STATE OF MICHIGAN
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
FOR THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
P.O. Box 30763, Lansing, MI 48909
(877) 833-0870; Fax: (517) 373-4147

IN THE MATTER OF:

[redacted]

Docket No. 15-002673 MHP
[redacted] [redacted]

Appellant
_____/

DECISION AND ORDER

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

After due notice, a hearing was held on [redacted]. Appellant's father, [redacted] and her mother [redacted] appeared on behalf of Appellant. Appellant is [redacted]t years old, and did not appear to testify. [redacted] – Manager of Medical Operations for [redacted] (MHP) appeared and testified on behalf of the Michigan Department of Health and Human Services (formerly Department of Community Health).

ISSUE

Did the MHP properly deny the Appellant's request for Increlex 10 mg medication?

FINDINGS OF FACT

Based on the competent, material, and substantial evidence presented, the Administrative Law Judge finds as material fact:

1. [redacted] is a Qualified Health Plan contracted with the State of Michigan Comprehensive Health Care Program.

2. Appellant is a minor child, date of birth [redacted], who was an enrolled member of [redacted] at the time of the request for services and who continues to be enrolled.

3. Appellant has been diagnosed with Rett's Syndrome.

4. The [redacted] member handbook and certificate of coverage were sent to Appellant and her parents at the time of enrollment.

5. The Member Handbook outlines coverage limitations, prior authorization requirements, limitations and exclusions, and pharmacy guidelines.

6. On [redacted] submitted a request to [redacted] a clinical study and request for Increlex medication for treatment of Rett's Syndrome.

7. On [redacted] denied the request. The [redacted] Pharmacist indicated that the level of evidence was not sufficient for approval at that time.

8. On [redacted] submitted a Prior Authorization form for Increlex 10mg medication for treatment of Rett Syndrome.

9. On [redacted], Notice of Denial was sent to Appellant, and [redacted] stating that usage of Increlex 10mg does not meet the coverage criteria as outlined in Priority Health's drug policy. The Food and Drug Administration has not approved this medication for Rett Syndrome. (Respondent's Exhibit A page C)

10. On [redacted] received Appellant's request for hearing which stated: This medication is already been approved to treat short stature and the condition CDKS which is very similar to Rett Syndrome.

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

On May 30, 1997, the Department received approval from the Health Care Financing Administration, U.S. Department of Health and Human Services, allowing Michigan to restrict Medicaid beneficiaries' choice to obtain medical services only from specified MHPs.

The Respondent is one of those MHPs.

> The covered services that the Contractor has available for enrollees must include, at a minimum, the covered services listed below. The Contractor may limit services to those which are medically necessary and appropriate, and which conform to professionally accepted standards of care. The Contractor must operate consistent with all applicable Medicaid provider manuals and publications for coverages and limitations. If new services are added to the Michigan Medicaid Program, or if services are

expanded, eliminated, or otherwise changed, the Contractor must implement the changes consistent with State direction in accordance with the provisions of Contract Section 2.024.

Although the Contractor must provide the full range of covered services listed below they may choose to provide services over and above those specified. The covered services provided to enrollees under this Contract include, but are not limited to, the following:

- Ambulance and other emergency medical transportation
- Blood lead testing in accordance with Medicaid Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) policy
- Certified nurse midwife services
- Certified pediatric and family nurse practitioner services
- Chiropractic services
- Diagnostic lab, x-ray and other imaging services
- Durable medical equipment (DME) and supplies
- Emergency services
- End Stage Renal Disease services
- Family planning services (e.g., examination, sterilization procedures, limited infertility screening, and diagnosis)
- Health education
- Hearing and speech services
- Hearing aids
- Home Health services
- Hospice services (if requested by the enrollee)
- Immunizations
- Inpatient and outpatient hospital services
- Intermittent or short-term restorative or rehabilitative services (in a nursing facility), up to 45 days
- Restorative or rehabilitative services (in a place of service other than a nursing facility)
- Medically necessary weight reduction services
- Mental health care – maximum of 20 outpatient visits per calendar year
- Out-of-state services authorized by the Contractor
- Outreach for included services, especially pregnancy-related and Well child care
- Parenting and birthing classes
- Pharmacy services
- Podiatry services

- Practitioners' services (such as those provided by physicians, optometrists and dentists enrolled as a Medicaid Provider Type 10)
- Prosthetics and orthotics
- Tobacco cessation treatment including pharmaceutical and behavioral support
- Therapies (speech, language, physical, occupational) excluding services provided to persons with development disabilities which are billed through Community Mental Health Services Program (CMHSP) providers or Intermediate School Districts.
- Transplant services
- Transportation for medically necessary covered services
- Treatment for sexually transmitted disease (STD)
- Vision services
- Well child/EPSDT for persons under age 21 [Article 1.020 Scope of [Services], at §1.022 E (1) contract, 2010, p. 22].

(1) The major components of the Contractor's utilization management (UM) program must encompass, at a minimum, the following:

(a) Written policies with review decision criteria and procedures that conform to managed health care industry standards and processes.
(b) A formal utilization review committee directed by the Contractor's medical director to oversee the utilization review process.
(c) Sufficient resources to regularly review the effectiveness of the utilization review process and to make changes to the process as needed.
(d) An annual review and reporting of utilization review activities and outcomes/interventions from the review.
(e) The UM activities of the Contractor must be integrated with the Contractor's QAPI program.

(2) Prior Approval Policy and Procedure

The Contractor must establish and use a written prior approval policy and procedure for UM purposes. The Contractor may not use such policies and procedures to avoid providing medically necessary services within the coverages established under the Contract. The policy must ensure that the review criteria for authorization decisions are applied consistently and require that the reviewer consult with the requesting provider when appropriate. The policy must also require that UM decisions be made by a health care professional who has appropriate clinical expertise regarding the service under review. [Contract, *Supra,* p. 49].

As stated in the Department-MHP contract language above, a MHP "must operate consistent with all applicable Medicaid Provider Manuals and publications for coverages and limitations."

MCL 500.340q requires health plans to provide coverage for off-label use of an FDA approved drug when there is evidence that the drug has been recognized for the treatment for which it has been prescribed. Priority Health's policy states that payment is disallowed for off-label use of medications not supported by clinical evidence.

The request for Increlex 10mg for treatment of Rett Syndrome was denied based on the [redacted] Medical Policy 11/0022 – Documentation Required for Off-Label Use of drugs: off label use of medications is approved when it is supported in one or more of the following compendia (drug references): The American Hospital Formulary Service Drug Information, Thomson Microdex DrugDex or DrugPoints, the National Comprehensive Cancer Network (NCCN) Guidelines, Clinical Pharmacology; or two articles from peer-reviewed medical literature whose primary purpose is to evaluate the use of the drug for the off-label diagnosis for which it is requested, and that support the proposed off-label use as generally safe and effective for the patient's diagnosis. In this case, upon review of the documentation submitted by Respondent, it was determined that documentation did not support approval of the drug under current circumstances. The first article includes a preliminary assessment and Phase I trial of a small group (12 girls) which was made to evaluate only safety, tolerability and pharma-kinetic properties of the drug. The study did not evaluate efficacy.

The second study considered by Respondent's Pharmacist was a study of six people. It was not a hypothesis testing study and did not evaluate the medication for safety. The Food and Drug Administration (FDA) has not approved Increlex for Appellant's diagnosis. The [redacted] Pharmacist determined that Increlex 10mg has not been determined as safe or efficacious for treatment of Rett Syndrome.

Appellant's Authorized Hearings Representative testified on the record that the FDA has already approved Increlex to treat short stature an CCDCK2 which is very similar to Rett Syndrome. Appellant participated in a trial in [redacted] and her condition significantly improved with the use of Increlex.

Appellant has failed to satisfy her burden of proving by a preponderance of the evidence that the MHP improperly denied the request for Increlex 10mg for treatment of Rett Syndrome under the circumstances. The [redacted] Handbook and Certificate of Coverage and the State of Michigan Medicaid Provider Manual detail the conditions required for coverage. In the instant case, the conditions required for coverage were not met based upon the medical information submitted with the Prior Authorization request. The Medicaid Health Plan (MHP), does not have discretion to approve Appellant's request for Increlex 10mg for treatment of Rett Syndrome. The decision to deny the request for authorization must be upheld.

DECISION AND ORDER

Based on the above findings of fact and conclusions of law, the Administrative Law Judge finds that the MHP's denial of the Appellant's request for Increlex 10mg for treatment of Rett's syndrome was proper under the circumstances.

IT IS THEREFORE ORDERED that:

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

Landis Y. Lain
Administrative Law Judge
for Director, Nick Lyon
Michigan Department of Health and Human Services

Date Signed: [redacted]

Date Mailed: [redacted]

LYL/db

cc: [redacted]

***** NOTICE *****

The Michigan Administrative Hearing System may order a rehearing on either its own motion or at the request of a party within 30 days of the mailing date of this Decision and Order. The Michigan Administrative Hearing System will not order a rehearing on the Department's motion where the final decision or rehearing cannot be implemented within 90 days of the filing of the original request. The Appellant may appeal the Decision and Order to Circuit Court within 60 days of the mailing date of the Decision and Order or, if a timely request for rehearing was made, within 60 days of the mailing date of the rehearing decision.