MEDICAID POLICY INFORMATION SHEET

Policy Analyst: Adriena Krul-Hall

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Initial ☐ Public Comment ☒ Final ☐

Brief description of policy:

This bulletin updates and clarifies the coverage parameters for medically necessary genetic and molecular testing. This policy also updates Medicaid coverage of noninvasive prenatal testing (NIPT) for common aneuploidies involving chromosomes 21, 18, and 13 and provides information on a Fee-For-Service (FFS) Medicaid out-of-state prior authorization (PA) waiver for laboratories performing genetic and molecular testing services.

Reason for policy (problem being addressed):

Medicaid's current genetic and molecular testing policy does not readily permit coverage of screening testing allowed under the program. Additionally, NIPT has become standard for aneuploidy screening regardless of the beneficiary's risk level. Finally, waiving the out-of-state PA requirements for genetic/molecular laboratories will allow FFS Medicaid to reduce administrative barriers for specialized testing routinely sent outside of Michigan for processing.

Budget implication:

☐ budget neutral
☒ will cost MDHHS $ FY 23 (May-Sept) - $572,500 Gross ($412,200 Federal/$160,300 State). FY 24 – $1.374 Million Gross ($961,800 Federal/$412,200 State), and is not 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?

Yes, Provider Enrollment, Office of Medical Affairs, and Program Review Division.

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: 2257-Lab	**Date:** February 8, 2023

Comments Due: March 15, 2023
Proposed Effective Date: May 1, 2023
Direct Comments To: Adriena Krul-Hall
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Policy Subject: Updates to Genetic and Molecular Testing Standards of Coverage; Updates to Medicaid Coverage of Noninvasive Prenatal Screening; and Waiver of Out-of-State Provider Prior Authorization Requirement for Genetic Testing Laboratories

Affected Programs: Medicaid, Healthy Michigan Plan, MIChild, Children's Special Health Care Services, Maternity Outpatient Medical Services (MOMS)

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

Summary: This bulletin updates and clarifies the coverage parameters for medically necessary genetic and molecular testing. This policy also updates Medicaid coverage of noninvasive prenatal testing (NIPT) for common aneuploidies involving chromosomes 21, 18, and 13 and provides information on a Medicaid out-of-state prior authorization (PA) waiver for laboratories performing genetic and molecular testing services.

Purpose: To update Medicaid's current genetic and molecular testing policy to reflect coverage of screening testing allowed under the program and align NIPT coverage with prenatal aneuploidy screening recommendations. The policy will also allow Medicaid to reduce administrative barriers for specialized testing routinely sent outside of Michigan for processing.

Cost Implications: FY 23 (May-Sept) - $572,500 Gross ($412,200 Federal/$160,300 State). FY 24 – $1.374 Million Gross ($961,800 Federal/$412,200 State)

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 and Physical Health and Aging Services Administration

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

Issued: April 1, 2023 (Proposed)

Subject: Updates to Genetic and Molecular Testing Standards of Coverage; Updates to Medicaid Coverage of Noninvasive Prenatal Testing; and Waiver of Out-of-State Provider Prior Authorization Requirement for Genetic Testing Laboratories

Effective: May 1, 2023 (Proposed)

Programs Affected: Medicaid, Healthy Michigan Plan, MIChild, Children's Special Health Care Services, Maternity Outpatient Medical Services (MOMS)

The purpose of this bulletin is to update and clarify the coverage parameters for medically necessary genetic and molecular testing. This bulletin also updates Medicaid coverage of noninvasive prenatal testing (NIPT) for common aneuploidies involving chromosomes 21, 18, and 13 and provides information on an out-of-state or beyond borderland area prior authorization (PA) waiver for laboratories performing genetic and molecular testing services. The information in this bulletin is effective for dates of service on and after May 1, 2023.

I. Updates to Genetic and Molecular Testing Policy

A. Standards of Coverage

Medicaid covers genetic and molecular tests when clinically indicated by one or more of the following:

- The test is necessary to confirm a suspected genetic disease/condition when a definitive diagnosis remains uncertain, and the results will directly impact the beneficiary's treatment or management.
- The test will guide treatment and management in a beneficiary already diagnosed with a disease/condition by one or more of the following:
  - Predicting progression, aggressiveness, or recurrence.
  - Selecting specific medications, treatments, and interventions.
  - The test will predict a risk of a genetic disease/condition or is necessary to detect an undiagnosed health condition in an asymptomatic beneficiary and the results will directly impact the beneficiary's treatment or management. Coverage of these screening tests is limited to tests recommended as Grade

A or B by the United States Preventive Services Task Force (USPSTF) or tests specially identified in Medicaid policy (e.g. screening for fetal trisomy 13, 18, or 21 using NIPT).

To be eligible for Medicaid reimbursement, the following additional requirements apply:

- The test must be ordered by a Medicaid-enrolled, licensed physician (MD or DO), physician assistant, or advanced practice registered nurse (e.g. Certified Nurse Practitioner [NP], Certified Clinical Nurse Specialist [CNS], and Certified Nurse-Midwife [CNM]), acting within their professional scope of practice.
- The beneficiary has one or more of the following:
  - Documented clinical features symptomatic of a disease/condition.
  - A 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.
  - Other disease/condition-specific criteria that places them at risk.
- Completion of a physical examination, medical history, family history/pedigree analysis, and conventional diagnostic testing (when appropriate and applicable), prior to testing.

B. Non-Covered Services

Genetic and molecular testing is **not** a covered service for:

- Criteria other than those outlined above.
- Establishing a diagnosis or condition that can be diagnosed by conventional diagnostic methods unless conventional testing is not required by Medicaid, or the genetic test is identified as Grade A or B recommendation by the USPSTF.
- Confirming a diagnosis or condition that was previously diagnosed by another testing method (e.g. conventional testing).
- When the need for the test is not clinically indicated for the beneficiary's condition.
- Purposes where the test results would not directly influence the management or treatment of the disease or condition.
- Informational purposes or management of a beneficiary's family member.
- Confirmatory testing performed for the validation of laboratory results.
- Screening or carrier testing for the sole purpose of family planning counseling and/or infertility services.
- Screening for medical research purposes.
- Minors under the age of 18 for adult-onset conditions that have no preventative or therapeutic treatments.
- Testing performed in a non-Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory.

C. Test Requirements

A Medicaid-covered genetic or molecular test must:

- Utilize a laboratory technology that is a U.S. Food and Drug Administration (FDA)-approved method for the identification of the genetically linked disease/condition.
- Be performed at a Medicaid-enrolled laboratory that is properly certified by CLIA to perform the test.
- Include detected genes, variants, or biomarkers that are shown, by sufficient evidence and scientifically valid methods, to be associated with the risk of, predisposition to, or occurrence of the disease.
- Have established analytical validity, clinical validity, and clinical utility as evidenced by the following:
  - Clinical performance supported by scientific evidence, peer-reviewed medical literature, definitive or well-established evidence-based guidelines.
  - Test results that can be independently replicated and are attainable outside of investigational settings when used under the usual conditions of medical practice.
  - Test results that provide as much health benefit as established alternatives.
  - Test results that reduce the need for further diagnostic testing or treatment, allow for less intensive treatment due to earlier detection, or help avoid ineffective interventions.

II. Updates to Noninvasive Prenatal Testing Coverage

A. Standards of Coverage

Medicaid covers medically necessary NIPT analyzing cell-free fetal DNA in maternal serum when used to screen for fetal trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), and trisomy 13 (Patau syndrome). NIPT is a screening test and a definitive prenatal diagnosis of one of these trisomies requires confirmation by invasive diagnostic testing.

Effective for services performed on or after May 1, 2023, Medicaid will extend NIPT coverage to all pregnant beneficiaries regardless of the beneficiary's age or risk factors when performed at or after 10 weeks of gestation. Medicaid will cover testing once per pregnancy. If medically necessary, and on a case-by-case basis, PA may be requested to allow for repeat testing.

The use of NIPT for fetal conditions other than those specified above is not covered. Parallel or simultaneously testing with multiple screening tests for aneuploidy will not be covered.

Medicaid recommends beneficiaries wishing to undergo NIPT screening receive pre- and post-test genetic counseling from a certified genetic counselor or a qualified healthcare professional.

B. PA

NIPT screening performed on or after May 1, 2023, will no longer require PA when performed by a Medicaid-enrolled laboratory.

III. Out-of-State Laboratories Performing Genetic and Molecular Testing

Medicaid covers non-emergent laboratory services provided by an out-of-state or beyond borderland area laboratory when:

- Medicare and/or private insurance has paid a portion of the service and the provider is billing for the coinsurance and/or deductible amount; or
- The service is not readily available within the state and the service has received PA by Michigan Department of Health and Human Services (MDHHS).

Due to the specialty nature of genetic and molecular services, testing may not be readily available through an in-state laboratory. As a result, laboratory specimens are routinely sent to facilities outside of Michigan for processing. In consultation with the MDHHS Office of Medical Affairs, MDHHS has concluded there to be an ongoing medical need for out-of-state laboratories to provide genetic and molecular testing for Medicaid beneficiaries. Therefore, effective for services rendered on and after May 1, 2023, Fee-for-Service (FFS) Medicaid will waive the out-of-state PA requirement for commercial laboratories performing genetic or molecular testing services. Services will continue to be subject to other clinical PA requirements that would apply if the provider were located in-state. Providers should refer to the Community Health Automated Medicaid Processing System (CHAMPS) Code Rate and Reference tool for service specific in-state authorization requirements.

Commercial laboratories performing genetic or molecular testing will be identified with a Clinical Laboratory Certified-Genetic Testing specialty designation within their CHAMPS provider enrollment record. Prior to May 1, 2023, MDHHS will automatically assign this new specialty to all laboratories with an active CHAMPS enrollment record who have submitted at least one FFS claim with a genetic/molecular service reported in the last two calendar years. Laboratories can also select the Clinical Laboratory Certified-Genetic Testing specialty when applying for Medicaid enrollment or when revalidating or updating their CHAMPS enrollment. Any laboratory selecting the new specialty with a primary service address located outside of Michigan or beyond the borderland area will be reviewed for qualification of an out-of-state PA requirement waiver. Commercial laboratories found to be performing genetic or molecular testing will be determined eligible.

Laboratory facilities that do not perform genetic or molecular testing should continue to select the Clinical Laboratory Certified specialty designation within their CHAMPS enrollment.

IV. FFS Medicaid PA Reminder

Providers are reminded that PA is required for most covered genetic and molecular tests regardless of where the laboratory is located (e.g., in-state or out-of-state). Providers should refer to the CHAMPS Code Rate and Reference tool for PA necessity. PA requests for FFS Medicaid beneficiaries must be submitted electronically via the direct data entry (DDE) application within CHAMPS and must include the Genetic and Molecular Laboratory Test Authorization Request form (MSA-2081). Specimen processing should not be completed until after the PA request has been approved by MDHHS. (Refer to the Laboratory chapter of the MDHHS Medicaid Provider Manual for complete submission instructions.)

After PA is issued, the information (e.g., authorization number, date of service, procedure code, modifier, and quantity) that was reported on the MSA-2081 must match the information submitted on the claim form. In addition, providers must report the authorization approval number on the claim. Failure to do so may result in a claim denial.

V. Medicaid Health Plans/Integrated Care Organizations

Medicaid Health Plans (MHPs) and Integrated Care Organizations (ICOs) must provide the full range of covered services described in this policy at a minimum and may choose to provide services over and above those specified. MHPs and ICOs are allowed to develop PA requirements and utilization management and review criteria that differ from FFS Medicaid requirements. MHPs/ICOs also follow their own PA criteria for out-of-network and/or out-of-state services. For beneficiaries enrolled in an MHP or ICO, the provider must check with the MHP/ICO for utilization review and PA requirements.