



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: April 19, 2022
MOAHR Docket No.: 22-000773
Agency No.: [REDACTED]
Petitioner: [REDACTED]

ADMINISTRATIVE LAW JUDGE: Robert J. Meade

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 April 14, 2022. Dr. Daniel Menkes, Professor and Chairman of Neurology, Oakland University William Beaumont School of Medicine, appeared and testified on Petitioner's behalf. [REDACTED] Petitioner appeared as a witness.

Leigha Burghdoff, Appeals Review Officer, appeared on behalf of the Respondent, Michigan Department of Health and Human Services (Respondent, MDHHS, or Department). Dr. David Wartinger, Physician Consultant, Office of Medical Affairs; Eric Neilson, Section Manager, Program Review Division; Dr. Timothy Conroy, Pediatrician, Office of Medical Affairs; and Alanna Velandra, Utilization Analyst, Program Review Division appeared as a witness for the Department. Dr. Jed Miller, Chief Medical Consultant, Office of Medical Affairs, appeared as an observer for the Department.

Exhibits:

Petitioner	None
Department	A – Hearing Summary, pp 1-69

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, diagnosed with spinal muscular atrophy (SMA). (Exhibit A, p 26; Testimony.)

2. On or around January 24, 2022, the Department received a prior authorization request for Spinraza injections for Petitioner. (Exhibit A, pp 25-63; Testimony.)
3. The prior authorization request included a Hammersmith Functional Motor Scale for the SMA test, which reflected a score of 0. (Exhibit A, pp 60-62; Testimony.)
4. On January 25, 2022, 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 [REDACTED] and because the prior authorization documentation did not demonstrate the effectiveness and safety of the drug. (Exhibit A, pp 12-13; Testimony.)
5. On February 17, 2022, the Michigan Office of Administrative Hearings and Rules (MOAHR) received Petitioner's Request for Hearing. (Exhibit A, pp 5-11.)

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 ameliorate defects and physical and mental illnesses and

¹ Medicaid Provider Manual, Practitioner, January 1, 2022, p 4.

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:

3.14 INJECTABLE DRUGS AND BIOLOGICAL PRODUCTS

3.14.A. COVERAGE OF THE INJECTABLE

Medicaid covers injectable drugs and biological products administered by a physician in the office, clinic setting, and

² Medicaid Provider Manual, Early and Periodic Screening, Diagnosis and Treatment, January 1, 2022, pp 1.

³ Medicaid Provider Manual, Pharmacy, January 1, 2022, p 17.

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 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's witness indicated Petitioner's request was denied for primarily two reasons. The first reason was Petitioner was not under the age of [REDACTED] as required by EPSDT policy, and the second reason was because the submitted documentation did not demonstrate the requested drug would be effective. Specifically, Petitioner's Hammersmith Functional Motor Scale score was a 0, meaning that there would be no way to measure any improvement. The Department's witness also noted that the documentation submitted indicated that Petitioner had shown no improvement on the drug in the past.

Petitioner's doctor argued that while the facts were not in dispute, the interpretation of those facts was. Petitioner's doctor indicated that the FDA has approved Spinraza for treatment of SMA in both pediatric and adult patients, and nowhere does it indicate that the use can be restricted by Medicaid policy. Petitioner's doctor also pointed out that Spinraza is not necessarily designed to improve a patient, but rather to mitigate or slow the patient's deterioration.

Petitioner testified that he became ventilator dependent in 2015, three years before he first started using Spinraza. Petitioner indicated that he became ventilator dependent because he caught the flu and would not have survived without the ventilator. Petitioner argued that treatment does not have to mean that the drug is going to cure the disease,

⁴ Medicaid Provider Manual, Practitioner, January 1, 2022, pp 16-17.

treatment can also just improve the patient's quality of life. Petitioner noted that just because he has limited use of his extremities, it should not be said that he cannot show any improvement. Petitioner testified that he really noticed a significant slowing of the progression of his disease while taking Spinraza. Petitioner also noted that if Spinraza had been available when he was a child, the severity of his disease would have been much less.

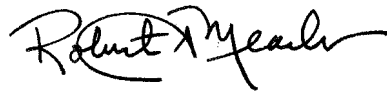
Based upon the evidence presented, I find sufficient evidence to affirm the Department's actions to deny Petitioner's request for Spinraza. Based on Petitioner's age, Spinraza injections could not be approved through the EPSDT program and Spinraza injections are only covered through the EPSDT program by Medicaid at this time. This policy does not allow for any exceptions. Simply put, Spinraza is currently only available through Medicaid for patients younger than age [REDACTED] and Petitioner is over age [REDACTED]. While the undersigned is sympathetic to Petitioner's arguments, he has no authority to ignore clear policy or provide any equitable relief. Furthermore, even if Spinraza were available for those over age [REDACTED] there is no evidence in the record that it would be effective for Petitioner. And, while the undersigned thinks there is some merit to Petitioner's argument that "treatment" can include the mitigation or slowing of the progression of a disease, Spinraza is simply not available through Medicaid at the present time for persons over age [REDACTED]. As such, the Department's decision is proper and must be upheld.

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**.



Robert J. Meade
Administrative Law Judge

RM:tem

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

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Petitioner

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