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: [redacted]
MAHS Docket No.: 16-003865
Agency No.: [redacted]
Petitioner: [redacted]

**ADMINISTRATIVE LAW JUDGE: Janice Spodarek**

## DECISION AND ORDER

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

After due notice, a hearing was held on [redacted]. [redacted] appeared as an authorized hearing representative on behalf of the Petitioner. [redacted], translator with [redacted] was retained by the State of Michigan to interpret on behalf of Petitioner.

[redacted], Clinical Pharmacist for [redacted], subcontracting pharmacy with the Michigan Department of Health and Human Services, represented the Department of Health and Human Services (Department or Respondent).

## ISSUE

Did the MHP properly deny the Appellant's prior authorization (PA) request for [redacted]?

## FINDINGS OF FACT

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

1. Appellant is a [redacted] year-old male Medicaid beneficiary. Appellant is enrolled with [redacted]. Appellant's pharmaceutical services are issued by the [redacted] Medicaid Administration (Respondent). (Exhibit A;Testimony).

2. On [redacted], the Respondent received a PA from Appellant's physician-[redacted], specialist in hepatology, for Viekira Pak for a diagnosis of

Chronic Hepatitis C. (Exhibit A.).

3. The Respondent forwarded the request for a review by the MDHHS for an initial and renewal therapy request. Harvoni is currently on the MDCH Drug Formulary Suspend List. (Exhibit A).

4. Petitioner's APRI and Metavir scores along with the absence of cirrhosis did not meet the Medicaid criteria. Petitioner's request was denied, and notices issued with information that if there is additional information, a new request may be submitted.

5. On [redacted] Petitioner filed a Letter of Appeal with no additional information. Following, a denial letter was issued stating that the initial denial stands (after [redacted] inadvertently issued an approval in error but which error was followed with a corrected denial).

6. No additional information has been received by the Respondent from Appellant's physician.

**7.** On [redacted] Appellant filed a request for an administrative hearing.

## 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 but may not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of the diagnosis, type of illness, or

condition of an enrollee. In general, the Contractor is responsible for covered services related to the following:

- The prevention, diagnosis, and treatment of health impairments
- The ability to achieve age-appropriate growth and development
- The ability to attain, maintain, or regain functional capacity

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 (only for enrollees under 21 years of age)
- 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 in accordance with Medicaid policy as stated in the Medicaid Provider Manual, Mental Health/Substance Abuse Chapter, Beneficiary Eligibility Section
- 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, 1.022 Work and Deliverables, at §1.022 E (1) contract, 12/5/2013, pp. 22-23].

* * *

(7) Pharmacy

The Contractor may have a prescription drug management program that includes a drug formulary. DCH may review the Contractor's formularies regularly, particularly if enrollee complaints regarding access have been filed regarding the formulary. The Contractor must have a process to approve physicians' requests to prescribe any medically appropriate drug that is covered under the Medicaid Pharmaceutical Product List (MPPL). [Article 1, 1.022 Work and Deliverables, at §1.022 E (7) contract, 12/5/2013, p. 27].

* * *

AA. Utilization Management

(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. 55].

The *Medicaid Provider Manual*, *Pharmacy*, Section 7, July 1, 2014, references the list of pharmaceutical products that are covered by the MDCH under Medicaid. This section states:

**SECTION 7 - MICHIGAN PHARMACEUTICAL PRODUCT LIST**

The Michigan Pharmaceutical Product List (MPPL) identifies the pharmaceutical products that are covered by MDCH. The MPPL pharmaceutical product coverages may vary by MDCH program or be limited by age, clinical parameters, and/or gender. The Point of Sale pharmacy claim adjudication also provides coverage information related to a specific beneficiary or prescription.

The MPPL is posted on the PBM's website. (Refer to the Directory Appendix for website information.) Providers must refer to the MPPL for the additions and deletions of drug products. Specific notification of changes will not be issued. [*Medicaid Provider Manual*, *Pharmacy*, Section 7, p. 13, July 1, 2014].

Health Plus' PA criteria for specialty injectable drugs for a psoriasis diagnosis requires:

Diagnosis of plaque psoriasis, AND
Prescription is written by a dermatologist, AND
Documented failure of, intolerance or contraindication to, at least 2 traditional therapies (e.g. PUVA, UVB, methotrexate, or cyclosporine). (Exhibit C).

Specific to the case here, the Respondent submitted the Michigan Medicaid Clinical and PDL Criteria required for Viekira Pak (Exhibit A.31). Specifically, Viekira Pak can be approved if the criteria is met, including minimum or equal to APRI scores (a marker that reflect liver involvement). (See Exhibit A).

Here, the Respondent argues that it is required by federal and state law to deny Petitioner's request as his scores did not meet the minimal criteria required and set by state standards to trigger eligibility. In addition, the medical evidence submitted does not show cirrhosis of the liver.

Petitioner argues that he will die without the drug. Petitioner argues that he needs this drug, the situation is urgent, and that his condition will deteriorate.

Petitioner has the burden of proof to establish that the Respondent erred in denying coverage. Here, Petitioner submitted no medical evidence to show that he met the Department's criteria required for the drug.

The purview of an administrative law judge (ALJ) is to review the Department's action and to make a determination if those actions are in compliance with Department policy, and not contrary to law. The ALJ must base the hearing decision on the preponderance of the evidence offered at the hearing or otherwise included in the record. Appellant has the burden of proof by a preponderance of evidence to show that the Respondent's actions were not in compliance with federal or state law, or with Departmental policy.

In addition, the Department is under strict federal mandates to ensure that the evidence in a beneficiary's file is supported by necessary verifications. If not, the State of Michigan may be subject to substantial financial penalties. 42 CFR 435.914.

After a careful review of the credible and substantial evidence of the entire record, this ALJ finds that Appellant did not bring forth credible or substantial evidence that the Respondent erred in denying Viekira Pak. Evidence of record is that the Respondent, as a subcontractor of MDHHS was required to deny the drug at this time based on the medical evidence submitted in conjunction with policy and procedure. Thus, under the above authority, based on these facts, this ALJ must uphold the denial.

It is noted that the Respondent indicated that should the medical evidence change, that Petitioner may resubmit for reconsideration.

**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 Petitioner's request for the Vikira Pak was proper based on the available evidence.

**IT IS THEREFORE ORDERED** that:

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

JS/cg

**Janice Spodarek**
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 -Dept Contact** [redacted]

**Petitioner** [redacted]

**DHHS Department Rep.** [redacted]