MDHHS Michigan Department of Health & Human Services

Medical Services Administration

BULLETIN MSA

Bulletin Number: MSA 21-33

Distribution: Hospitals, Laboratories, Medicaid Health Plans

Issued: August 17, 2021

Subject: Coverage of Rapid Whole Genome Sequencing (rWGS) Testing

Effective: As Indicated

Programs Affected: Medicaid, Healthy Michigan Plan, MIChild, Children's Special Health Care Services (CSHCS)

Note: Implementation of this policy is contingent upon approval of a State Plan Amendment (SPA) by the Centers for Medicare & Medicaid Services (CMS).

This bulletin establishes Medicaid coverage of Rapid Whole Genome Sequencing (rWGS) testing and provides a hospital reimbursement separate from the Diagnosis Related Group (DRG) payment. Effective for dates of service on or after September 1, 2021, separate reimbursement will be available for rWGS when clinical and authorization criteria are met. These changes are in response to Michigan Department of Health and Human Services (MDHHS) Fiscal Year budget appropriations in Public Act 166 of 2020, Section 1907, which provides rWGS for critically ill infants who meet established criteria. rWGS aims to assist clinicians with rapidly determining a diagnosis and limiting the number of unnecessary procedures performed on beneficiaries.

rWGS Coverage

The Medicaid program covers medically necessary rWGS for the evaluation of critically ill infants up to one year of age admitted to an inpatient intensive care unit including, but not limited to, a neonatal/pediatric intensive care unit (NICU/PICU), with a complex illness of unknown etiology.

rWGS is medically necessary when **all** the following apply:

- 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, or
  - 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, or
- Family genetic history related to beneficiary's condition.

Non-Covered rWGS

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 neonates,
- Trauma, or
- Meconium aspiration.

Provider Requirements

rWGS must be ordered by the beneficiary's treating physician. Prior to ordering rWGS, the beneficiary must be evaluated by a medical geneticist or other physician sub-specialist including, but not limited to, a neonatologist or pediatric Intensivist 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.

Pre- and post-test genetic counseling by an appropriate provider is also recommended.

Test Results

The purpose of rWGS is to identify a molecular diagnosis in a timely manner to directly support medical or surgical management and outcomes. In general, 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 utilize laboratories whose average expected turnaround time for rWGS processing meets these established time frames.

Reference Laboratories

In the instance the hospital refers the beneficiary's specimen to a reference laboratory for rWGS testing, the hospital is required to bill Medicaid for rWGS services provided by the reference laboratory. The reference laboratory must hold the required Clinical Laboratory Improvement Amendments (CLIA) certification required to perform the test. The hospital and the reference laboratory must also have an agreement (as defined as "arrangement" in section 1861(w)(1) of the Social Security Act) to provide such services. The referring hospital is responsible for reimbursing the reference laboratory for the services.

Authorization

Authorization of rWGS is required for separate reimbursement. Authorization requests must be submitted to MDHHS within 30 days of the date of service using the Genetic and Molecular Laboratory Test Authorization Request form (MSA-2081), which can be accessed on the MDHHS website at www.michigan.gov/medicaidproviders >> Policy, Letters & Forms >> Forms. Supporting clinical documentation must accompany the MSA-2081 and should clearly detail the medical necessity of the rWGS as defined in this policy. Providers should refer to the Authorization Requirements and Documentation subsection in the Laboratory Chapter of the MDHHS Medicaid Provider Manual for complete submission instructions. rWGS authorization requests received more than 30 days after the date of service or requests not approved by MDHHS will not be eligible for separate Medicaid reimbursement.

Hospitals must report the authorization number in the applicable form locator or loop for the claim to be paid. The information (e.g., authorization number, procedure code, modifier, and quantity) that was approved on the authorization should match the information on the claim form.

Billing and Reimbursement

Effective for dates of service on or after September 1, 2021, MDHHS will establish a separate payment methodology to reimburse hospitals for costs associated with rWGS testing when the test is provided in an inpatient hospital setting prior to discharge, clinical criteria are met, and MDHHS authorization is obtained.

To receive reimbursement for rWGS, the facility will be required to submit a separate invoice using the 837P or CMS-1500 Professional claim format. The hospital's National Provider Identifier (NPI) must be reported as the billing provider with place of service 21 (Inpatient Hospital) reported in the service location field/loop. The beneficiary's inpatient hospital

attending provider should be entered in the rendering provider form locator or loop, and the rWGS ordering provider should be reported in the ordering/referring provider locator or loop. If the applicable attending and ordering/referring provider information is not reported on the claim, or if these providers are not enrolled in the Michigan Medicaid program, the claim cannot be paid.

When billing for rWGS, the provider must use the following Current Procedural Terminology (CPT) procedure codes:

81425 - Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis

81426 - Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (e.g., parents, siblings) (List separately in addition to code for primary procedure.)

0094U - Genome (e.g., unexplained constitutional or heritable disorder or syndrome); rapid sequence analysis Rady Children's Institute for Genomic Medicine (RCIGM) laboratories)

Payment for rWGS will be made in accordance with the Medicaid fee schedule in effect on the date-of-service for the procedure code(s) billed. Laboratory fee schedules are available on the MDHHS website at www.michigan.gov/medicaidproviders >> Billing & Reimbursement >> Provider Specific Information >> Laboratory.

Medicaid Health Plan (MHP) Carve Out

MHPs are not responsible for the additional rWGS payment. MDHHS will reimburse hospitals separately for rWGS for both Fee-For-Service (FFS) and MHP beneficiaries. Hospitals must request rWGS authorization and submit claims directly to the Community Health Automated Medicaid Processing System (CHAMPS) for both FFS and MHP beneficiaries. This policy does not change existing MHP payment liability.

Manual Maintenance

Retain this bulletin until the information is incorporated into the MDHHS Medicaid Provider Manual.

Questions

Any questions regarding this bulletin should be directed to Provider Inquiry, Department of Health and Human Services, P.O. Box 30731, Lansing, Michigan 48909-8231, or e-mailed to ProviderSupport@michigan.gov. When you submit an e-mail, be sure to include your name, affiliation, NPI number, and phone number so you may be contacted if necessary. Typical Providers may phone toll-free 1-800-292-2550. Atypical Providers may phone toll-free 1-800-979-4662.

An electronic version of this document is available at www.michigan.gov/medicaidproviders >> Policy, Letters & Forms.

Approved

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