RICK SNYDER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
Christopher Seppanen
Executive Director

MIKE ZIMMER
DIRECTOR

[redacted]

Date Mailed: [redacted]
MAHS Docket No.: 16-000435
Agency No.: [redacted]
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Colleen Lack

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], the Petitioner, appeared on her own behalf. [redacted], friend, appeared as a witness for the Petitioner. [redacted], Assistant General Counsel, represented the Medicaid Health Plan (MHP), Meridian Health Plan. [redacted], Manager Specialty Pharmacy, appeared as a witness for the MHP.

During the hearing proceedings, the MHP's Administrative Hearing packet was admitted as Exhibit A, pp. 1-36.

ISSUE

Did the Medicaid Health Plan properly deny Petitioner's request for the medication Harvoni?

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 Medicaid beneficiary enrolled in the Respondent MHP.

2. On or about [redacted], the MHP received a prior authorization request submitted on behalf of Petitioner by her doctor and requesting the medication Harvoni. (Exhibit A, p. 6)

3. At the time the prior authorization request was processed, Harvoni was not found on the Medicaid Pharmaceutical Product List (MPPL) or the Managed Care Common Formulary.

4. On [redacted], the MHP sent Petitioner and her doctor written notice that the prior authorization request was denied. (Exhibit A, pp. 7-16)

5. The notice stated the reason for the denial was that Harvoni is not a covered benefit on the 2015 MHP Medicaid Formulary. (Exhibit A, p. 7)

6. On [redacted], the Michigan Administrative Hearing System (MAHS) received the request for hearing filed in this matter. (Exhibit A, pp. 3-4)

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.

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 Medicaid Health Plans.

The Respondent is one of those MHPs and, as provided in the Medicaid Provider Manual (MPM), is responsible for providing covered services pursuant to its contract with the Department:

> The Michigan Department of Health and Human Services (MDHHS) contracts with Medicaid Health Plans (MHPs), selected through a competitive bid process, to provide services to Medicaid beneficiaries. The selection process is described in a Request for Proposal (RFP) released by the Office of Purchasing, Michigan Department of Technology, Management and Budget. The MHP contract, referred to in this chapter as the Contract, specifies the beneficiaries to be served, scope of the benefits, and contract provisions with which the MHP must comply. Nothing in this chapter should be construed as requiring MHPs to cover services that are not included in the Contract. A copy of the MHP contract is available on the MDHHS website. (Refer to the Directory Appendix for website information.)

> MHPs must operate consistently with all applicable published Medicaid coverage and limitation policies. (Refer to the General Information for Providers and the Beneficiary Eligibility chapters of this manual for additional information.) Although MHPs must provide the full range of covered services listed below, MHPs may also choose to provide services over and above those specified. MHPs are allowed to develop prior authorization requirements and utilization management and review criteria that differ from Medicaid requirements. The following subsections describe covered services, excluded services, and prohibited services as set forth in the Contract.
>
> *MPM, October 1, 2015 version*
> *Medicaid Health Plan Chapter, page 1*
> *(Emphasis added by ALJ)*

Regarding prior authorization, the Pharmacy section of the MPM states:

> **8.2 PRIOR AUTHORIZATION REQUIREMENTS**
>
> PA is required for:
>
> - Products as specified in the MPPL. Pharmacies should review the information in the Remarks as certain drugs may have PA only for selected age groups, gender, etc. (e.g., over 17 years).
> - Payment above the Maximum Allowable Cost (MAC) rate.
> - Prescriptions that exceed MDHHS quantity or dosage limits.
> - Medical exception for drugs not listed in the MPPL.
> - Medical exception for non-covered drug categories.
> - Acute dosage prescriptions beyond MDHHS coverage limits for H2 Antagonists and Proton Pump Inhibitor medications.
> - Dispensing a 100-day supply of maintenance medications that are beneficiary-specific and not on the maintenance list.

- Pharmaceutical products included in selected therapeutic classes. These classes include those with products that have minimal clinical differences, the same or similar therapeutic actions, the same or similar outcomes, or have multiple effective generics available.

MPM, October 1, 2015 version
Pharmacy Chapter, page 14
(Emphasis added by ALJ)

Similarly, the introduction section of the Michigan Department of Health and Human Services Managed Care Common Formulary states:

> In order to streamline drug coverage policies for Medicaid and Healthy Michigan Plan members and providers, the Michigan Department of Health and Human Services (MDHHS) has created a formulary that is common across all contracted Medicaid Health Plans (MHPs) for the next Comprehensive Health Plan Contract. The development of the Common Formulary is required under Section 1806 of Public Act 84 of 2015.
>
> Drugs Reimbursed through Fee-For-Service Benefit (Carve-Out)
>
> The list of drugs that are currently reimbursed through the Fee-for-Service benefit will remain unchanged. This list can be found at **Michigan.fhsc.com >> Providers >> Drug Information >> Medicaid Health Plan Carve Out.**
>
> ***
>
> Medicaid Health Plans May Be Less Restrictive
>
> As part of the Common Formulary, minimum requirements will be established for drug utilization management policies such as quantity limits, age and gender edits, prior authorization criteria and step therapies. MHPs may be less restrictive, but not more restrictive, than the coverage parameters of the Common Formulary.
>
> Standard Prior Authorization Form
>
> A standard prior authorization form, FIS 2288, was created to simplify the process of requesting prior authorization for

prescription drugs. The form is available at **Michigan.gov/difs >> Forms >> Insurance.**

Michigan Pharmaceutical Product List

As a reminder, with the exception of products that are carved out, MHPs must have a process to approve provider requests for any prescribed medically appropriate product identified on the Medicaid Pharmaceutical Product List (MPPL), found at **Michigan.fhsc.com >> Providers >> Drug Information >> MPPL and Coverage Information.** Products that are listed on the MPPL but are not listed on the MCO Common Formulary are available for coverage consideration through a non-formulary prior authorization process.

Medically Accepted Indications

Medically accepted indications will also be considered for approval. Medically accepted indications include any use of a drug which is approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in the compendia listed in Section 1927(g)(l)(B)(i) of the Social Security Act.

http://www.michigan.gov/documents/mdhhs/Managed_Care_Common_Formulary_Listing_506275_7.pdf

This medically accepted indications provision in particular, is consistent with the Social Security Act § 1927(d), *42 USC 1396r-8(d)*, which provides as follows:

LIMITATIONS ON COVERAGE OF DRUGS –

(1) PERMISSIBLE RESTRICTIONS –

(A) A state may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

A state may exclude or otherwise restrict coverage of a covered outpatient drug if –

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6);

(ii) the drug is contained in the list referred to in paragraph (2);
(iii) the drug is subject to such restriction pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or
(iv) the State has excluded coverage of the drug from its formulary in accordance with paragraph 4.

(2) LIST OF DRUGS SUBJECT TO RESTRICTION –The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.
(B) Agents when used to promote fertility.
(C) Agents when used for cosmetic purposes or hair growth.
(D) Agents when used for the symptomatic relief of cough and colds.
(E) Agents when used to promote smoking cessation.
(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
(G) Nonprescription drugs.
(H) Covered outpatient drugs, which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
(I) Barbiturates
(J) Benzodiazepines

(3) UPDATE OF DRUG LISTINGS.—The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) REQUIREMENTS FOR FORMULARIES — A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3)).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer, which has entered into and complies with an agreement under subsection (a) (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act but is a medically accepted indication, based on information from appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) <u>The state plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph</u> (5),

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

(5) REQUIREMENTS OF PRIOR AUTHORIZATION PROGRAMS — A State plan under this title may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval –

(A) Provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
(B) Except with respect to the drugs referred to in paragraph (2) provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(Emphasis added by ALJ)

42 SC 1396r-8(k)(6) MEDICALLY ACCEPTED INDICATION -

The term “medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

The MHP explained that Petitioner’s prior authorization request for Harvoni was denied because this medication was not a covered benefit on the MHP Medicaid Formulary or the MPPL. The MHP acknowledged that it did not consider medical necessity when Petitioner’s prior authorization request was denied. (MHP Testimony; Exhibit A, pp. 1 and 4) The Manager Specialty Pharmacy testified that Harvoni was not a covered benefit until the beginning of [redacted], when the state made their determination regarding coverage of this medication. Accordingly, it appears that at the time of this prior authorization request, Harvoni was just not listed in the MPPL or the MHP Medicaid Formulary because the state had not yet made their coverage determination.

The recent Michigan Department of Health and Human Services (MDHHS) coverage determination was to make Harvoni one of the drugs reimbursed through the Fee-for-Service benefits as a carve-out medication. Accordingly, if he has not already done so, Petitioner’s doctor may wish to file another prior authorization request for Harvoni on Petitioner’s behalf as a care-out medication through Fee-For-Service benefits. The MHP indicated they would be able to contact Petitioner’s doctor’s office and let them know about the MDHHS determination for this medication and the carve-out process.

The MHP’s denial of Petitioner’s prior authorization request without any consideration of medical necessity is not fully supported by the above cited policy and law. It is understood that at the time the prior authorization request was processed, MDHHS had not made a coverage determination for Harvoni, therefore it was not listed on the MPPL or the Managed Care Common Formulary. The above cited MPM provisions require that MHPs must operate consistently with all applicable published Medicaid coverage and limitation policies. Under the pharmacy section of the MPM, prior authorization is

required for medical exception for drugs not listed in the Medicaid Pharmaceutical Product List (MPPL). This suggests that if a medication is not listed in the MPPL or the Managed Care Common Formulary, such as when the MDHHS coverage determination is pending, any request a MHP receives for the medication should be subject to prior authorization for a medical exception. Additionally, the introduction section of the Michigan Department of Health and Human Services Managed Care Common Formulary does not require the MHP to deny a medication that is not listed. Rather, it states that MHPs may be less restrictive, but not more restrictive, than the coverage parameters of the Common Formulary. While there is language in the introductory section addressing how a MHP should address products listed on the MPPL but not in the Managed Care Common Formulary, it does not appear that there is any specific direction for when the product is not listed on the MPPL, such as when the MDHHS coverage determination is pending. Lastly, the introduction section of the Michigan Department of Health and Human Services Managed Care Common Formulary also states that medical accepted indications will also be considered for approval.

Overall, the above cited authority does not support the MHP's decision to deny Petitioner's prior authorization request for Harvoni without any consideration of medical necessity. However, because MDHHS has since determined that Harvoni is a carve out medication, the MHP would be unable to re-consider Petitioner's prior authorization request. Accordingly, the MHP's denial is upheld.

DECISION AND ORDER

The Administrative Law Judge, based on the above Findings of Fact and Conclusions of Law, decides that the MHP's determination to deny Petitioner's prior authorization request for Harvoni is upheld.

IT IS, THEREFORE, ORDERED that:

The Medicaid Health Plan's decision is **AFFIRMED**.

Colleen Lack

CL/cg

Colleen Lack
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]

Community Health Rep [redacted]