

Chapter 11

Laboratory/Pathology, Radiology & Diagnostic Services

Laboratory/pathology, radiological and diagnostic services enable physicians and other licensed practitioners to identify the existence, nature or extent of illness, injury, or health deviation in a patient.

Contrast Material: The phrase “with contrast” represents contrast material administered intravascularly, or intra-articularly injections for imagine enhancement.

Laboratory: A facility that performs laboratory testing on specimens derived from humans for the purpose of providing information on diagnosis, prevention care, health assessment or treatment of diseases or impairment.

Panel Codes: are groups of laboratory test (components) that are frequently performed together. Tests included in each panel are listed by name with the CPT code identified in parenthesis. In order to report a panel code, all listed tests must be performed.

Pathology: A service requiring additional medical interpretive decision, consisting of a written report performed by a pathologist, at the request of a physician.

Provider Performed Microscopy Procedures (PPMP): It allows physician office laboratories to perform a limited number of microscopy procedures. Certified PPM approved procedures are subject to change at any time.

Radiology: Radioactive substance’s radiant energy and with the diagnostic and treatment of diseases by means of both ionizing and non-ionizing radiation.

Waived Complexity: CMS has identified a number of simple laboratory procedures that can be performed in the physician offices after obtaining a Certificate of Waiver. Waived tests are subject to change at any time, so review all Medicare mailing for changes to waived test.

Laboratory/Pathology Services

Eligible Providers

To be eligible as a provider of laboratory services, a vendor must be certified under the CLIA program.

Providers of lab services must have their CLIA certificate number on file with PrimeWest Health. If you did not indicate your certificate number on your PrimeWest Health enrollment application, or your office has obtained a certificate since your original enrollment, please provide PrimeWest Health Provider Enrollment with the certificate number.

It is the responsibility of providers to keep their CLIA certification number current and up to date with their most recent level of certification on file with PrimeWest Health.

Covered Services

PrimeWest Health covers all laboratory tests paid under the Clinical Diagnostic Laboratory fee schedule from (CMS).

To be eligible for PrimeWest Health payment as a laboratory/pathology service, the service must be:

- Ordered and provided by or under the direction of a physician or other licensed practitioner of healing arts within the scope of practice as defined by state law;
- Provided in a hospital or independent laboratory;
- Directly related to the diagnosis and treatment of a member's health status; and
- Authorized under the laboratory's CLIA certification.

Clinical Laboratory Improvement Amendment (CLIA)

Congress passed the Clinical Laboratory Improvement Amendment (CLIA) in 1988, establishing a minimum quality of standards for all laboratory testing to ensure high quality of testing regardless of the laboratory location.

PrimeWest Health follows Medicare guidelines. All hospitals and physician owned and free-standing laboratories require CLIA certification. PrimeWest Health will not cover lab services provided by laboratories without CLIA certification.

CMS CLIA Requirements

The Centers for Medicare & Medicaid Services (CMS), formerly known as the Center for Medicare and Medicaid (CMS), requires all providers performing laboratory testing to register with the CLIA program. Inquiries about CLIA certification should be directed to CMS.

Registration is through the CMS's Health Standards and Quality Bureau. If the provider performs clinical laboratory testing and has not received CLIA information, please write:

CMS CLIA PROGRAM
P.O. Box 26689
Baltimore, MD 21207-0489

Medicaid Internet Site: Use the Internet as a means to obtain updates about CLIA certification. This site is updated on a regular basis. CLIA waiver tests, provider performed microscopy procedures (PPMP), and tests required under CLIA edit are subject to change at anytime. Providers are advised to review this site on a regular basis. <http://cms.hhs.gov/clia/default.asp>

How to Apply for a CLIA certificate: form CMS-116
<http://cms.hhs.gov/cmsforms/downloads/cms116.pdf>

Provider Enrollment Criteria

Providers of any level of laboratory services must have their CLIA certificate number on file with PrimeWest Health in order to be paid for laboratory services. PrimeWest Health requires the certification number and the expiration dates.

If you did not indicate your certificate number on your PrimeWest Health enrollment application, or your office has obtained a certificate since your original enrollment, please provide PrimeWest Health with the following information: provider name, PrimeWest Health provider number, CLIA certificate number and expiration date. Send or fax to:

PrimeWest Health
2209 Jefferson Street, Suite 101
Alexandria, MN 56308
Fax: 320-762-8750

Billing CLIA Waiver Tests

Waived laboratories must meet only the following requirements under CLIA:

- Enroll in the CLIA program;
- Pay applicable certificate fees biennially; and
- Follow manufacturers' test instructions.

Laboratories with waiver certification (certification type 2) are approved to bill only for waiver tests.

To bill CLIA waiver tests, the procedure code must have the modifier QW. Do not use the CLIA number on the claim form.

Provider Performed Microscopy Procedures (PPMP)

PPMP laboratories must meet only the following requirements under CLIA:

- Enroll in the CLIA program;
- Pay applicable certificate fees biennially; and
- Certain quality and administrative requirements.

Laboratories with a provider performed microscopy procedure (PPMP) certification may perform PPMP tests as well as those granted CLIA waiver status. Certified PPM approved procedures are subject to change at any time.

Billing Technical Component of Surgical Pathology

The technical component of surgical pathology and supplies is not subject to CLIA requirements. When providing only these services, do not apply for CLIA certification. Billing for the technical component of a lab test includes:

- The slide preparation for interpretation by the physician; and
- Other usual pre-slide preparation.

Do not use modifiers 22 & 52 on pathology codes. Use the TC modifier when billing for CPT pathology codes (88300-88399).

Automated Multichannel Laboratory Organ or Disease Oriented Panels

The organ and disease panel codes represent chemistry tests that are frequently performed in combinations on automated multichannel equipment. When combinations of these tests are provided for a member on the same date, claims submitted to PrimeWest Health are subject to a payment cap specified by CMS for the Medicare program.

The organ and disease panel codes are defined in the Physician's Current Procedural Terminology (CPT) manual. If other tests are performed in addition to those indicated for a particular panel, report the tests on individual lines on the claim along with CPT panel codes 80048 through 80090 (codes are subject to change per CPT and American Medical Association yearly).

All multichannel laboratory tests performed on the same date/same member, must be submitted on one claim form. Billing the complete automated chemistry panel is advisable, if all tests are done. If the laboratory diagnostic tests do not fit on one claim form, follow the instructions for multiple claims (see below).

Submitting Multiple Claims for Automated Tests/Panels

If the number of claim lines is insufficient for the number of tests provided, use additional claim forms (paper clipped) with a cover letter stating, "The attached claim forms must be processed as one claim." Tests submitted with multiple claims other than described above will be denied as a duplicate test.

If subsequent tests are provided for the same patient on the same date, submit a replacement claim on a separate claim form, and include the additional tests on one claim form.

PrimeWest Health will process Medicare crossover claims as submitted per Medicare's billing instructions.

Handling/Specimen Collection

PrimeWest Health will cover the collection and handling (if applicable) for each type of specimen listed below, per member per day:

- Routine venipuncture for collection of specimens, use 36415.
- Collection of pap smears, use Q0091.
- Catheterization for collection of a specimen, single homebound, nursing facilities, use P9612.
- Catheterization for collection of a specimen, multiple patients, use P9615.
- Newborn screening for metabolic disorder.

A “handling fee” for laboratory specimens will be paid when the laboratory provider requests a **lead collection kit** from the Minnesota Department of Health (MDH). Enter MDH’s provider number in box 24J or the Rendering Provider field in MN-ITS.

Laboratory Services in a Physician's Office

PrimeWest Health requires all physician office laboratories to be CLIA certified in order to receive payment. CLIA regulations include the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Claims will be denied for physician office laboratories that do not meet CLIA requirements - either because the laboratory’s CLIA certificate has expired, or the billed test is not covered by the laboratory’s CLIA certificate, or the services rendered are outside the effective dates of the CLIA certificate.

Payment for a laboratory service performed in a CLIA certified physician’s laboratory will not exceed the amount paid for similar services performed in an independent laboratory. Physicians may also send laboratory specimens to independent or outpatient hospital laboratories.

Reference (Outside) Lab

Providers may choose to bill for laboratories services sent to a reference lab by indicating the reference lab’s PrimeWest Health provider number on the CMS-1500 in box 24J. The claim line must include the lab procedure code, place of service 81 (independent lab), and modifier 90 (reference lab). Reference laboratories must be CLIA certified for the level of services they are providing.

Independent Pathologist Services

Independent pathologists do not need CLIA certification. The laboratory requires CLIA certification. Pathology and Laboratory (CPT 80049-89399): If a pathologist must review a test result and render an opinion, the modifier 26 should be attached to indicate that only a professional component was provided.

- Independent pathologists who bill for the professional component of laboratory services must indicate the hospital’s or independent laboratory’s PrimeWest Health or NPI provider ID number in box 24J or the Rendering Provider field in MN-ITS .
- Use modifier 26 and modifier 90 in box 24D.

- If modifier 90 is used, the system will look at the treating provider field for CLIA certification.
- Do not use CLIA numbers on claims to PrimeWest Health.

Modifiers

Modifier 51 is distinct procedural services, multiple services submitted by a laboratory for the same patient on the same day. These situations usually involve microbiology where samples or cultures are taken from a patient from different anatomical sites or different wounds, use the same CPT code, and are tested on the same day.

Modifier 90 Reference (outside) laboratory identifies laboratory procedures performed by a CLIA certified lab other than the treating or reporting physician.

Modifier 91 indicates repeat clinical diagnostic laboratory test (CPT code) on the same date of services, at different intervals to obtain subsequent, additional test results. Bill laboratory services in units that are run on the same day and NOT repeated. The 91 modifier may only be used for laboratory tests paid under the clinical laboratory fee schedule. Example: repeating an arterial blood sample or potassium at different intervals on the same day.

The 91 modifier can be used to bill repeat laboratory services, except for the following CPT codes: 82962, 84520, 87040, 87088, 87103, 87186, Q0111, and P9604 (non- inclusive list).

The 91 modifier may **not** be used when:

- There are standard CPT/HCPCS codes available that describe a series of results (e.g., glucose tolerance tests, evocation/suppression tests, etc.);
- Tests are run to confirm initial results due to testing problems with the specimen or equipment; and/or
- For any other reason when a normal, one-time, reportable result is required.

When billing pathology codes, modifiers 76, 77, and 91 are allowed. Modifiers 22 and 52 cannot be used when billing pathology codes.

Billing in Units

Laboratory tests that are not repeats are to be billed in units. Do not use the repeat modifier. Examples: Blood, urine etc. cultures should be billed in “units of.” Multiple organism ID is billed in “units of” units are set up to identify the most common type of organisms. One CPT code for a genetic/cyto test may cover up to 15 different components (results).

Minnesota Family Planning Program (MFPP) Billing

MFPP-certified Physicians

For patients you find to have presumptive eligibility (PE) for MFPP, bill lab tests to MHCP when:

- The lab tests are performed in-house, or you bill for the lab tests that are sent to an outside lab;
- The lab tests are performed on the same day as other family planning services; and
- The patient's primary diagnosis is in the V25 – V25.9 range.

If you send the tests to an independent lab, **and the independent lab bills MHCP**, give the independent lab the following information:

- Primary diagnosis code in the V25 – V25.9 range; add secondary diagnosis codes as appropriate;
- Recipient's MFPP ID number, or, if the PE member does not yet have an MHCP ID number, at least two of three patient identifiers (date of birth, SSN, first and last name) so that the lab is able to verify eligibility on EVS/MN-ITS; and.
- The primary, ordering provider's PrimeWest Health ID number.

MFPP does not allow a recipient to be billed for covered services. If the independent or outside lab can not bill PrimeWest Health directly, provide the clinic address with the recipient's name. The lab may then send the bill to the clinic, and the clinic should bill Prime West Health directly for labs performed.

Independent Labs

If the MFPP recipient for whom the lab tests are ordered does not have a PrimeWest Health ID number, independent labs should:

- Perform the lab tests;
- Wait 3 business days;
- Use the information from the MFPP provider to obtain the recipient's PrimeWest Health ID number; and
- Bill PrimeWest Health for the lab tests performed.

PrimeWest Health will pay for lab tests listed in the MFPP section's Lab Services chart that are performed during the PE period under the conditions that the MFPP-certified provider found the patient presumptively eligible and requested the independent lab to perform the tests.

After a recipient's MFPP ID number is determined and available on EVS/MN-ITS (usually 3 business days after the physician determines PE), all PrimeWest Health enrolled labs are required to perform labs tests ordered for members.

Pap Smear Billing

PrimeWest Health covers one professional and one technical component for pap smear testing, per specimen per day.

- For the professional component, bill either of these codes: 88141, P3001, G0124, or G0141;
- For the technical component, bill **one** CPT or HCPCS code; and
- For pap smear collection, use Q0091.

Cytogenetic Testing

PrimeWest Health covers cytogenetic testing performed on any PrimeWest Health member. Documentation in the medical record must reflect the medical necessity for the testing. All claims submitted for payment of cytogenetic testing must contain the specific diagnosis related to the tests being performed. Use the most specific ICD-9 code available. (Some cytogenetic tests require authorization.) Bill in units.

PrimeWest Health does **not** cover cytogenetic testing for:

- Legal, paternity, or informational purposes, unless it is medically necessary for the member to receive cytogenetic testing;
- Family members who are not PrimeWest Health members; and
- Fetus testing.

Lead Toxicity Testing

The lead toxicity screening test consists of a capillary or venous blood lead test, hemoglobin (Hgb), hematocrit (HCT), and other age-appropriate exams or tests (as noted in the schedule of age-related screening standards). Refer to the [Child and Teen Checkup \(EPSDT\) section of the Children's Services chapter](#) (Ch. 9) for more information pertaining to lead toxicity testing.

The following lead testing services are **not** covered:

- Paint chip, water and soil testing; and
- Assessments performed by a registered environmental health specialist/sanitarian.

Drug Testing

Drug screening for routine work related issues or testing related to chemical dependency treatment are not covered. This test reports qualitative screening to detect the presence of specific drugs or classes of drugs.

Laboratory Testing for HIV Tropism (Trofile)

HIV Tropism testing is considered medically necessary for selecting patients for treatment with HIV co-receptor antagonists.

Tropism testing is covered for patients who meet all of the following criteria:

- Failed antiretroviral treatments
- Evidence of viral replication
- Diagnosis of 042

Report using CPT 87999 with description of HIV Tropism.
Limit of once per lifetime.

Billing

- Use 80100-80103 to report qualitative screening to detect the presence of specific drugs or class of drugs. Code 80100 is a drug screen for multiple drug classes chromatographic method. Code 80101 is a single drug class method. One specimen is used to screen for several different drug types. This test screens for common classes of drugs. Drug screening is used to identify drug toxicity and drug abuse. The screen reports what drugs are present in the specimen, and in which class (e.g., tricyclic antidepressants, phenothiazines, amphetamines, barbiturates, cannabinoids, methadone).
- When drugs or a single drug is detected, use 80102 to confirm the drug type present in the drug screen which is reported separately.
- Use the confirmatory drug test (80102) to report illegal substances or those required by law.
- Use the following CPT procedure codes when the specific drug being tested is known. Quantitative screening tests are coded by procedure. Refer to the “Chemistry Section” in CPT or the “Therapeutic Drug Assay” section of CPT.

Radiology/Diagnostic Services

Eligible Providers

To be eligible as a provider of independent x-ray services or portable x-ray services, a vendor must be certified by CMS for participation in the Medicare program.

Covered Services

To be eligible for PrimeWest Health payment for radiology, or diagnostic services, the service must:

- Be ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts within the scope of practice as defined by state law;
- Provided in a facility other than a hospital outpatient department or clinic, if an independent service;
- Meet the requirements for certification by Medicare; and
- Be directly related to the diagnosis and treatment of a member’s health status.

Professional Component

The professional component of a radiology procedure includes the professional services of the physician and the:

- Examination of patient when indicated;
- Performance or supervision of the procedure;
- Interpretation; and
- Written report of the examination.

The professional component is applicable in an encounter when the physician submits a charge for professional services only. It does not include the cost of personnel, materials, space, equipment, or other facilities.

Technical Component

The technical component of a radiology procedure code includes the personnel and materials, including:

- Contrast media and drugs;
- Film or xerography;
- Space;
- Equipment; and
- Other facilities.

Oral and/or rectal contrast administration alone does not qualify as a study “with contrast.”

Total Components

Total components include both technical and professional components and are covered by PrimeWest Health. Do not use modifiers when billing for the total components.

Mammography

PrimeWest Health covers medically necessary mammography services.

All facilities (hospital, outpatient department, clinic, radiology practice, mobile unit, physician’s office, or other facility) providing diagnostic and screening mammography services are required to have FDA certification under the Mammography Quality Standards Act (MQSA). No facility may conduct an examination or procedure involving mammography unless the facility has obtained an MQSA certificate.

Use “V” diagnosis codes when billing mammography screening services:

- Principal diagnosis code for non-high risk, use V76.12;
- Principal diagnosis for high-risk, use V76.11; and
- Applicable secondary diagnosis codes, use V10.3, V16.3 or V15.89

Computerized Tomography and Magnetic Resonance Imaging

PrimeWest Health covers medically necessary MRI’s, CT scans, bone density studies and MRI’s for angiography. Magnetic resonance spectroscopy (MRS), and positron emission tomography (PET), and brain mapping require authorization. Refer to the [Authorization chapter](#) (Ch. 5). (non inclusive list, subject to change)

Billing

When more than one provider is involved in providing and billing a procedure, the providers must establish a written agreement as to which component each provider will bill.

For example, a physician bills for the professional component of the service he/she provided, (bill on the CMS-1500 claim) while the hospital bills for the technical component (on the UB-04). Or, the hospital bills on the UB-04 for the total component (professional and technical) and the physician would not bill, but rather be paid by the hospital. Both the physician and the hospital cannot be paid for both components.

When a physician or clinic is billing for services performed, and the equipment is owned by either the physician or clinic, the service cannot be separated into a technical and professional component.

CPT or HCPCS (level 1, 2, 3 codes and modifiers when required) must be used on all claims.

Claims submitted for payment of CT and MRI scans must have a specific medical diagnosis. Use the most complete and highest level of specificity ICD-9 CM diagnosis code. PET scans are billed using CPT coding.

Professional Component

The professional component represents the professional services of the physician which includes:

- Examination of the patient;
- Performance or supervision of the procedure;
- Interpretation; and
- Written report.

Inpatient professional component services should be billed on the CMS-1500 using a 26 modifier.

When a physician provides the professional component of an outpatient service, he/she may only bill the professional component using a 26 modifier.

The professional component is applicable in any duration in which the physician submits a charge for professional services.

Injection of contrast material is part of the “with contrast” CT, MRI and MRA procedures.

Technical Component

The technical component includes the charges for personnel, materials, usual contrast media, drugs, film or xenograft, space, equipment and other facility charges, but excludes the cost of radioisotopes and low osmolar contrast materials.

The technical component of all inpatient services is included in the inpatient DRG and billed on the UB-04.

For a provider transporting their own equipment to another site, the technical components may be billed by the provider owning the equipment. To identify a charge for the technical component, enter the procedure code with a TC modifier.

Total Components

Total components include the technical and professional component. Use the appropriate procedure code without a modifier.

Interventional Radiologic Procedures and Diagnostic Studies with Injection

These types of procedures include professional, technical, and injection components.

Use of radiopharmaceuticals is regulated by the Nuclear Regulatory Commission (NRC) under strict procedures and guidelines. Persons administering radiopharmaceuticals should have either a license from the NRC or be credentialed by an institution having a board license from the NRC.

Professional Component: Bill the appropriate procedure code that states supervision and interpretation only, and use modifier 26.

Technical Component: Bill the appropriate procedure code that states supervision and interpretation only, and the TC modifier.

Injection Component: Bill radiology procedures using the appropriate CPT code that indicates “with contrast,” if available. Contrast media provided in a hospital must be billed with the appropriate CPT or HCPCS code on the UB-04.

Contrast Material: Bill separately using most appropriate HCPCS code.

Contrast Media Provided in an Inpatient Hospital: Bill the appropriate CPT or HCPCS code on the UB-04.

Legal References

Minnesota Rules [9505.0305](#)

Minnesota Rules [9505.0445](#)

State Medicaid Manual, Section 4385 B

42 CFR 440.30

42 CFR 441.17

42 CFR 441.56

42 CFR 493