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: October 27, 2016
MAHS Docket No.: 16-012300
Agency No.: [redacted]
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Steven Kibit

DECISION AND ORDER

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

After due notice, a telephone hearing was held on October 25, 2016. Petitioner appeared and testified on her own behalf. [redacted], a Clinical Pharmacist with Magellan Medicaid Administration (MMA), represented the Michigan Department of Health and Human Services (DHHS or Department).

ISSUE

Did the Department properly deny Petitioner's prior authorization requests 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. MMA contracts with the Department to review prior authorization requests for specified medications. (Testimony of Respondent's representative).

2. On July 13, 2016, MMA received a prior authorization request submitted on Petitioner's behalf by a [redacted] and requesting the medication [redacted] for Petitioner. (Exhibit A, pages 8-22).

3. The request form and attached medical documentation indicated that Petitioner had been diagnosed Chronic Hepatitis C, but that she had a Metavir score of F0-F2 and no history of HIV, severe renal impairment, or other comorbidities. (Exhibit A, page 9).

4. After finding that the request did not meet Michigan Medicaid Clinical and PDL Criteria, MMA forwarded the request to the Department for a physician review. (Testimony of Respondent's representative).

5. On July 13, 2016, a [redacted] reviewed the request and determined that it should be denied. (Exhibit A, page 23).

6. That same day, she emailed MMA and advised it that the request should be denied on the basis that:

> Deny, current Medicaid criteria for treatment is that patients are in the most severely affected, classified as F3 and F4 by serum markers imaging or have certain comorbid conditions. From the information presented this patient does not meet this criteria.
>
> *Exhibit A, page 23*

7. MMA then sent Petitioner's doctor an electronic notice of denial. (Exhibit A, page 24).

8. On July 14, 2016, MMA also sent Petitioner written notice that the prior authorization request for Harvoni has been denied. (Exhibit A, page 25).

9. In that written notice, MMA stated that Petitioner's prior authorization request was denied because it did not meet criteria. (Exhibit A, page 25).

10. On July 21, 2016, another prior authorization request for Harvoni was received. (Testimony of Respondent's representative).

11. In addition to the same clinical information as before, the second prior authorization request also included a Letter of Medical Necessity from Dr. [redacted]. (Exhibit A, pages 6-7).

12. In that letter, Dr. [redacted] stated, among other things, that:

> Hepatitis C is a curable virus, and waiting to treat until the disease has progressed enough to cause life threatening complications such as live failure and hepatocellular carcinoma is unnecessary and not supported by National guideline recommendations.
>
> *Exhibit C, page 6*

13. MMA again forwarded the request to the Department for a physician review. (Testimony of Respondent's representative).

14. On July 21, 2016, a Dr. [redacted] reviewed the second request and determined that it should also be denied. (Exhibit A, page 26).

15. That same day, she emailed MMA and advised it that the request should be denied on the basis that:

> Deny, does not meet current Medicaid criteria. Medicaid has begun Hep C treatment with patients that are either F3, F4, co-infected with HIV, post liver transplant or who have other Hep C co-morbidities.
>
> *Exhibit A, page 26*

16. MMA then sent Petitioner's doctor an electronic notice of denial. (Exhibit A, page 27).

17. On July 22, 2016, MMA also sent Petitioner written notice that the second prior authorization request for Harvoni has been denied. (Exhibit A, page 28).

18. In that written notice, MMA stated that Petitioner's prior authorization request was denied because it did not meet criteria. (Exhibit A, page 28).

19. On August 3, 2016, MMA received a third prior authorization request submitted on Petitioner's behalf and requesting Harvoni, with only the same letter from Petitioner's doctor in support. (Exhibit A, pages 30-31).

20. On August 4, 2016, MMA then sent Petitioner's doctor notice that the request had already been previously reviewed and denied by the Department on July 13, 2016 and July 21, 2016, with letters of denial sent to Petitioner, and that the physician must submit new clinical documentation if she wanted reconsideration of the decisions. (Exhibit A, pages 29, 32).

21. On September 6, 2016, the Michigan Administrative Hearing System (MAHS) received the request for hearing filed by Petitioner with respect to the above denials. (Exhibit A, page 2).

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.

The Social Security Act § 1927(d), 42 USC 1396r-8(d), also provides as follows:

> (d) 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).
>
> (B) 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.

(K) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

* * *

(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) 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 (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.

A Prior Authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(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).
>
> *Exhibit A, pages 43-45*

The Department is, therefore, authorized by federal law to develop both a formulary of approved prescriptions and a prior authorization process.

It has done so and, with respect to initial requests for Harvoni, the Michigan Medicaid Clinical and PDL Criteria provides that the request may only be approved if the patient has, among other things, either a documented Metavir fibrosis score consistent with a Metavir score of F3 or F4; a comorbid condition such as HIV co-infection, prior liver transplant, or severe extra hepatic manifestation of Hepatitis C; or an APRI score greater than or equal to 1.5 or a FIB-4 score greater than or equal to 3.25. *See* Exhibit A, pages 33-34. Moreover, as provided in Respondent's exhibit, both a June 22, 2016 letter from the Department's Chief Medical Officer, and the Minutes to a December 8, 2015 meeting of the MDHHS Pharmacy and Therapeutics Committee, also reflect the Department's determination that requests for Harvoni will be reviewed on a case-by-case basis and that coverage at this time is only being provided for those most severely impacted by Hepatitis C. *See* Exhibit A, pages 38-42.

Accordingly, as testified to by Respondent's witness, MMA forwarded the requests onto the Department for a physician review. The physician reviewers then determined that the requests should be denied as the submitted documentation failed to demonstrate that Petitioner met any of the above criteria.

In response, Petitioner testified that the Department is putting her health at risk and that her Chronic Hepatitis C is not going to go away. Instead, it is only going to worsen and Petitioner questioned why she has to wait until she is severely affected. Petitioner also testified that she is healthy right now, but things can change quickly and that she watched her girlfriend die a horrible death from Hepatitis C.

Petitioner bears the burden of proving by a preponderance of the evidence that Respondent erred in denying her prior authorization requests.

Given the record in this case, Petitioner has failed to meet that burden of proof and the Respondent's decisions must be affirmed. As discussed above, the Department has been authorized by federal law to develop both a formulary of approved prescriptions and a prior authorization process; it has done so; and, with respect to Harvoni, it has made any approval subject to specific guidelines regarding the severity of an applicant's Hepatitis C. It is undisputed that Petitioner does not meet the guidelines for approval and, consequently, the Respondent properly denied Petitioner's requests.

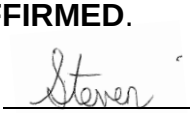
Petitioner's dispute is with the Department's current policy, but the undersigned Administrative Law Judge lacks any authority to overrule or make exceptions to that policy. Similarly, he also lacks jurisdiction to rule on any constitutional arguments or grant equitable remedies. He is bound by the applicable policy and, based on that policy, Respondent's decisions must be affirmed.

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 prior authorization requests for the medication Harvoni.

IT IS, THEREFORE, ORDERED that:

The Department's decisions are **AFFIRMED**.



SK/tm

Steven Kibit
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]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted] [redacted], [redacted] [redacted]