STATE OF MICHIGAN
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
FOR THE DEPARTMENT OF COMMUNITY HEALTH
P.O. Box 30763, Lansing, MI 48909
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IN THE MATTER OF:

[redacted],

Docket No. 15-002392 MHP
Case No. [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, an in person hearing was held on [redacted]. Appellant personally appeared and testified.

[redacted], Attorney at Law, appeared on behalf of Respondent [redacted], (MHP), subcontractor with the Michigan Department of Community Health (MDCH). [redacted], Pharmacist and Manager of Specialty Pharmacy appeared as a witness for the MHP.

ISSUE

Did the MHP properly deny the Appellant's prior authorization (PA) request for the drug Harvoni?

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 Meridian Health Plan, Respondent MHP herein. (Exhibit A;Testimony).

2. On or about [redacted], the MHP received a PA from Appellant's physician for Harvoni. Appellant's diagnosis is listed as chronic hepatitis C. (Exhibit A.5).

3. Harvoni is not on the MDCH Drug Formulary. (Exhibit A).

4. On [redacted] the MHP issued a denial for the Harvoni on the grounds that the drug Harvoni is not included in the MDCH/MHP drug formulary, and is not a covered benefit for Medicaid Health Plan enrollees and correspondingly the

MHP. (Exhibit A.8-9).

5. On [redacted] Appellant filed a request for an administrative hearing. (Exhibit A.24).

6. On [redacted] an Internal Review was conducted. On [redacted] the results were issued in a letter stating that the Level I appeal were reviewed by a licensed pharmacist finding that the initial denial was in compliance with the covered benefit criteria and upheld. (Exhibit A.33-34).I

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).

Here, the MHP argues that it is required by federal and state law, and MDCH policy and procedure, to follow the drug formulary for drug coverages. For the drug Harvoni, the MDCH Pharmacy and Therapeutics Committee has not made final recommendations

for coverage. Thus, as it is not on the MDCH Drug Formulary, the drug is not a covered benefit for Medicaid Health Plan enrollees, including Meridian Health Plan members.

Appellant argues that he needs this drug, the situation is urgent, and that his condition will deteriorate.

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 MHP'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 MHP erred in denying Harvoni. Evidence of record is that the MHP, as a subcontractor of MDCH was required to deny the drug at this time. Thus, under the above authority, based on these facts, this ALJ must uphold the denial.

It is noted that the manufacturer of Harvoni has, at times, set up the drug for individuals who are not covered without a fee. Such an arrangement is outside the purview of the MHP; Appellant's physician, or, the MHP may be able to assist Appellant in contacting the drug company. That is not reviewed here; however, it may benefit Appellant if he were to pursue the same.

The Appellant failed to satisfy his burden of proving by a preponderance of the evidence that the MHP improperly denied his PA request for Harvoni. Thus, this ALJ must uphold the denial as it complies with federal and state requirements.

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 the drug Harvoni was proper.

IT IS THEREFORE ORDERED that:

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

Janice Spodarek
Administrative Law Judge
for Nick Lyon, Director
Michigan Department of Community Health

Date Signed: [redacted]

Date Mailed: [redacted]

JS/[redacted]

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.