified by CMS for which the individual provider is CLIA certified. A list of laboratory codes with their proper certifications can be found on the CMS website at http://www.cms.hhs.gov/. Refer to the West Virginia Medicaid website, http://www.wvdhhr.org/bms/, the Clinical Lab Fee Schedule, for a list of covered and non-covered laboratory services.

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.

529.3.1 PATHOLOGY SERVICES

West Virginia Medicaid covers various pathology services for Medicaid members. These may be subject to medical necessity review, appropriateness criteria, and any prior authorization requirements.

Pathology services must be requested by a treating provider regarding an abnormal condition which results 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 RBRVS fee schedule, and appropriate modifiers must be billed. The total component is eligible for reimbursement to a laboratory which employs the pathologist.

529.3.1.2 SPECIMEN COLLECTION

West Virginia Medicaid covers the collection of specimens either through routine venipuncture, finger, heel or ear stick, and catheterization (urine collection), etc. 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 the collecting provider's office or laboratory 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 for 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.

For information regarding specimen collection of homebound members please refer to *Chapter 508, Home Health Services*.

529.4 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 include, but are not limited to:

- Blood tests required for marriage, employment, paternity determination, etc.
- Drug screenings which are:
    - Done routinely as a result of a provider's/facility's procedure and/or policy
    - Not based on medical necessity
    - Work related
- Fertility services such as embryo/sperm collections and banking
- Experimental/research/investigational/trial examinations, testing, or screening
- Services not ordered by the member's treating provider
- Services that are provided to members who are not eligible to receive them on the date provided
- Reports to providers of service
- 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
- 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 medically 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
- Handling and/or conveyance of specimens for transfer from one site to another
- Any lab service the facility is not CLIA certified to provide.

529.5 PRIOR AUTHORIZATION

For laboratory services requiring prior authorization for medical necessity by the Utilization Management Contractor (UMC), the referring/treating provider must submit the appropriate CPT code with clinical documentation and any other pertinent information to be used for clinical justification of services, prior to services being

rendered to the UMC. Some laboratory tests may require prior authorization by and/or coordinated with Rational Drug Therapy Program (RDTP). Refer to www.wvdhhr.org for a list of services requiring prior authorization.

The UMC and/or RDTP review all requests for services requiring prior authorization. When the medical documentation does not meet medical necessity criteria or additional information is not received, a denial letter is sent to the member or their legal representative, the requesting provider and facility. This denial letter notes the reason for the denial and includes information regarding the member's right to a fair hearing and a Request for Hearing Form for completion. In addition, the letter sent to the provider contains information regarding their right to a reconsideration of the denial.

Prior authorization does not guarantee payment. Prior authorization is required regardless of place of service. Nationally recognized medical appropriateness criteria, or other criterion that has been approved by BMS, may be utilized for medical necessity reviews of laboratory services requiring prior authorization.

Retrospective authorization is available (1) for West Virginia Medicaid covered services denied by the member's primary payer, (2) retroactive Medicaid eligibility, and (3) the next business day following a medically necessary emergency procedure occurring on weekends, holidays, or at times when the UMC is unavailable. A request for consideration of retrospective authorization does not guarantee approval or payment.

529.6 DOCUMENTATION REQUIREMENTS

In addition to the documentation requirements identified in *Common Chapter 300, Provider Participation Requirements, 320.5 Document and Retain Records*, providers and facilities submitting claims for Medicaid reimbursement must maintain complete, individual, accurate and legible records. Records must include documentation of services provided to Medicaid members and billed to West Virginia Medicaid.

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. The written order, along with the results of the laboratory services, must be kept on file at least five years with the billing facility and have a copy in the members' medical record. These records must be made available upon request to the Bureau for Medical Services, Federal/State Auditors and Investigators, or BMS contracted agencies.

The laboratory must maintain records that indicate the daily accession of specimens. At a minimum, these records must contain the following information:

- Member identification: Name, address, birth date, Medicaid Identification Number
- Specimen identification if other than by member name
- Written order from requesting provider
- Name of provider submitting specimen

- Date of specimen collection
- Date specimen received
- Type of specimen
- Tests requested and performed
- Date test performed
- Test results and date reported to provider
- Specimens and test requests referred to other laboratories, and the name and location of the reference laboratory.

529.7 BILLING

West Virginia Medicaid utilizes Current Procedure Terminology (CPT) and/or Healthcare Procedure Coding System (HCPCS) codes for billing of services provided to Medicaid members. These codes are recommended by CMS and can be found in procedure code books published by the American Medical Association. Some services are not assigned a CPT or HCPCS code; therefore, an unlisted code may be available for the service provided. The appropriate unlisted code with the documentation describing the service performed must be submitted on a paper claim for payment consideration. Use of an unlisted code when a national CPT code is available is not reimbursable.

There are laboratory tests that are frequently performed as a group (profile) on automated equipment. For any combination of these tests, the provider shall use the code which correctly designates the number of tests included in the profile. The provider shall not "unbundle" and bill separately for tests included as part of a group, profile or panel. West Virginia Medicaid utilizes clinical auditing bundling software for prepayment review of claims. Unbundling of codes is not eligible for reimbursement. When all individual component tests that make up a particular panel are ordered and performed, West Virginia Medicaid rebundles all components into the panel. Furthermore, when components of one panel are duplicated in another panel, only one panel code may be billed. Individual tests not included in the panel may be billed separately.

The clinical laboratory that provides covered services must perform both the technical and professional components of the service. The technical component is the test procedure. The professional component is the report that interprets the test results and identifies those that are outside the normal range. The date of service the technical component is performed is the appropriate date of service for both the professional and technical components.

Laboratories will only be reimbursed for the tests the CLIA certification authorizes. CLIA Waived tests that require a modifier must be billed with the appropriate modifier in order to be eligible for payment. Claims must be submitted to the BMS Fiscal Agent within 12 months of the date of service. Refer to *Chapter 800, General Administration*, for more information on timely filing.

Practitioners not in a group practice shall bill laboratory services with their individual National Provider Identification (NPI). Practitioners affiliated with groups shall bill with

their individual NPI and group NPI. The laboratory CLIA number that has been submitted to enrollment will be appropriately applied.

Medicaid is the payer of last resort. Third-party Liability (TPL) is a method of ensuring that Medicaid is the last payer to reimburse for covered Medicaid services. Refer to *Chapter 600, Reimbursement Methodologies*, for further information regarding TPL.

529.7.1 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. 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 Resource-Based Relative Value Scale (RBRVS) fee schedule, and appropriate modifiers must be billed.

529.8 MANAGED CARE ORGANIZATION

Unless otherwise noted in this manual or appendices, these services are the responsibility of the Managed Care Organization (MCO). If the Medicaid member is enrolled in a West Virginia MCO, MCO requirements must be met for reimbursement. Medicaid will not reimburse for services provided when MCO or PAAS requirements are not met. Medicaid members enrolled in the PAAS Program do not require the primary care provider's referral for lab services.

529.9 MOUNTAIN HEALTH CHOICES

Mountain Health Choices (MHC) is the name of West Virginia Medicaid's Program where members have a choice of benefit packages. This program promotes member choice, member responsibility and health improvement. This program was developed as a result of the Deficit Reduction Act 2005 and allows for the tailoring of benefit packages to meet the needs of certain populations. This program is a part of the redesign of Medicaid to promote wellness and to prevent and/or manage the progression of chronic diseases by encouraging healthier lifestyles for Medicaid members.

The services outlined in this manual are covered for children and adults in both the Basic and Enhanced Benefit packages.