MEDICAID POLICY INFORMATION SHEET

Policy Analyst: Adriena Krul-Hall

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Initial ☐ Public Comment ☒ Final ☐

Brief description of policy:

The bulletin provides notification of the revisions to the Laboratory chapter in the Michigan Department of Health and Human Services (MDHHS) Medicaid Provider Manual. The revised chapter includes the incorporation of laboratory information from the Practitioner and Hospital chapters, updates terminology, and expands and clarifies existing policy.

Reason for policy (problem being addressed):

The revised laboratory chapter will add and update coverage information, remove outdated information, and reduce duplication within the Medicaid Provider Manual.

Budget implication:

☒ budget neutral
☐ will cost MDHHS $, and (select one) budgeted in current appropriation
☐ will save MDHHS $

Is this policy change mandated per federal requirements?

No

Does policy have operational implications on other parts of MDHHS?

No

Does policy have operational implications on other departments?

No

Summary of input:

☐ controversial
☒ acceptable to most/all groups
☐ limited public interest/comment

Supporting Documentation:

State Plan Amendment Required: ☐ Yes ☒ No If Yes, please provide status: ☐ Approved ☐ Pending ☐ Denied Date: Approval Date:	Public Notice Required: ☐ Yes ☒ No If yes, Submission Date:

DRAFT FOR PUBLIC COMMENT Michigan Department of Health and Human Services		
	Project Number: 2220-Lab	**Date:** August 4, 2022

Comments Due: September 8, 2022
Proposed Effective Date: November 1, 2022
Direct Comments To: Adriena Krul-Hall
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Policy Subject: Revisions to the Laboratory Chapter of the Medicaid Provider Manual

Affected Programs: Medicaid, Healthy Michigan Plan, MIChild, Children's Special Health Care Services, Maternity Outpatient Medical Services, Emergency Services Only

Distribution: Practitioners, Independent Clinical Laboratories, Hospitals, Local Health Departments, Federally Qualified Health Centers, Rural Health Clinics, Tribal Health Centers, Medicaid Health Plans, Integrated Care Organizations

Summary: The bulletin provides notification of the revisions to the Laboratory chapter in the Michigan Department of Health and Human Services (MDHHS) Medicaid Provider Manual. The revised chapter includes the incorporation of laboratory information from the Practitioner and Hospital chapters, updates terminology, and expands and clarifies existing policy.

Purpose: The revised laboratory chapter will add and update coverage information, remove outdated information, and reduce duplication within the Medicaid Provider Manual.

Cost Implications: Budget neutral

Potential Hearings & Appeal Issues: Aware of None

State Plan Amendment Required: Yes ☐ No ☒ **If yes, date submitted:**	**Public Notice Required: Yes ☐ No ☒** **Submitted date:**

Tribal Notification: Yes ☐ No ☒ - Date:

THIS SECTION COMPLETED BY RECEIVER

☐ **Approved**	☐ **No Comments**
	☐ **See Comments Below**
☐ **Disapproved**	☐ **See Comments in Text**

Signature:	**Phone Number**

Signature Printed:	
Bureau/Administration *(please print)*	**Date**

Comment001 **Revised 6/16**

Proposed Policy Draft

Michigan Department of Health and Human Services
Behavioral & Physical Health and Aging Services Administration

Distribution: Practitioners, Independent Clinical Laboratories, Hospitals, Local Health Departments, Federally Qualified Health Centers, Rural Health Clinics, Tribal Health Centers, Medicaid Health Plans, Integrated Care Organizations

Issued: October 1, 2022 (Proposed)

Subject: Revisions to the Laboratory Chapter of the Medicaid Provider Manual

Effective: November 1, 2022 (Proposed)

Programs Affected: Medicaid, Healthy Michigan Plan, MIChild, Children's Special Health Care Services, Maternity Outpatient Medical Services, Emergency Services Only

This bulletin provides notification of the revisions to the Laboratory chapter in the Michigan Department of Health and Human Services (MDHHS) Medicaid Provider Manual. The revised chapter includes the incorporation of laboratory service information from the Practitioner and Hospital chapters, updates terminology, and expands and clarifies existing policy. There are no changes to covered laboratory services, coverage parameters (frequency/quantity limits, age parameters, etc.) or services that require prior authorization (PA). The bulletin is effective for services provided on and after November 1, 2022.

Summary of Chapter Updates

Key updates include:

- Expanded and clarified information on covered laboratory services
- Revised descriptions and parameters of each laboratory type
- Updated CLIA information including circumstances when a separate CLIA number is required and Medicaid's alignment with CMS' identification of laboratory services subject to CLIA waived and non-waived certification.
- Removed outdated information pertaining to physician self-referrals, microbiology studies, and Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID)
- Added billing and reimbursement information related to laboratory services performed at a provider-based hospital clinics and freestanding dialysis centers
- Expanded Outpatient Hospital laboratory reimbursement information
- Clarified Medicaid's laboratory order requirement
- Added coverage information related to drug screening, newborn screening, pap smears, and pregnancy related tests

- Updated terminology and reorganized information throughout the chapter
- When the updated Laboratory chapter is incorporated into the MDHHS Medicaid Provider Manual, duplicated laboratory information contained in the Practitioner and Hospital chapters will be removed.

Medicaid Health Plans and Integrated Care Organizations

Medicaid Health Plans (MHPs) and Integrated Care Organizations (ICOs) must provide the full range of covered services described in the laboratory chapter at a minimum and may choose to provide services over and above those specified. MHPs and ICOs are allowed to develop prior authorization requirements and utilization management and review criteria that differ from Fee-for-Service (FFS) Medicaid requirements. For beneficiaries enrolled in an MHP or ICO, the provider must check with the health plan for clinical review and prior authorization specifics.

Medicaid Provider Manual

LABORATORY - DRAFT

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Medicaid Provider Manual

SECTION 1 - GENERAL INFORMATION

This chapter applies to laboratory services performed in practitioner offices, hospital laboratories, and independent clinical laboratories.

Medicaid covers diagnostic laboratory services and pathology procedures reasonable and necessary to guide detection, diagnosis, management, and/or treatment of a specific medical condition, illness, or injury. Testing performed in a profile, panel, or battery is covered only when all the included tests are reasonable and necessary for the beneficiary.

Covered laboratory and pathology services must be:

- Recommended and ordered by the beneficiary's treating physician or other licensed practitioner working within their scope of practice as determined under State law.
- Provided in accordance with evidence based generally accepted standards of medical practice.
- Clinically appropriate in terms of type, frequency, extent, site, and duration for the beneficiary's symptoms, diagnosis, illness, or injury.
- Used in the clinical management of the beneficiary's specific medical condition.
- Provided in accordance with all applicable Medicaid clinical criteria, requirements, policies, and/or provisions of coverage.
- Not primarily for the convenience of the beneficiary or provider.
- Performed in a laboratory appropriately certified by the Clinical Laboratory Improvement Amendments (CLIA).

The beneficiary's medical record must include sufficient documentation to support the need for the laboratory service.

Medicaid covers a limited number of screening laboratory services including, but not limited to, those specified for the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Program, recommended as Grade A or B by the United States Preventive Services Taskforce, or identified in Medicaid policy. All other screening laboratory tests not reasonable or necessary for the diagnosis or management of the beneficiary's specific condition are not covered. This includes laboratory screening tests performed for investigational purposes only or as part of a clinical evaluation when the need for the test is not clinically indicated.

1.1 LABORATORY TYPES

1.1.A. PRACTITIONER'S OFFICE LABORATORY

Medicaid covers laboratory services provided in a physician's, physician assistant's (PA), nurse practitioner's (NP), clinical nurse specialist's (CNS), certified nurse midwife's (CNM), podiatrist's, or dentist's office laboratory when they are appropriate to be performed in the office. Practitioner's Office Laboratory (POL) reimbursement is limited to services listed on the applicable provider's fee schedule. Coverage includes procedures contained in the CLIA Physician Performed Microscopy list for appropriately

certified physicians. For the purposes of Medicaid, a POL meets the following parameters:

- A physician, PA, NP, CNS, CNM, podiatrist, dentist, or group of practitioners maintains the laboratory.
- The laboratory performs testing only on specimens generated by the practitioners of the practice. The laboratory does not accept specimens from other physicians, clinics, or laboratories outside of the practice.
- Laboratory services are billed using the practitioner's or group practice's National Provider Identifier (NPI) number.
- The laboratory holds a CLIA certificate of registration, compliance (COC), accreditation (COA) waiver (COW) or a certificate of Physician Performed Microscopy Procedures (PPMP) from the Centers for Medicare & Medicaid Services (CMS).

A practitioner may not charge for laboratory tests when a specimen is obtained but sent out of the office (i.e., skin lesions, pap smears, etc.) for analysis.

1.1.A.1. Provider-Based Outpatient Hospital Clinics

Medicaid covers laboratory services provided in a provider-based outpatient hospital clinic when they are appropriate to be performed in a clinic setting. Outpatient provider-based hospital clinics are not considered POLs by Medicaid and must meet the following parameters:

- Owned and operated by a hospital.
- May be located on the same campus as the main hospital or located off-campus.
- Holds a CLIA certificate of registration, COC, COA, COW, or PPMP from CMS from CMS separate from the hospital if located off campus.
- Beneficiaries are treated as hospital outpatients for billing purposes.

1.1.A.2. Other Clinics

Medicaid covers medically necessary laboratory services provided in a variety of clinics including, but not limited to, family planning clinics, urgent care centers (UCCs), school-based clinics, rural health clinics (RHC), federally qualified health centers (FQHC), and Indian health centers (i.e., tribal FQHCs and tribal health centers [THC]), when they are appropriate to be performed in these settings. These clinics are not considered POLs by Medicaid and covered laboratory services are limited to those listed on the applicable Medicaid clinic fee schedule. Providers should refer to the Family Planning Clinics, Urgent Care Centers, School Based Services, Tribal Health Centers, Rural Health Clinics, and Federally Qualified Health Centers chapters in this manual for additional information related to these clinics.

1.1.B. Independent Clinical Laboratory

Medicaid covers laboratory services performed by an independent clinical laboratory. Independent laboratories are limited to providing only the laboratory services listed on the Medicaid Laboratory Fee Schedule. For the purposes of Medicaid, an independent clinical laboratory meets the following parameters:

- A freestanding clinical laboratory that is independent of a physician office, hospital, or hospital-based facility.
- May be owned by a physician, group practice, a pharmacy, or a non-physician.
- Laboratory services are billed using the independent clinical laboratory's NPI number.
- Holds a CLIA certificate of registration, COC, COA, or COW from CMS.

1.1.C. Hospital Outreach Laboratory

Medicaid covers laboratory services performed by a clinical laboratory located in or as part of a hospital. Laboratory services performed (either directly or under arrangement) for non-hospital patients (i.e., those who are neither a registered outpatient nor inpatient hospital patient), are considered performed by a hospital outreach laboratory.

For the purposes of Medicaid, a hospital outreach laboratory meets the following parameters:

- Furnishes laboratory tests to patients other than inpatients or registered outpatients of the hospital.
- Holds a CLIA certificate of registration, COC, or COA from CMS.
- Laboratory services are billed using either the hospital's NPI number or the hospital clinical laboratory's NPI number.
- Bills for services using Form CMS-1450 14x TOB.

1.2 Ordering Practitioner

Laboratory services provided to Medicaid beneficiaries can be ordered by the following Medicaid enrolled practitioners:

- Physicians (MD or DO)
- Physician assistant (PA)
- Advanced practice registered nurse (APRN) [including certified nurse practitioners (NP), certified clinical nurse specialists (CNS) and certified nurse midwives (CNM)]
- Certified Registered Nurse Anesthetists (CRNA)
- Podiatrist (DPM)
- Dentist (DDS or DMD)

Providers should only order laboratory services that fall within the practitioner's scope of practice. To be eligible for Medicaid reimbursement, claims for laboratory services must indicate the Medicaid enrolled, allowable ordering provider.

Medicaid does not cover any laboratory tests ordered by a chiropractor.

The ordering practitioner must document the medical necessity of laboratory tests in the beneficiary's medical record, regardless of where the test(s) is performed. The ordering practitioner is held responsible if they order excessive or unnecessary laboratory tests, regardless of who actually renders the laboratory services. The ordering practitioner is also held responsible for the medical necessity of every laboratory test that is ordered as part of a custom- or laboratory-designed panel. The ordering practitioner may be subject to corrective action related to these services, including recoupment of funds. The laboratory also may be subject to corrective action, including the recoupment of funds, if it submits a claim for laboratory services not specifically ordered by a practitioner.

These ordering requirements apply to all Medicaid beneficiaries. Claims for beneficiaries with Medicare or private insurance coverage will not be exempt from this requirement. (Refer to the specific Billing & Reimbursement chapters for additional information.)

Laboratory services performed by a laboratory or its employees may not be billed to the ordering practitioner.

1.3 Order Requirement

A signed order, a signed requisition, or a signed medical record supporting the provider's intent to order tests satisfies the order requirement for laboratory tests.

1.4 Standing Orders

Medically necessary laboratory services ordered and performed due to standing orders are eligible for reimbursement when they are based on clinical treatment protocols applicable to the specific beneficiary. Standing orders for routine screening tests are not covered unless the medical necessity is documented in the beneficiary's medical record. Ordering providers must maintain documentation of the standing order, medical necessity, duration, and frequency of the testing in the beneficiary's medical record.

1.5 Specimen Source

A tested laboratory specimen may be from any source unless the source is specified in the procedure code description.

1.6 Out Of State/Beyond Borderland Laboratories

Medicaid reimburses enrolled out of state laboratories who are beyond the borderland area only if the service meets the criteria outlined in Medicaid policy. Laboratories should refer to the Out of State/Beyond Borderland Providers subsection located within the General Information for Providers chapter of this manual for more information. Non-emergent lab services performed by an out of state/beyond borderland laboratory must be prior authorized unless Medicare and/or private insurance has paid a portion of the service and the laboratory is billing Medicaid only for the coinsurance and/or deductible amounts.

Managed Care Plans follow their own prior authorization criteria for out of network/out of state services. Laboratories participating in a Medicaid Health Plan (MHP) should contact the plan for prior authorization information.

1.7 Repeat Tests

Medicaid does not cover tests or services that are duplicated due to laboratory error.

SECTION 2 - BILLING INFORMATION

Refer to the Billing & Reimbursement chapters of this manual for additional information about billing.

2.1 DATE OF SERVICE

When billing Medicaid for services rendered, the date of service (DOS) indicated on the claim must be the date the specimen is collected. Laboratory tests performed on a stored specimen must use the date the specimen was obtained from storage as the specimen collection date.

2.2 MEDICAL NECESSITY

The beneficiary's medical record and claims (with applicable attachments when required) must contain documentation of the medical necessity of the laboratory service including, but not limited to, descriptions of the beneficiary's symptoms and other findings that led the practitioner to order the laboratory test(s). An explanation of the laboratory testing method or the results of the diagnostic tests, whether normal or abnormal, is not documentation of medical necessity. For approval of payment, the laboratory procedure(s) must be specific and appropriate to the beneficiary's documented condition and diagnosis.

2.3 CLINICAL LABORATORY IMPROVEMENT AMENDMENTS CERTIFICATION

All providers must have a Clinical Laboratory Improvement Amendments (CLIA) certification to perform laboratory testing on specimens. CLIA certification includes a certificate of waiver, certificate for provider-performed microscopy procedures, certificate of registration, certificate of compliance, or a certificate of accreditation. A CLIA certification is needed for each location where laboratory testing is performed unless one of the following exceptions applies:

- The laboratory is not at a fixed location.
- The laboratory is a not-for-profit or Federal, State, or local government laboratory engaged in limited public health testing.
- The laboratory is located within the same physical location or street address as a hospital. The lab must be in a contiguous building on the same campus as the hospital and must be under common direction.

To be eligible for Medicaid reimbursement, a clinical laboratory must be certified to perform the specialties or subspecialties of tests billed to Medicaid as of the date the tests are performed. A laboratory's CLIA number must be present on the claim and laboratory providers are limited to billing the lab services that they are CLIA certified to perform.

Procedure codes subject to CLIA certification change each year. Medicaid aligns with CMS' identification of laboratory services subject to CLIA waived and non-waived certification. When performing tests that use waived methodologies, laboratories must enter the QW modifier with the appropriate Current Procedural Terminology (CPT) code to denote the waived test when billing Medicaid for services rendered.

Questions regarding CLIA certification should be addressed to the state licensing agency. (Refer to the Directory Appendix for contact information.)

2.4 Procedure Codes

Laboratories should refer to the current edition of the CPT or Healthcare Common Procedure Coding System (HCPCS) manuals published by the American Medical Association (AMA) for the appropriate procedure code to use when billing Medicaid. The descriptor assigned to a code represents the definition of the item/service that can be billed using that code. The laboratory is also subject to any pathology and laboratory guidelines listed in the CPT/HCPCS manual that provide definitions and/or instructions for specific tests.

If no established procedure code adequately describes the item, use the appropriate Not Otherwise Classified (NOC) CPT/HCPCS procedure code. All laboratory NOC codes require prior authorization (PA).

For specifics regarding the CPT and HCPCS codes used to denote covered services, refer to the Additional Code/Coverage Resource Materials subsection of the General Information for Providers chapter or the Medicaid Code and Rate Reference tool on the MDHHS website for more information. (Refer to the Directory Appendix for website information.)

2.5 Component Billing

Most pathology procedures are billed together as a complete or global service, and a single charge is made for both professional and technical components. However, some pathology procedures are composed of professional and technical components that are billed separately by the laboratory facility and the practitioner. In these instances, the procedure code requires the use of a modifier to accurately identify the service component provided. Providers should not bill for component services when the entire procedure is performed.

Payment for the technical component to the laboratory includes personnel, materials, space, equipment, report of test results, and other items.

The professional component represents the professional services of a pathologist/hematologist. Medicaid covered professional components are limited to certain services as noted on the Practitioner and Medical Clinic Fee Schedule located on the MDHHS website. (Refer to the Directory Appendix for website information.) Payment for this component includes:

- Examination of the beneficiary, when indicated.
- Performance and supervision of the procedure.
- Reading, interpretation, and written report of the findings.
- Consultation with the ordering physician.

Refer to the Additional Code/Coverage Resource Materials subsection of the General Information for Providers chapter for additional information regarding coverage parameters.

When the laboratory performs services for hospital inpatients, only the pathologist/hematologist can bill the professional component (the pathologist's services) directly to Medicaid. The technical component is included in the reimbursement to the hospital for the inpatient services.

2.6 Other Insurance

If the beneficiary has another insurance plan (e.g., Medicare or commercial insurance) and the service is a covered benefit, the provider must follow the requirements of the other insurance plan(s) including, but not limited to, PA and standards of coverage. (Refer to the Coordination of Benefits chapter for more information.)

Medicaid reimburses laboratories for the coinsurance and deductible amounts subject to Medicaid's reimbursement limitations on all Medicare-approved claims even if Medicaid does not normally cover the service.

2.7 Billing for Services Performed by Reference Laboratories Under Arrangement with Enrolled Hospital Laboratories

Following Medicare guidelines and applicable state and federal laws in situations where an enrolled hospital laboratory must refer a specimen to another laboratory for testing, the hospital laboratory will be allowed to bill Medicaid for the arranged services provided by the reference laboratory under the following conditions:

- The reference laboratory holds the required CLIA certification and state licensure, if required, to perform the test;
- The enrolled hospital laboratory and the reference laboratory have a contractual agreement (as defined as "arrangement" in section 1861(w)(1) of the Social Security Act) to provide such services, with the referring hospital laboratory responsible for reimbursing the reference laboratory for the services; and
- If the service requires PA, the enrolled hospital laboratory must request and receive PA approval for the service to be performed by the reference laboratory. The PA number must be included on the claim.

The definitions of reference laboratory and referring laboratory may be found in the Glossary Appendix.

2.8 Billing For Laboratory Services Performed In A Hospital Clinic

Hospital owned or affiliated practices must bill for laboratory services performed in the office or clinic using the institutional claim format. Refer to the Hospital chapter for complete billing and reimbursement information.

2.9 Test Results

Reimbursement is made for tests performed using a method that yields quantitative results unless the nomenclature specifies a different method.

The mathematical calculation of two or more results to produce an index or ratio or any other result may not be billed as a separate independent test.

SECTION 3 - REIMBURSEMENT

Unless otherwise specified within Medicaid policy, Medicaid's reimbursement for laboratory services includes:

- collection, handling, and conveyance of the specimen(s);
- all supplies, reagents, equipment, and instrumentation used in the test's processing; and
- lab test results and analysis.

3.1 PRACTITIONER'S OFFICE OR INDEPENDENT CLINICAL LABORATORY

Reimbursement rates for laboratory services provided by a practitioner's office or independent clinical laboratory are established by MDHHS as a fee screen for each procedure. Medicaid uses the Medicare Clinical Laboratory Fee Schedule (MCLFS) prevailing fees as a guideline or reference in determining the maximum fee screens for individual laboratory procedures. Services are reimbursed at a maximum rate of 90% of the MCLFS. Minimally, the Medicaid Clinical Laboratory fee schedule is updated annually following the January release of the MCLFS.

A pathologist or hematologist, when billing separately, will be reimbursed for the professional component of pathology services. The professional component must be billed with the appropriate modifier and will be paid according to the rates established by the MDHHS Practitioner Fee Schedule.

3.2 OUTPATIENT HOSPITAL

Laboratory services provided by outpatient hospitals are reimbursed through the Medicaid Outpatient Prospective Payment System (OPPS). Laboratory tests provided in conjunction with other services are generally packaged as ancillary services and do not receive separate reimbursement unless otherwise indicated by the procedure code's OPPS payment status indicator and/or determined under OPPS claim processing rules. If the beneficiary is not considered a hospital patient, laboratory services provided by the hospital outreach laboratory are eligible for separate Medicaid reimbursement.

Generally, Medicaid follows Medicare's OPPS laboratory coverage and reimbursement policies whenever possible and appropriate. In instances where there are program differences, the differences will be reflected through the application of the MDHHS specific status indicator. Procedure codes associated with the identified laboratory services will appear on the MDHHS OPPS Wraparound Code List and reimbursement rates will appear on the Carrier Priced Laboratory Codes List. Both lists are available on the MDHHS website. (Refer to the Directory Appendix for website information.)

A beneficiary cannot be charged for any covered laboratory procedure, including those that are determined not to be medically necessary.

3.3 END STAGE RENAL DISEASE (ESRD) FACILITY

Reimbursement for routine laboratory services related to maintenance hemodialysis, peritoneal dialysis, and continuous cycling peritoneal dialysis (CCPD) dialysis are included in Medicaid's dialysis composite rate and may not be billed separately unless it is medically necessary to perform the services in excess of the frequencies indicated by Medicaid policy. This includes routine laboratory tests performed by either a

dialysis facility or by an outside laboratory. Providers should refer to the Dialysis (Hemodialysis and Peritoneal Dialysis) subsection of the Hospital chapter for laboratory tests included in the composite rate.

Laboratory services included in the composite rate should be billed to the dialysis facility when performed by an outside laboratory. The dialysis facility and the outside laboratory must coordinate billing to ensure duplicate payments do not occur. A freestanding dialysis center that performs its own laboratory tests and needs to bill for services outside of those included in the composite rate must enroll with Medicaid as an independent laboratory. Freestanding dialysis centers enrolled as independent laboratories are subject to the Out of State /Beyond Borderland Provider Medicaid policy. Provider should refer to the Out of State/Beyond Borderland Providers subsection located within the General Information for Providers chapter of this manual for more information.

SECTION 4 - SPECIAL COVERAGE

4.1 CHILDREN'S SPECIAL HEALTH CARE SERVICES COVERAGE

For beneficiaries with Children's Special Health Care Services (CSHCS) coverage only, CSHCS covers laboratory services related to the beneficiary's qualifying diagnosis and related conditions. Services should be ordered by the beneficiary's authorized CSHCS specialty provider and performed by a CSHCS approved laboratory to be eligible for reimbursement.

4.2 ANATOMIC PATHOLOGY

Cryopreservation (frozen cell storage and thawing) is a covered service for bone marrow transplants only.

4.3 ARSENIC TESTING

Arsenic testing is not covered when performed on hair and nail specimens.

4.4 CREATININE BLOOD TESTS

Serum creatinine laboratory tests are Medicaid covered. Tests should calculate and report the estimated Glomerular Filtration Rate (eGFR) for beneficiaries. The eGFR may be calculated based on a formula that combines the creatinine level with the beneficiary's age, gender, and other factors.

4.5 EVOCATIVE/SUPPRESSION TESTING

Medicaid does not cover these panel codes. Report the individual tests.

4.6 DRUG SCREENING/MONITORING

Drug monitoring is an important tool for a variety of reasons including, but not limited to, beneficiary compliance/adherence to a prescribed regimen, determination of substances prior to initiating pharmacologic treatment, and substance misuse or abuse. Medicaid covers presumptive and/or definitive drug testing when medically necessary. The beneficiary's medical record must include the testing frequency, rationale for the drugs/drug classes ordered, rationale for the type(s) of testing ordered (presumptive, definitive, or both), and the results. Laboratories performing validity testing on specimens utilized for drug testing should not separately bill for the validity testing.

4.7 NEWBORN LABORATORY SCREENING

Newborn laboratory screening (via heel stick) includes testing for rare genetic, metabolic, blood, or other disorders recommended by the Advisory Committee on Heritable Disorders in Newborns and Children and Michigan's Newborn Screening Quality Assurance Advisory Committee. Blood samples should be sent by the birthing hospital, center, or other healthcare facility to the MDHHS Bureau of Laboratories Newborn Screening Section for processing. If the birth occurs outside of these entities, then it is the responsibility of the attending provider to collect and send the sample to the MDHHS laboratory. In the event of an abnormal test result, the results shall be reported by the MDHHS laboratory to the newborn's physician or healthcare provider, parent or legal guardian, and the appropriate Newborn Screening (NBS) Program coordinating center or specialty referral center.

Newborn screening reimbursement is included in Medicaid's payment to the birthing hospital, birthing center, or other healthcare facility through the facility's Diagnosis Related Group (DRG) rate and is not separately reimbursable.

If a NBS disorder is suspected, follow-up diagnostic laboratory testing is a Medicaid covered benefit.

4.8 Organ or Disease Orientated Panels

Medicaid covers select AMA-approved organ-or disease-orientated panels. All tests within the panel must be medically necessary. When a complete panel is ordered and all the tests within the panel are performed on the same date of service, the laboratory must report a panel code. When some, but not all, the tests identified in a panel are performed, the laboratory should report the services as individual tests. If a group of tests overlaps two or more panels, the laboratory must report the panel that incorporates the greater number of tests to fulfil the code definition and report the remaining tests as individual tests.

4.9 Pap Smear

Pap smear screening is a covered service when provided in accordance with Medicaid's preventive services policy as outlined in the Preventive Services subsection of the Practitioner chapter. More frequent pap smears may be covered when medically necessary. If a suspect smear requires additional interpretation by a pathologist, this service is also covered. Coverage for obtaining the cervical smear is included as a part of the pelvic examination and is not eligible for separate reimbursement.

4.10 Pathology Clinical Consultation

Pathology clinical consultations are covered when billed by a hematologist/pathologist for the review of abnormal laboratory test results if:

- The abnormality relates to the beneficiary's medical condition and corresponding medical care.
- The referring provider orders the review and records the order in the beneficiary's medical record.
- Additional medical interpretative judgement is required.
- A detailed report is sent to the referring provider.

Consultations cannot be billed for routine quality control review. (Refer to the current CPT manual for the guidelines for the provision of this service.)

4.11 Pregnancy Related Laboratory Services

Medicaid covers routine pregnancy testing (serum or urine human chorionic gonadotropin [hCG] qualitative method) and medically necessary prenatal or pregnancy related laboratory services required to support the health of the fetus or pregnant beneficiary.

4.12 Specimen Collection

Specimen collection is process of obtaining tissue, blood, urine, stool, or other bodily fluids for laboratory analysis. Specimen collection is considered to be an integral part of the laboratory testing procedure and

is included in the reimbursement for the processing of the specimen. A separate specimen collection fee is allowed in special circumstances where the drawing, packaging, and mailing of a blood specimen are the only services provided. These situations are rare and include:

- A beneficiary is referred to a laboratory for the sole purpose of drawing, packaging, and mailing a blood sample to MDHHS for analysis (e.g., blood lead or human immunodeficiency virus (HIV) viral load). MDHHS provides specimen containers and mailing kits for the analysis. Requests for supplies and the samples for analysis should be sent to the MDHHS Bureau of Laboratories. (Refer to the Directory Appendix for contact information.)
- A beneficiary requires blood laboratory tests that are not performed in conjunction with other reimbursable services. Whenever possible, the beneficiary should be sent to the laboratory that is performing the test(s). If this is not practical (i.e., the laboratory is not a local facility) and the sole purpose of a visit is to draw, package, and mail the sample to a laboratory, the blood-handling fee may be billed by the practitioner. The blood-handling fee is not a benefit when any other service is reimbursable on the same date of service.

Procedure code 36415 (routine venipuncture for collection of specimen[s]) must be used when billing Medicaid for the drawing, packaging, and mailing of the blood sample. Only one collection fee for each beneficiary encounter, regardless of the number of specimens drawn, will be allowed. Blood specimen collection may only be billed when the laboratory is not owned, operated, or financially associated with the provider site in which the specimen was collected.

4.13 Urinalysis

The analysis of urine for the diagnosis and monitoring of illness and disease is covered by Medicaid.

If a single urine specimen is analyzed for the same chemical, element, compound, or substance by more than one method (i.e., automated, non-automated, qualitative, semi qualitative, non-culture bacteriuria screen), only one method may be reported.

4.14 Blood Count

A practitioner's order for a complete blood count (CBC) with white blood cell (WBC) differential includes a red blood cell count (RBC), WBC count; hemoglobin (Hgb); hematocrit (Hct); mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red cell distribution width (RDW), WBC differential, and a platelet count (PLT). If automated instrumentation yields additional test results, the additional tests are not separately reimbursable unless medically necessary and specifically ordered by a practitioner.

4.15 Microbiology Studies

Definitive culture procedure codes may not be billed in combination with other microbiology codes that duplicate the identification of a microbe.

Coverage and reimbursement for gram fluorescent/acid fast is included in the reimbursement for microbiology when performed on the same date of service (DOS) for the same beneficiary.

SECTION 5 – GENETIC AND MOLECULAR TESTING

5.1 GENERAL INFORMATION

A genetic test or molecular test as defined in §17001 of Public Act 368 of 1978 means the analysis of human deoxyribonucleic acid (DNA), ribonucleic acid (RNA), chromosomes, and those proteins and metabolites used to detect inheritable or somatic disease related genotypes or karyotypes. These specialized diagnostic laboratory tests may identify increased risks of health problems, help choose treatments, or assess patient responses to treatments.

Whenever possible, Michigan Medicaid follows Medicare guidelines. Medicare does not cover a genetic test for a clinically affected individual for purposes of medical research, family planning, disease risk assessment of other family members when the treatment and surveillance of the beneficiary will not be affected, or in any other circumstance that does not directly affect the diagnosis or treatment of the beneficiary.

Medicaid reimburses medically necessary genetic testing when one of the following apply:

- The test is necessary to establish a molecular diagnosis when a definitive diagnosis remains uncertain and a genetic diagnosis is suspected, and the results will directly impact the treatment or management of the disease.
- A definitive diagnosis has been made through conventional diagnostic testing and the test is necessary to guide treatment or management of the disease, including selection of specific medication and/or medication dose to ensure efficacy and safety.

And all of the following are met:

- The testing must be ordered by a licensed physician (MD or DO), PA, or APRN [including NPs, CNSs, and CNMs] who is an enrolled provider.
- The beneficiary has documented clinical features symptomatic of a condition or disease or is at risk of inheriting the disease based upon personal history, family history, documentation of a genetic mutation and/or ethnic background.
- A physical examination, history, pedigree analysis, and completion of conventional diagnostic testing must be completed prior to testing.
- If applicable, the testing method is a Food and Drug Administration (FDA) approved method for the identification of a specific genetically linked inheritable disease as evidenced by the following measures:
  - The genotypes to be detected by a genetic test must be shown, by scientifically valid methods, to be associated with the occurrence of the disease;
  - The analytical validity, clinical validity, and clinical utility of the test must be established;
  - The observations must be independently replicated and subject to peer review; and
  - The clinical testing laboratory must be an enrolled provider who is properly certified by CLIA.

The clinical utility of all requested genes and gene variants must be established and documented in the beneficiary's medical record regardless of where the test(s) is performed.

Testing is allowed once during the beneficiary's lifetime per disease for diagnostic purposes. If medically necessary, and on a case-by-case basis, PA may be requested to allow for exceptions to this restriction.

Providers must follow state law (Public Act 368 of 1978, Section 333.17020 Genetic test; informed consent) regarding informed consent for predictive genetic testing. This includes any statutory requirements for pre- or post-testing genetic counseling. There must be made available, upon request, documentation of informed consent provided before testing. This documentation must include the limitations of the test, possible outcomes, and methods for communicating and maintaining confidentiality of results.

Genetic testing is not considered a covered benefit for:

- Criteria other than those outlined above.
- Testing to confirm a diagnosis or disorder that can be diagnosed by conventional diagnostic methods.
- Testing for conditions or purposes where the test results would not directly influence the management or treatment of the disease or condition (e.g., a disease without known treatment).
- Testing for informational purposes or management of a beneficiary's family member.
- Confirmatory testing for validation of laboratory results.
- Screening for investigational or research purposes.
- Minors under the age of 18 for adult-onset conditions that have no preventative or therapeutic treatments.
- Testing that has not been performed in a CLIA-certified laboratory.
- Testing for the sole purpose of family planning counseling and infertility services.
- Testing attributable to standing laboratory orders. Testing must be ordered for a specific beneficiary and the medical record and/or order must clearly document the medical necessity of the specific diagnostic test to be performed

5.2 Authorization Requirements

Authorization is required for most genetic and molecular laboratory tests. (Refer to the Community Health Automated Medicaid Processing System (CHAMPS) Code Rate and Reference tool for authorization necessity.) Authorization requests must be submitted to MDHHS within 30 days of the DOS using the Genetic and Molecular Laboratory Test Authorization Request form (MSA-2081). Specimen processing should not be completed until after the authorization request has been approved. (Refer to the Forms Appendix for a copy of the form, including form completion instructions.)

Authorization requests require medical documentation submitted by the beneficiary's Medicaid enrolled treating/ordering provider (i.e., MD, DO, PA, NP). Medical necessity letters or test request forms submitted by the performing laboratory and signed by the treating/ordering provider will not be accepted as a substitute for clinical documentation from the medical record or completion of MSA-2081. The completed MSA-2081 and supporting clinical documentation must document the following:

- Indication for the test. Indications should be beneficiary specific and clinical in nature.
- Clinical notes that clearly detail the beneficiary's related signs and symptoms.
- Family history relevant to the beneficiary's condition and test being requested. A family pedigree analysis must be made available upon request.
- Other related testing or clinical findings of the beneficiary or family member.
- Clinical documentation supporting that the test results will be used to significantly alter the management or treatment of the disease. This definitive treatment or action plan should be specific to the beneficiary and completed by the provider who will manage the beneficiary using the test results.
- The name and NPI number of the laboratory performing the test.
- The name, specialty, and NPI number of the provider ordering the test.

5.2.A. AUTHORIZATION SUBMISSION

The MSA-2081 must be:

- Typed – All information must be clearly typed in the designated boxes; and
- Thorough – Complete information, including the appropriate CPT/HCPCS diagnostic testing procedure codes with applicable modifiers, must be provided on the form. Form MSA-2081 and all documentation must include the beneficiary's name and other identifying information (i.e., beneficiary identification [ID number] or date of birth [DOB]).

Authorization requests must be submitted electronically to the MDHHS Program Review Division via Direct Data Entry (DDE) utilizing CHAMPS whenever possible. Providers should enter the request directly into the CHAMPS Prior Authorization Request List page. All authorization requests must include form MSA-2081 and supporting clinical documentation. Documents should be electronically uploaded within the Additional Documents section of the CHAMPS authorization request. If the supporting documentation is unable to be uploaded, items may be faxed separately to the MDHHS Program Review Division using the bar-coded fax cover sheet generated by CHAMPS when the fax option is selected. A notation that documentation has been separately faxed should be made in the Procedure Code Comment field of the electronic authorization request. If the correct bar-coded fax cover sheet is not used, faxed documentation may not be associated to the authorization request.

Providers unable to submit authorization requests electronically may submit authorization requests via fax or mail to the MDHHS Program Review Division. (Refer to the Directory Appendix for contact information.) Providers must include only one authorization request per fax.

Providers may check the status of an authorization request on the CHAMPS Prior Authorization Request List page. An electronic copy of the determination letter may also be viewed within CHAMPS. A copy of the letter will be mailed to the provider and beneficiary. The letter must be retained in the beneficiary's medical record.

5.2.B. Beneficiary Eligibility

Approval of a laboratory test listed on form MSA-2081 confirms that the service is authorized for the beneficiary. Approval does not guarantee beneficiary eligibility or reimbursement. To ensure payment, the provider must verify the beneficiary's eligibility prior to processing the laboratory specimen

5.2.C. Billing Authorized Services

After an authorization is issued, the information (e.g., authorization number, procedure code, modifier, and quantity) that was approved must match the information submitted on the claim form.

5.2.D. Reimbursement

Most laboratory services have established fee screens that are published in the MDHHS Laboratory Fee Schedule. For NOC procedure codes and procedure codes without established fee screens, the approved reimbursement amount is indicated on the authorized MSA-2081.

5.2.E. Retroactive Authorization

Laboratory authorizations must be requested within 30 days of the DOS unless the beneficiary was not eligible on the DOS and a subsequent eligibility determination was made retroactive to the DOS. If the MDHHS eligibility file does not show that retroactive eligibility was approved, requests for authorization received more than 30 days after the DOS will be denied.

5.3 Genetic Counseling

Medicaid covers medically necessary genetic counseling services as defined in section 333.17001 (Act 368 of 1978) when ordered and performed by a Medicaid-enrolled physician, PA, or APRN (NPs, CNSs, and CNMs). Genetic counseling may also be provided by a Medicaid-enrolled licensed Genetic Counselor. Genetic Counselors should refer to the Practitioner chapter for additional information.

Counseling is covered when provided in consideration of, or in conjunction with, genetic testing, or provided in relation to a genetic or congenital condition. Services are considered medically necessary when there is an expectation that a genetically inherited or acquired condition exists, and the beneficiary displays clinical features or is at risk of inheriting the disease/condition based upon factors including, but not limited to, personal history, family history, documentation of a genetic mutation, and/or ethnic background.

5.4 Medicaid Health Plans

The genetic and molecular testing standards of coverage, PA, and documentation requirements outlined within this chapter apply to beneficiaries served by Fee-for-Service (FFS) Medicaid. For beneficiaries enrolled in a Medicaid Health Plan (MHP), the provider must check with the beneficiary's plan for coverage and PA requirements.

5.5 Multi-Gene Panels

Medicaid defines multi-gene panels as any assay that simultaneously tests for more than one gene associated with a condition or symptom. The term "gene", when used throughout this section, will be used to indicate a gene, region of a gene, and/or variant(s) of a gene.

Genes assayed on the same DOS will be considered assayed in parallel if the result of one assay does not affect the decision to complete the assay on another gene, and the genes are being tested for the same indication. If a laboratory assays multiple genes simultaneously in parallel, then those genes will be considered part of the same panel. As a panel constitutes a single procedural service, one procedure code must be submitted for the panel. The laboratory should not report multiple individual procedure codes describing the gene component test results.

If a procedure code is available for the multi-gene panel test, this procedure code should be utilized. If no procedure code accurately describes the panel performed, an unlisted molecular pathology or unlisted molecular multi-analyte assay with algorithmic analysis procedure code (as applicable) may be used. When an unlisted procedure code is reported, providers should include the name of the panel test in box 21 of form MSA-2081. The test name should also be reported in the Procedure Code Comment field in the MDHHS CHAMPS authorization form.

Genes assayed on the same DOS will be considered assayed serially when the results of one or more gene analyses determines whether additional analyses are reasonable and necessary. When genes are serially assayed, the laboratory should submit claims with the genes reported individually.

5.6 Rapid Whole Genome Sequencing

Medicaid covers medically necessary rapid whole genome sequencing (rWGS) testing for the evaluation of critically ill infants admitted to an inpatient intensive care unit with a complex illness of unknown etiology. rWGS is medically necessary when all the following apply:

- The beneficiary is one year of age or less;
- The beneficiary's signs or symptoms suggest a rare genetic condition that cannot be diagnosed by a standard clinical work-up;
- The beneficiary's signs and symptoms suggest a broad, differential diagnosis that could require multiple genetic tests if rWGS was not performed;
- Timely identification of a molecular diagnosis is necessary in order to guide clinical decision making, and the rWGS results will guide the treatment and/or management of the beneficiary's condition; and
- At least one of the following clinical criteria apply to the beneficiary:
  - Multiple congenital anomalies
  - Specific malformations highly suggestive of a genetic etiology
  - An abnormal laboratory test suggests the presence of a genetic disease or complex metabolic phenotype (e.g., abnormal newborn screen, hyperammonemia, or lactic acidosis not due to poor perfusion)
  - Refractory or severe hypoglycemia

- Abnormal response to therapy related to an underlying medical condition affecting vital organs or bodily systems
- Severe hypotonia
- Refractory seizures
- A high-risk stratification on evaluation for a Brief Resolved Unexplained Event (BRUE) with any of the following features:
  - Recurrent events without respiratory infection
  - Recurrent witnessed seizure-like events
  - Required cardiopulmonary resuscitation (CPR)
  - Abnormal chemistry levels (e.g., electrolytes, bicarbonate, lactic acid, venous blood gas, glucose) suggestive of inborn error of metabolism
  - Abnormal cardiac diagnostic testing results suggestive of possible channelopathies, arrhythmias, cardiomyopathies, myocarditis, or structural heart disease
  - Family genetic history related to beneficiary's condition

rWGS is not covered when one of the following reasons explains the beneficiary's admission:

- An infection or sepsis with normal response to therapy
- Confirmed prenatal/postnatal genetic diagnosis consistent with the beneficiary's condition
- Hypoxic-Ischemic Encephalopathy (HIE) with a clear precipitating event
- Isolated prematurity
- Isolated Transient Tachypnea of the Newborn (TTN)
- Isolated unconjugated hyperbilirubinemia
- Nonviable neonate
- Trauma
- Meconium aspiration

5.6.A. Provider Evaluation

Prior to ordering rWGS, the beneficiary must be evaluated by a medical geneticist or other physician sub-specialist with expertise in the conditions and/or genetic disorder for which testing is being considered. The consultation must be documented in the beneficiary's medical record and if performed via telemedicine, should follow all the requirements specified in Medicaid's telemedicine policy.

5.6.B. Test Results

Generally, a preliminary test report from the performing laboratory should be provided to the beneficiary's ordering physician in less than seven days and a final report in less than 14 days. Hospitals should only utilize laboratories whose average expected turnaround time for rWGS processing meets these established time frames.

5.6.C. Prior Authorization

rWGS requires MDHHS approval. Providers should refer to the Authorization Requirements and Documentation subsection in this chapter for submission instructions.

5.6.D. Billing and Reimbursement

Reimbursement for rWGS testing is available to Medicaid enrolled hospitals performing rWGS (directly or through a reference laboratory arrangement) when the test meets Medicaid's coverage guidelines and authorization is obtained. Costs associated with inpatient rWGS testing are excluded from the DRG payment and reimbursement will be made in accordance with the Medicaid laboratory fee screens.

For MHP enrolled beneficiaries, rWGS testing services provided in the inpatient hospital setting prior to discharge are carved-out of the MHPs contract. Such services will be reimbursed by FFS per Medicaid policy.

SECTION 6 – NONCOVERED SERVICES

Noncovered laboratory services and items include, but are not limited to, the following:

- Laboratory testing not reasonable or medically necessary for the diagnosis or management of the beneficiary's specific condition.
- Services not ordered by the beneficiary's treating provider.
- Laboratory services determined to be not medically necessary by a beneficiary's' eligible other insurance benefits (i.e., Medicare).
- Laboratory services for the treatment of infertility including embryo/sperm collection and banking.
- Repeat tests required because of technical or professional errors in performance of original test or interpretation of test results.
- Any laboratory service the laboratory is not CLIA certified to provide.
- "Profiles", "batteries" or "panels" of tests that include tests not necessary for the diagnosis or treatment of the beneficiary's specific condition.