RICK SNYDER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
Christopher Seppanen
Executive Director

SHELLY EDGERTON
DIRECTOR

[redacted]

Date Mailed: March 7, 2017
MAHS Docket No.: 17-000167
Agency No.: [redacted]
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Steven Kibit

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and 42 CFR 431.200 *et seq.,* and upon the Petitioner's request for a hearing.

After due notice, a telephone hearing was held on February 28, 2017. Petitioner appeared and testified on her own behalf through the use of an interpreter. [redacted], Appeals Review Officer, represented the Respondent Department of Health and Human Services (DHHS or Department). [redacted] Medical Consultant, also testified as a witness for the Department.

ISSUE

Did the Department properly deny Petitioner's prior authorization request for genetic testing?

FINDINGS OF FACT

The Administrative Law Judge, based upon the competent, material and substantial evidence on the whole record, finds as material fact:

1. Petitioner is a thirty-five-year-old woman served by Fee-For-Service Medicaid. (Exhibit A, pages 11-12).

2. On December 15, 2016, the Department received a prior authorization request submitted on Petitioner's behalf for genetic testing. (Exhibit A, pages 13-19).

3. The anticipated dates of services were identified as December 15, 2016 through March 15, 2017. (Exhibit A, page 13).

4. The supporting documentation was very difficult to read, but also appeared to state that Petitioner was pregnant; had an abnormal prenatal exam; and that a whole-genome chromosomal microarray (CMA) for product of conception (POC) was being requested. (Exhibit A, pages 14-15).

5. On December 20, 2016, the Department sent Petitioner written notice that her prior authorization request was denied. (Exhibit A, pages 9-10).

6. Specifically, the notice provided that the request was denied because: "There is insufficient or illegible information. It is not clear why this testing is medically necessary or how it will directly impact treatment decisions. If necessary please resubmit with current H & P and genetic counseling report detailing such information." (Exhibit A, page 9).

7. That same day, the Department also sent a similar notice of denial to the provider who submitted the prior authorization request on Petitioner's behalf. (Exhibit A, page 20).

8. On January 13, 2017, the Michigan Administrative Hearing System (MAHS) received the request for hearing filed in this matter. (Exhibit A, pages 5-8).

CONCLUSIONS OF LAW

The Medical Assistance Program is established pursuant to Title XIX of the Social Security Act and is implemented by Title 42 of the Code of Federal Regulations (CFR). It is administered in accordance with state statutes, the Social Welfare Act, the Administrative Code, and the State Plan under Title XIX of the Social Security Act Medical Assistance Program.

Medicaid covered benefits are addressed for the practitioners and beneficiaries in the Medicaid Provider Manual (MPM). Regarding the specific request in this case, the applicable version of the MPM states:

5.5 GENETIC AND MOLECULAR TESTING

> The following standards of coverage and prior authorization and documentation requirements apply to beneficiaries served by Fee-for-Service Medicaid. For beneficiaries enrolled in a Medicaid Health Plan, the provider must check with the beneficiary's plan for coverage and prior authorization requirements.

5.5.A. STANDARDS OF COVERAGE

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 or 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.

Genetic testing is considered a covered benefit when it is medically necessary to establish a molecular diagnosis and treatment of a genetic disease and all of the following are met:

- The testing must be ordered by a physician (MD or DO) 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.

- Following history, physical examination, pedigree analysis, and completion of conventional diagnostic testing, a definitive diagnosis remains uncertain and a genetic diagnosis is suspected.

- The test results will be used to significantly alter the management or treatment of the disease.

- If applicable, the testing method is an 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 and clinical validity 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.

Testing is allowed once during the beneficiary's lifetime per disease for diagnostic purposes. If medically necessary, and on a case-by-case basis, prior authorization 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 pre-testing 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.

- The sole purpose of family planning counseling and infertility services.

5.5.B. PRIOR AUTHORIZATION REQUIREMENTS AND DOCUMENTATION

For genetic testing that requires prior authorization, the following documentation must be submitted prior to the testing being performed:

- Indication for the test.

- Clinical notes that clearly detail the beneficiary's related signs and symptoms, including relevant family history. A family pedigree analysis must be made available upon request.

- Other related testing or clinical findings of the beneficiary or family member.

- Documentation supporting that the test results will be used to significantly alter the management or treatment of the disease.

- The name and NPI number of the laboratory performing the test.

MPM, October 1, 2016 version
Laboratory Chapter, pages 9-11

Here, the Department denied Petitioner's request for genetic testing pursuant to the above policies.

Specifically, the Department's physician witness testified that the Department has very clear guidelines, including documentation requirements, that must be met to approve the broad genetic testing requested by Petitioner, and that those specific guidelines were not met in this case given how illegible the prior authorization request was and the lack of sufficient supporting documentation. He also testified that Petitioner and her provider are free to submit a new prior authorization request for the genetic testing along with the required documentation, but that it is not clear if the test has already been performed, when it is performed, or why. The Department's witness further testified that it appears that Petitioner also underwent an amniocentesis, but that, while such tests are typically approved, he cannot address the amniocentesis as it is not at issue in this case and he did not have the relevant information

In response, Petitioner testified that she is unclear as to what this hearing is about, but that she filed the request for hearing after receiving a letter stating that a blood test would not be covered. She also testified that she has undergone two different tests and, while she has not received any bills, she needs to know if she should prepare to pay for the tests. She further testified that she and her doctor can have the prior authorization request resubmitted with legible and additional information if necessary.

Petitioner bears the burden of proving by a preponderance of the evidence that the Department erred in denying her prior authorization request. Moreover, the undersigned Administrative Law Judge reviews the Department's decision in light of the information that was available at the time the decision was made.

Given the record and applicable policies in this case, Petitioner has failed to meet her burden of proof and the Department's decision must be affirmed. The above policy expressly provides that, for genetic testing to be approve, the submitted documentation must include the indication for the test; clinical notes that clearly detail the beneficiary's related signs and symptoms; other related testing or clinical findings; documentation supporting that the test results will be used to significantly alter the management or treatment of the disease; and the name and NPI number of the laboratory performing the test. In this case, insufficient documentation was submitted and, to the extent the prior authorization request is even legible, there are no clinical notes and it clearly fails to establish the medical necessity for the test or how its results will be used to significantly alter the management or treatment of the disease. Accordingly the prior authorization request was properly denied.

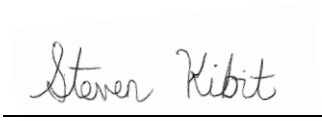
To the extent that Petitioner has new or updated information she wants to provide, she and her doctor are free to submit a new prior authorization request at any time. Moreover, as noted by the Department's representative, even though the request in this case was denied, Petitioner may not be responsible for paying for the genetic testing if the provider performed it after accepting Petitioner as a Medicaid patient and failing to get prior approval for the test. Nevertheless, regardless of what happens in the future, the denial at issue in this case must be affirmed given record in this case.

DECISION AND ORDER

The Administrative Law Judge, based on the above Findings of Fact and Conclusions of Law, decides that the Department properly denied Petitioner's prior authorization request for genetic testing.

IT IS, THEREFORE, ORDERED that:

The Department's decision is **AFFIRMED**.



SK/tm

Steven Kibit
Administrative Law Judge
for Nick Lyon, Director
Department of Health and Human Services

NOTICE OF APPEAL: A party may appeal this Order in circuit court within 30 days of the receipt date. A copy of the circuit court appeal must be filed with the Michigan Administrative Hearing System (MAHS).

A party may request a rehearing or reconsideration of this Order if the request is received by MAHS within 30 days of the date the Order was issued. The party requesting a rehearing or reconsideration must provide the specific reasons for the request. MAHS will not review any response to a request for rehearing/reconsideration.

A written request may be mailed or faxed to MAHS. If submitted by fax, the written request must be faxed to (517) 335-6088; Attention: MAHS Rehearing/Reconsideration Request.

If submitted by mail, the written request must be addressed as follows:

Michigan Administrative Hearings
Reconsideration/Rehearing Request
P.O. Box 30763
Lansing, Michigan 48909-8139

DHHS Department Rep.

[redacted]

[redacted]

[redacted]

[redacted]