



GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
MICHIGAN OFFICE OF ADMINISTRATIVE HEARINGS AND RULES

ORLENE HAWKS
DIRECTOR

[REDACTED]
[REDACTED] MI [REDACTED]

Date Mailed: January 10, 2022
MOAHR Docket No.: 21-005394
Agency No.: [REDACTED]
Petitioner: [REDACTED]

ADMINISTRATIVE LAW JUDGE: Corey Arendt

DECISION AND ORDER

Following Petitioner's request for a hearing, this matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and 400.37; 7 CFR 273.15 to 273.18; 42 CFR 431.200 et seq; 42 CFR 438.400 et seq; and Mich Admin Code, R 792.11002.

After due notice, a hearing was held on January 5, 2022. [REDACTED], the Petitioner, appeared on her own behalf. Leigha Burghdoff, Appeals Review Officer, appeared on behalf of the Respondent, the Department of Health and Human Services (Department). Dr. David Wartinger, Consultant to the Michigan Department of Health and Human Services, Office of Medical Affairs, appeared as a witness for the Department.

Exhibits:

| | |
|------------|---------------------|
| Petitioner | None |
| Department | A – Hearing Summary |

ISSUE

Did the Department properly deny Petitioner's request for prior authorization for Spinraza injections?

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 [REDACTED]-year-old Medicaid beneficiary, born [REDACTED] 1989. (Exhibit A, p 7.)
2. Petitioner's diagnoses include spinal muscle atrophy (SMA), chronic back pain, gastroesophageal reflux disease, quadriplegia, renal calculi, restrictive lung

disease, and scoliosis. (Exhibit A, p 27.)

3. On or around October 19, 2021, the Department received a prior authorization request for Spinraza injections, for Petitioner. (Exhibit A, pp 11-52.)
4. The October 19, 2021, prior authorization request included 2 Hammersmith Infant Neurological Examination (HINE) scores from June 28, 2019, and September 9, 2021. Both examinations reflected scores of 0. (Exhibit A, pp 15, 49-51.)
5. On October 28, 2021, the Department issued a Notification of Denial to Petitioner stating the request for Spinraza injections was denied because Petitioner was older than the age of 21 and because the prior authorization documentation did not demonstrate the effectiveness and safety of the drug. (Exhibit A, pp 9-10.)
6. On November 9, 2021, the Michigan Office of Administrative Hearings and Rules (MOAHR) received Petitioner's Request for Hearing. (Exhibit A, pp 5-8.)

CONCLUSIONS OF LAW

The Medical Assistance Program (MA) 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 statute, the Social Welfare Act, the Administrative Code, and the State Plan under Title XIX of the Social Security Act Medical Assistance Program.

1.9 PRIOR AUTHORIZATION

Medicaid requires prior authorization (PA) to cover certain services before those services are rendered to the beneficiary. The purpose of PA is to review the medical need for certain services.¹

The MPM addresses the EPSDT program:

SECTION 1 – GENERAL INFORMATION

Federal regulations require state Medicaid programs to offer early and periodic screening, diagnosis, and treatment (EPSDT) services to Medicaid eligible beneficiaries younger than 21 years of age; however, beneficiary participation is voluntary. The intent of EPSDT is to provide necessary health care, diagnostic services, treatment, and other measures according to section 1905(a) and 1905(r) [42 U.S.C. 1396d] of the Social Security Act (1967) to correct or

¹ Medicaid Provider Manual, Practitioner, July 1, 2021, p 4.

ameliorate defects and physical and mental illnesses and conditions discovered whether or not such services are covered under the state plan. State Medicaid programs are required to provide for any services that are included within the mandatory and optional services that are determined to be medically necessary for children under 21 years of age. Accordingly, EPSDT well child visits and any needed follow-up services are covered by Medicaid.

EPSDT visits cover any medically necessary screening and preventive support services for children, including nutritional and at-risk assessments as well as resulting health education and mental health services. These services are available to all children for the purpose of screening and identifying children who may be at risk for, but not limited to, drug or alcohol abuse, child abuse or neglect, trauma, failure to thrive, low birth weight, low functioning/impaired parent, or homeless or dangerous living situations.

EPSDT visits are to be performed in accordance with the American Academy of Pediatrics (AAP) periodicity schedule, its components, and medical guidelines. Michigan recognizes the AAP definition of "medical necessity" as:

Health care interventions that are evidence based, evidence informed, or based on consensus advisory opinion and that are recommended by recognized health care professionals to promote optimal growth and development in a child and to prevent, detect, diagnose, treat, ameliorate, or palliate the effects of physical, genetic, congenital, developmental, behavioral, or mental conditions, injuries, or disabilities.

EPSDT requires the coverage of medically necessary inter-periodic screenings outside of the AAP periodicity schedule. Coverage for such screenings is required based on an indication of a medical need to diagnose an illness or condition that was not present at the regularly scheduled screening or to determine if there has been a change in a previously diagnosed illness or condition that requires additional services.

Medically necessary services include habilitative or rehabilitative services that are expected to attain, maintain, or regain functional capacity and to achieve maximum health

and function. A service need not cure a condition in order to be covered under EPSDT, and maintenance services or services that improve the child's current health condition are also covered in EPSDT because they ameliorate a condition. The common definition of ameliorate is "to make more tolerable." Thus, services such as physical and occupational therapy are covered when they have an ameliorative, maintenance purpose. Maintenance services are defined as services that sustain or support rather than those that cure or improve health problems. It is important to identify illnesses and conditions early and to treat any health problems discovered in children before they become worse and more costly. Services are covered when they prevent a condition from worsening or prevent development of additional health problems. Refer to the Special Coverage Provisions section of the Healthy Michigan Plan chapter for the definition of "habilitative services".²

The pharmacy chapter of the MPM addresses prior authorization denials:

8.6 PRIOR AUTHORIZATION DENIALS

PA denials are conveyed to the requester. PA is denied if:

- The medical necessity is not established.
- Alternative medications are not ruled out.
- Evidence-based research and compendia do not support it.
- It is contraindicated, inappropriate standard of care.
- It does not fall within MDHHS clinical review criteria.
- Documentation required was not provided.³

The practitioner chapter of the MPM addresses injectable drugs and biological products:

3.13 INJECTABLE DRUGS AND BIOLOGICAL PRODUCTS

3.13.A. COVERAGE OF THE INJECTABLE

Medicaid covers injectable drugs and biological products administered by a physician in the office, clinic setting, and in the beneficiary's home. The drug or biological product must be Food and Drug Administration (FDA) approved and reasonable and necessary according to accepted standards

² Medicaid Provider Manual, Early and Periodic Screening, Diagnosis and Treatment, July 1, 2021, pp 1.

³ Medicaid Provider Manual, Pharmacy, p 17.

of medical practice for the diagnosis or treatment of the illness or injury of the beneficiary. There must be sufficient clinical evidence demonstrating the effectiveness and safety of the drug or biological product.

An injectable drug is covered if the drug is:

- Specific and effective treatment for the condition for which it is being given.
- Given for the treatment of a particular documented diagnosis, illness, or condition (e.g., vitamin injections which are not specific replacement therapy for a documented deficiency or disease and are given simply for the general good and welfare of the patient).
- Administered by the recommended or accepted administration method for the condition being treated.
- Administered according to the recommended dosing schedule and amount for the condition being treated.⁴

The Department witness indicated Petitioner's request was denied for primarily two reasons. The first reason was Petitioner was not under the age of 21 and the second reason was because the submitted documentation did not demonstrate the requested drug would be effective. Specifically, the Petitioner's two most recent HINE scores reflected scores of 0 and no improvement.

Petitioner did not dispute the reasoning and rational provided by the Department and questioned whether there might be other tests that the Department could use in the future. Petitioner herself questioned why the HINE score was provided by her treating providers to support a request for Spinraza.

Based upon the evidence presented, I find sufficient evidence to affirm the Department's actions to deny Petitioner's request for Spinraza. Based on Petitioner's age, Spinraza injections could not be approved through the EPSDT program. Further, the submitted documentation did not support medical necessity.

As discussed, another prior authorization request can be submitted with additional supporting documentation.

⁴ Medicaid Provider Manual, Practitioner, July 1, 2021, pp 16-17.


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 request for prior authorization for Spinraza injections based on the submitted documentation.

IT IS, THEREFORE, ORDERED that:

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

CA/dh



Corey Arendt
Administrative Law Judge

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 Office of Administrative Hearings and Rules (MOAHR).

A party may request a rehearing or reconsideration of this Order if the request is received by MOAHR 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. MOAHR will not review any response to a request for rehearing/reconsideration.

A written request may be mailed or faxed to MOAHR. If submitted by fax, the written request must be faxed to (517) 763-0155; Attention: MOAHR Rehearing/Reconsideration Request.

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

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

DHHS -Dept Contact

Gretchen Backer
400 S. Pine, 6th Floor
PO Box 30479
Lansing, MI 48909

DHHS Department Rep.

M. Carrier
Appeals Section
PO Box 30807
Lansing, MI 48933

Petitioner

[REDACTED]
MI [REDACTED]

Agency Representative

Leigha Burghdoff
P.O. Box 30807
Lansing, MI 48909