# Laboratory and Pathology Services

**Revised:** June 10, 2025



## Eligible Providers

All providers of laboratory services to Minnesota Health Care Programs (MHCP) members must meet the following requirements:

- Be an enrolled MHCP provider
- Have a current Clinical Laboratory Improvement Amendments (CLIA) certificate to receive reimbursement for a laboratory service classified under the Clinical Laboratory Improvement Amendments program. If you did not indicate your CLIA certificate number on your MHCP enrollment application, or your organization has an updated or new certificate, you must fax the following to MHCP Provider Eligibility and Compliance at 651-431-7462:
  - CLIA certificate numbers and expiration dates
  - Provider name
  - National Provider Identifier (NPI)

## Eligible Members

Medical Assistance (MA) and MinnesotaCare members are eligible for laboratory and pathology services.

## Covered Services

MHCP follows Medicare payment guidelines and most Medicare coverage policy guidelines and indications. To be eligible for MHCP payment as a laboratory or pathology service, the service must:

- Be ordered and provided by or under the direction of a member's treating physician (MD, OD, DPM, DDS) or practitioner (nurse practitioner, clinical nurse specialist, physician assistant or certified professional midwife) who gives a consultation or treats a member for a specific medical condition within his or her scope of practice as defined by state law
- Yield results that are used by the treating physician or practitioner in the screening, diagnosis or management of a member's specific medical condition
- Meet Medicare or DHS coverage criteria
- Be allowed under the laboratory's CLIA certification if the service is classified under the CLIA program

## Billing

### Reference and Outside Lab Services

In conjunction with Section 1902(a)(32) of the Social Security Act, MHCP does not reimburse providers for lab tests they did not complete unless they meet an exception as noted under Exceptions.

Do not include lab services you did not complete on your claim. When a specimen is sent to another provider, the ordering provider must also send all necessary information required for that provider to claim for the service.

This policy applies only to lab services where the costs are paid fee for service. This policy applies to all services reported on claim format 837I and 837P. Lab services that are part of an all-inclusive inpatient hospital (diagnosis-related group) DRG or nursing facility rate are not affected.

**Exceptions**
An outpatient hospital laboratory or provider-based clinic may continue to bill for laboratory services performed by a reference or outside lab only if the lab is providing services either as part of the hospital or when operating under an arrangement that is within the scope of the hospital's certification. In this situation, MHCP can either pay the laboratory directly or pay the hospital with which it is affiliated. (Refer to Medicare direct payment requirements in the Code of Federal Regulations, title 42, section 447.10.)

A staff-model clinic that is part of a health maintenance organization (HMO) licensed by the Minnesota Department of Health under Minnesota Statutes, 62D may bill for lab tests performed at other sites within the same HMO. Lab services performed by a reference or outside lab that is not part of the same HMO must be billed by the lab that performed the test. HMOs wishing to use this exception must provide Minnesota Department of Human Services (DHS) a list of the staff-model clinics or labs (including the NPIs) within the HMO that will be billing for services that other labs within the same HMO provide.

**Minnesota Family Planning Program (MFPP) Lab Tests and Services**
Refer to the MFPP Billing, Lab Services entry on the MFPP section of the Provider Manual for information regarding MFPP lab tests and services.

**Unlisted Codes**
According to the HCPCS codebook, if you provide a service that is not accurately described by HCPCS CPT procedure codes, you may report the service using an unlisted procedure code.

You must determine if another more-specific code could describe the procedure or service being performed or provided before considering using an unlisted or not otherwise classified procedure code. If there is not a more specific code available, you may use an unlisted code and must attach documentation to the claim to justify the use of the unlisted procedure code and to describe the procedure or service rendered. If the documentation includes multiple tests, you must note which test is being claimed with the unlisted code.

**Date of Service**
Do not bill a date span for services defined as multiple treatments or units of service.

**Units**
Bill laboratory tests that are not repeats in units; do not use the repeat modifier. Examples: Bill blood, urine and other cultures in "units of." Bill multiple organism IDs in "units of."

**Test Components**
When billing for lab services and you own the equipment used, the services cannot be separated into a professional and technical component. Bill the appropriate code without a modifier.

**CLIA Tests**
To bill CLIA waiver tests, certain procedure codes must have the modifier QW. Do not use your CLIA number on the claim transaction. Do not use the QW modifier for services excluded from CLIA edits or for waived tests that don't require modifier QW.

**Automated Multichannel Laboratory Organ or Disease-Oriented Panels**

The organ and disease-oriented panel codes represent chemistry tests 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 MHCP are subject to a payment cap specified by CMS for the Medicare program.

All multichannel laboratory tests performed on the same date for the same member must be submitted on one claim transaction. Billing the complete automated chemistry panel is advisable if all tests are done. Additional tests for the same date and same member submitted on a separate claim are considered part of the panel and will be denied as a duplicate test.

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

The Physician's Current Procedural Terminology (CPT) manual defines the organ and disease-oriented panel codes. 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.

Do not separately report individual laboratory tests that are components of a multichannel test analysis.

MHCP will process Medicare crossover claims as submitted per Medicare's billing instructions in the Medicare Claims Processing Manual (PDF).

### Specimen Collection and Handling

MHCP will no longer reimburse for collection of blood by access port in conjunction with another service. These services are incidental or included in a primary service.

MHCP will cover collection and handling (if applicable) for each of the following types of specimens per member per day:

- Routine venipuncture for collection of specimens
- Catheterization for collection of a specimen, single homebound, nursing facilities
- Catheterization for collection of a specimen, multiple members

### Minnesota Department of Health (MDH) Newborn Screening Program

MHCP will reimburse for the MDH newborn screening for metabolic disorder card in the diagnosis-related group (DRG) or facility fee **only** when provided in an inpatient or birthing center setting. Do **not** bill separately from facility fee.

MHCP will cover the cost of the newborn screening metabolic disorder card when screening **cannot** be completed at the inpatient hospital or birthing center setting with HCPCS code S3620, if MDH requests a repeat newborn screening card, bill S3620 and modifier 76 or 77.

Birthing center is defined as a facility licensed for the primary purpose of performing low-risk deliveries that is not a hospital or licensed as part of a hospital and where births are planned to occur away from the mother's usual residence following low-risk pregnancy.

### MDH Infectious Disease Reporting

MHCP will only cover handling and conveyance of specimen (CPT 99000) if both of the following conditions are met:

- A specimen (biological) is required to be submitted to MDH for infectious disease reporting
- The provider uses a third-party courier and incurs a fee to deliver the biological to MDH

You may claim the courier expense using the 837P or 837I claim and must identify the rendering provider number as MDH (use UMPI M306253800).

In all other instances, CPT 99000 is incidental to the primary service and is not covered.

### Laboratory Services in a Physician's Office

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.

### Pathology Services

Bill pathology services reported with modifier 26 using the 837P. A CLIA-certified provider NPI must also be included in one of the three provider fields: rendering, pay-to or service facility location.

### Genetic Testing

MHCP covers genetic testing when medically necessary. Genetic testing is considered medically necessary when all of the following conditions are met and documented in the medical record:

- The member displays clinical features or is at direct risk of inheriting the genetic condition in question (pre-symptomatic)
- The result of the test will have a clinically significant impact on the treatment being delivered for a disease or syndrome
- The testing method is considered scientifically valid for the identification of a specific genetically linked inheritable disease
- Appropriate genetic counseling occurs before and after testing. Counseling documentation supports the intent to change therapy based on the results of the testing

Genetic testing is not covered when performed in the absence of symptoms or high-risk factors for an inheritable disease or when knowledge of genetic status will not affect treatment decisions. Tests for conditions that are treated symptomatically are not appropriate since the treatment would not change due to the test results.

Exome and genome testing requirements will be reviewed on a case-by-case basis. Claims must include an attachment that explains the medical necessity for the test and indicates how the results of the test will influence treatment. We will pend each case until it is reviewed for the medical necessity of the test and what the results of the test will have on treatment.

Pharmacogenetic panel testing may require prior authorization. Pharmacogenetic testing is covered when all the following are met:

- The patient's clinical evaluation has identified a condition requiring a medication with a known gene-drug interaction and the test results will directly influence the management of that medication.
- The test is required by the medication's FDA-approved label.
- The test is supported by strong scientific evidence, has undergone a transparent, peer-reviewed evaluation process, and is listed by the FDA as a gene-drug interaction that can guide treatment decisions or impact the safety or effectiveness of the medication. Refer to the FDA's Table of Pharmacogenomic Biomarkers in Drug Labeling and Table of Pharmacogenetic Associations webpages.
- A drug trial is considered impractical due to safety concerns or other factors prior to genetic testing.

The following tests are not medically reasonable and necessary:

- Genetic testing where either analytical validity, clinical validity, or clinical utility has not been established.
- Germline testing, which looks at inherited DNA changes present from birth, is typically done once in a person's lifetime and is not medically necessary to perform more than once per member's lifetime.
    - A person's inherited genetic makeup does not change, and repeat testing does not add new clinical value, thus, repeating a germline genetic test for the same information in the same member is not necessary..

MHCP does not cover cytogenetic testing for:

- Legal, paternity or informational purposes
- Family members who are not MHCP members
- Fetus testing

**Rapid Whole Genome Sequencing**

Rapid whole genome sequencing is a genetic test medically necessary when all of the following criteria are met:

- Critically ill infant or child in the intensive care unit (ICU) with no unifying diagnosis.
- Clinical circumstances present the need for rapid testing in time-sensitive cases as a last resort to guide clinical decision making in treatment or management of patient's genetic condition.
- Test must be ordered by the infant's treating physician and, before ordering testing, infant must be evaluated by a medical geneticist or other physician subspecialist with expertise in the conditions or genetic disorder for which the testing is being considered

AND

One of the following is met:

- Critically ill infant or child with a history of multiple hospitalizations or readmissions within 30 days of discharge for an unexplained condition which no diagnosis has been reached despite extensive workup and previous testing in the identification of rare genetic disease variant; or
- Clinical presentation does not fit a well-defined gene analysis test that is available or previous extensive workup and testing has failed to receive a diagnosis.

**Genetic Mutation Testing**

The BRCA Genetic Testing and Presumptive Eligibility Services defines coverage criteria.

**Genetic Testing for Breast Cancer**

Genetic testing for breast cancer aims to help breast cancer patients and their physicians determine whether adjuvant chemotherapy would be beneficial. Genetic testing is considered medically necessary for members with all of the following breast cancer characteristics:

- Stage I or II breast cancer
- Breast tumor is estrogen-receptor positive
- Breast tumor is HER2-receptor negative
- Tumor size 0.6-1 cm with moderate or poor differentiation or unfavorable features, or tumor size greater than 1 cm
- Negative lymph nodes (nodes with micrometastases greater than 2 mm in size)
- Test result will be used to guide decision making about adjuvant chemotherapy

**Home Monitoring of Anticoagulant Therapy**

Home use of Prothrombin Time (PT) testing and International Normalization Ratio (INR) monitoring may be covered for members taking oral anticoagulation and with mechanical heart valves, chronic

atrial fibrillation or venous thromboembolism if all the following medical indications are present and if prescribed by the treating physician:

- The patient must have been anticoagulated for at least three months before the use of the home INR device
- The patient must receive face-to-face education from the treating provider on anticoagulation management and must demonstrate the correct use of the device before its use in the home
- The patient must continue to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring
- Self-testing with the device should not occur more frequently than once a week

The treating physician must also order the home monitoring supplies for these conditions.

### 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 Checkups (C&TC) section of the MHCP Provider Manual for more information pertaining to lead toxicity testing.

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

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

### HIV Tropism (Trofile assay) Testing

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

MHCP covers tropism testing for members who meet all of the following criteria:

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

Report HIV Tropism Testing using CPT 87999 with the description "HIV Tropism" in the line note. Limit of once per lifetime.

### Drug Testing

MHCP allows coverage for urine drug testing (UDT) that is medically necessary. Document medical necessity, specific to each patient, in the patient's medical record and include it in the plan of care. Documentation should specify how the test results will be used to guide decision making.

Drug or drug classes for which screening is performed, should only reflect those likely to be present based on the patients' medical history or current clinical presentation. An appropriately licensed health care professional must order the UDT. The ordering health care professional must sign and date the orders and must specify all drugs and drug classes to be tested as well as the clinical indication or medical necessity for the drug test.

Standing orders or orders to "conduct additional testing as needed" are not sufficiently detailed to verify medical necessity.

If the provider of the drug testing is different than the ordering or referring clinician, that provider must maintain hard-copy documentation of the lab results along with copies of the order for the drug test. Copies of test results alone without documentation of the treating clinician's request are not sufficient

to support the drug testing services. The frequency of drug testing should be individualized to the treatment plan.

UDT after the identification of the patient's drugs or use or abuse profile must be limited to the specific drugs present on the initial profile.

The patient's medical record must include an appropriate number of UDTs billed over time based on the stage of screening, treatment, or recovery; the rationale for the drugs or drug classes ordered; and the results must be documented in the medical record and used to direct care.

The maximum number of allowed presumptive UDTs for SUD must meet medical necessity and be documented in the clinician's medical record.

- For patients with 0 to 30 consecutive days of abstinence, presumptive UDT is expected at a frequency of one to three presumptive UDTs in seven consecutive days. More than three presumptive UDTs in seven consecutive days are not medically necessary and are not covered.
- For patients with 31 to 90 consecutive days of abstinence, presumptive UDT is expected at a frequency of one to three presumptive UDTs in seven consecutive days. More than three presumptive UDTs in seven consecutive days are not medically necessary and are not covered.
- For patients with greater than 90 consecutive days of abstinence, presumptive UDT is expected at a frequency of one to three UDTs in 30 consecutive days. More than three physician-directed UDTs in 30 consecutive days are not medically necessary and are not covered.

Definitive UDT may be considered medically necessary under the following conditions:

- When accurate and reliable results are necessary to integrate treatment decisions and clinical assessment. Presumptive testing is positive and to accurately determine the specific drugs in the patient's system.
- Providers must document the frequency and exceptions with the rationale for the confirmation testing order in the medical record
  - For patients with 0 to 30 consecutive days of abstinence, definitive UDT is expected at a frequency not to exceed one physician-directed testing profile in seven consecutive days. More than one UDT in seven consecutive days is not medically necessary and not covered.
  - For patients with 31 to 90 consecutive days of abstinence, definitive UDT is expected at a frequency of one to three physician-directed testing profile in 30 consecutive days. More than three definitive UDTs in 30 consecutive days is not medically necessary and is not covered.
  - For patients with greater than 90 consecutive days of abstinence, definitive UDT is expected at a frequency of one to three physician-directed testing profiles in 90 consecutive days. More than three definitive UDTs in 90 consecutive days is not medically necessary and is not covered.

Routine definitive drug screens with negative results are not deemed medically necessary and are not covered.

Report drug screening using CPT codes 80305-80307 or HCPC codes G0480-G0483. CPT codes 80300-80304 and 80320-80377 are no longer covered.

Required drug screening for employment-related issues or when court ordered are not medically necessary and are not covered. For services other than medication assisted therapy, drug testing costs are not included in the Behavioral Health Fund rate.

## Definitions

**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 impairments.

**Panel Codes:** Groups of laboratory test (components) frequently performed together. Tests included in each panel are listed by name with the CPT code identified in parenthesis. 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.

**Professional Component:** A physician's exam (when indicated), performance or supervision, interpretation or written report of a diagnostic test.

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

**Technical Component:** Includes the personnel and materials, including contrast media and drugs, film or xerography, space, equipment or other facilities.

**Waived Complexity:** CMS has identified several 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 mailings for changes to waived test.

## Legal References

Minnesota Statutes, 144.123 (Fees for Diagnostic Services; Exceptions)
Minnesota Statutes, 144.125 (Tests of Infants for Heritable and Congenital Disorders)
Minnesota Statutes, 245G.22 (Opioid Treatment Programs)
Minnesota Statutes, 256B.0625, subdivision 54 (Services provided in birth centers)
Minnesota Statutes, 256.969, subdivision 29 (Reimbursement for fee increase for early hearing detection and intervention program)
Minnesota Rules, 4605.7040 (Disease and Reports; Clinical Materials Submissions)
Minnesota Rules, 9505.0305 (Laboratory and X-ray Services)
Minnesota Rules, 9505.0445 (Payment Rates)
State Medicaid Manual, chapter 4, section 4385 B
Code of Federal Regulations, title 42, section 440.30 (Other laboratory and X-ray services)
Code of Federal Regulations, title 42, section 441.17 (Laboratory services)
Code of Federal Regulations, title 42, section 441.56 (Required activities)
Code of Federal Regulations, title 42, section 493 (Laboratory Requirements)