[redacted]
[redacted] **MI** [redacted]

Date Mailed: February 10, 2020
MOAHR Docket No.: 20-000019
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 February 6, 2020. The Petitioner appeared on his own behalf and offered testimony. [redacted], Petitioner's mother, appeared as a witness on behalf of Petitioner. John Lambert, Appeals Review Officer, appeared on behalf of the Department of Health and Human Services (Department). Dr. David Wartinger, Medical Consultant, 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]. (Exhibit A, p 5; Testimony.)

2. Petitioner's diagnoses include muscular dystrophy and restrictive lung disease. (Exhibit A, p 14.)

3. On October 24, 2019, the Department received a prior authorization request from

Dr. Melanie Taylor requesting Spinraza injections, for Petitioner. (Exhibit A, pp 7-13-23.)

4. On or around December 18, 2019, Department personnel reviewed the request and determined it "does not meet criteria established that includes [Early and Periodic Screening, Diagnosis, and Treatment] EPSDT criteria. (Exhibit A, p 10; Testimony.)

5. On December 19, 2020 and December 20, 2020, the Department sent a Petitioner Notification of Denials stating the request for Spinraza injections was denied because Spinraza is covered under EPSDT guidelines, which covers Medicaid beneficiaries younger than 21 years of age. (Exhibit A, pp 6-9; Testimony.)

6. On January 3, 2020, the Michigan Office of Administrative Hearings and Rules (MOAHR) received Petitioner's Request for Hearing. (Exhibit A, p 4.)

7. Spinraza injections do not resurrect dead nerve cells. (Testimony.)

8. Petitioner's Hammersmith Functional Motor Scale reflects Petitioner lacks the presence of motor function/strength/coordination. Petitioner's nerve cells are no longer functioning. (Exhibit A, p 11; Testimony.)

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.
>
> *Medicaid Provider Manual (MPM), Practitioner Section, July 1, 2019, p 4.*

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 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”.
>
> *MDHHS MPM,*
> *EPSDT Section, (July 1, 2019, p. 1).*

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.
>
> *MPM, Pharmacy Section, July 1, 2019, p 16.*

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 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.

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3.13.B. PHYSICIAN-ADMINISTERED DRUGS AND BIOLOGICAL PRODUCTS NOT COVERED BY MEDICAID HEALTH PLANS

MDHHS will maintain a list of specific Medicaid program covered physician-administered drugs and biological products that are not covered by MHPs. This list of physician administered drugs and biological products, carved out from MHP coverage, will be reimbursed as a Fee-for-Service (FFS) benefit for all beneficiaries in FFS and for those enrolled in an MHP.

A list of the specific drugs covered under this policy will be maintained on the MDHHS website. The list may be modified as new drugs are approved or added to the physician administered carve-out. No notice of changes to the list will be issued directly to providers. (Refer to the Directory Appendix for website information.)

3.13.B.1. PRIOR AUTHORIZATION REQUIREMENTS FOR CARVE-OUT INJECTABLE DRUGS AND BIOLOGICAL PRODUCTS

Certain drugs on the carve-out list of physician-administered drugs and biological products not covered by MHPs may require prior authorization (PA). The purpose of PA is to review the medical need for certain services. It does not serve as an authorization of fees or beneficiary eligibility.

When indicated on the MDHHS-maintained list, PA requests will require a completed Practitioner Special Services Prior Approval-Request/Authorization form (MSA-6544-B), a Program Review Division (PRD) documentation checklist, and all supporting documentation. Providers are to contact the PRD to obtain the PRD documentation checklist for drugs and biological products that require PA. Once all required documentation is collated, information must be submitted according to form MSA-6544-B completion and submission instructions. (Refer to the Forms Appendix for a copy of the form and completion instructions and to the Directory Appendix for PRD contact information.)

MPM, Practitioner Section, July 1, 2019, pp 16-18.

Spinraza (nusinersen) injection is included in the list of Medicaid program covered injectable drugs and biological products that are carved out from Medicaid Health Plan (MHP) coverage and are reimbursed as a fee-for-service (FFS) benefit for all FFS and MHP enrollees. Nusinersen is listed as having been added to this list, with HCPCS Code J2326, on January 1, 2018. Prior authorization is required. *MDHHS Medicaid Health Plan Injectable Drugs and Biologicals Carve-Out, November 2019.*

The Department's witness explained that the request for Spinraza for Petitioner could not be approved under the EDSDT policy because Petitioner is not under age 21. The Department's witness went on to explain that Spinraza does not resurrect dead nerve cells and as a result presents very little benefit, if any, to adults or patients where nerve cells had already died. The witness indicated that in Petitioner's case, Petitioner's nerve cells had already died as evidenced by the Petitioner's Hammersmith score (0 out of 66).

The Petitioner argued that they have seen testimonials were Spinraza worked on individuals older than the age of 21. The Petitioner however did not present any medical literature to corroborate the claims made in the testimonials. The need for medical literature to support the use of Spinraza in adults would relate to the policy in the pharmacy chapter of the MPM regarding denials of prior authorization when evidence-based research and compendia do not support the requested drug/service.

Based upon a totality of the evidence presented, I find sufficient evidence to affirm the Departments denial. The policy is clear in that Petitioner must be below the age of 21 to be eligible for Spinraza. As a result, I do not find the Petitioner to have met their burden to show the Department erred in denying the request for Spinraza.

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.

IT IS, THEREFORE, ORDERED that:

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

CA/sb

Corey Arendt
Administrative Law Judge
for Robert Gordon, 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 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
Agency Representative	John Lambert PO Box 30807 Lansing, MI 48909