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: July 13, 2016
MAHS Docket No.: 16-006985
Agency No.: [redacted]
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Landis Lain

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 July 12, 2016. Petitioner [redacted] and Patient Advocate, [redacted] appeared to testify on behalf of the Petitioner. [redacted], Clinical Pharmacist represented [redacted] Medicaid Administration (MMA or Department or Respondent).

Respondent's Exhibit A pages 1-161 were admitted as evidence.

ISSUE

Did the Department properly deny Petitioner's request for prior authorization?

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 recipient.

2. Petitioner is diagnosed with Hepatitis C.

3. On March 13, 2016, Magellan Medical Administration clinical staff received a request for a prior authorization for the medication Harvoni from Dr. [redacted], for treatment of Petitioner's Hepatitis C.

4. The Michigan Medicaid program guidelines state that a review by the Michigan Department of Health and Human Services is required for an initial and renewal therapy request.

5. The request was forwarded to [redacted], a physician reviewer with the State of Michigan.

6. Upon review, [redacted] denied the request stating: "Concur with denial. Does not meet the criteria for coverage. The P & T Committee recommendation adding DAAs to the PDL in December, 2015, with coverage consistent with the AASLD guidance. MDHHS has begun coverage for those with greatest liver involvement F3/F4 or individuals that would experience a more rapid progression of the disease. This patient has F0-F2 and no comorbid conditions."

7. [redacted]'s office was notified of the denial.

8. On May 28, 2016 an Adequate Action/Denial Notice was sent to Petitioner.

9. On June 1, 2016, the Michigan Administrative Hearing System received a Request for hearing to contest the denial of the prior authorization request.

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.

Social Security Act § 1927(d), [*42 USC 1396r-8(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).
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

(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).

42 USC 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 Department is authorized by federal law to develop a formulary of approved prescriptions and a prior authorization process. The Department may not approve an outpatient drug when the prescribed use is not approved by federal law or if the use of the medication is not supported by one or more approved compendia described in federal law. Michigan Department of Health and Human Services Pharmacy and Therapeutic Committee in on December 8, 2015 determined that Hepatitis C medicines would be added to the Medicaid formulary with a clinical prior authorization. The clinical authorization should allow treatment to be phased in to address the sickest of the patients to be treated initially. Those with greatest viral involvement (metavir score of F3 and F4 by biopsy or through serum markers/scans) will be addressed first. Prescribers will be specialists or work in collaboration with a specialist (hepatologist, gastroenterologist and infectious disease) Abstinence of IVD and alcohol abuse along with compliance must be attested to by the prescriber in collaboration with the patient and address ways to decrease the risk of reinfection.

In review of this case, Petitioner has liver involvement at a level less than F3 and no comorbid condition. The beneficiary's (Petitioner's) labs are well below the level which is indicative of significant liver involvement. For example, patient's (Petitioner's) APRI value of 0.55 is much lower than an expected value of 1.5, consistent with liver disease at the level of F3. The treating physician, in fact, completed the prior authorization form indicating a metavir score of F0-F2. Clinically, the Petitioner has no signs of significant liver disease, such as ascites (fluid on the abdomen), enlarged spleen, or any other signs. There is no documentation of a comorbid condition such as HIV, renal disease or cryglobulinemia. Because the documentation submitted did not demonstrate the severity of disease which the P 7 T committee recommended, the request for Harvoni was denied.

The Department's evidence clearly showed that the Petitioner had not satisfied the Medicaid criteria for approval of the medication Harvoni for treatment of Hepatitis C based upon the evaluation from one of the aforementioned medical professionals.

In review, based on the clinical judgment of the state reviewing physician and the credible testimony of the Department's witness, the Petitioner has failed to prove, by a preponderance of the evidence, that the Department's denial was improper. The Department's decision to deny prior authorization for Harvoni, based on this record was supported with sufficient evidence and the credible testimony of the Magellan representative.

Petitioner has failed to satisfy the burden of proving by a preponderance of the evidence that the MMA improperly denied the requested medication. The denial is based upon Medicaid benefit exclusion. [redacted] does not have discretion to approve Petitioner's request for items when he fails to meet the medical criteria for eligibility. The decision to deny the request for authorization must be upheld under the circumstances.

Petitioner argues that current treatment would be much less expensive than waiting until his condition has worsened to treat Petitioner with Harvoni. Arguments that the medication is too expensive for Petitioner to pay for out of pocket and that the policy is unfair are equitable arguments to be excused from Department policy.

Petitioner's grievance centers on dissatisfaction with the department's current policy. The Petitioner's request is not within the scope of authority delegated to this Administrative Law Judge pursuant to a written directive signed by the Department of Health and Human Services Director, James K. Haveman, which states:

> Administrative Law Judges have no authority to make decisions on constitutional grounds, overrule statutes, overrule promulgated regulations or overrule or make exceptions to the department policy set out in the program manuals.

Furthermore, administrative adjudication is an exercise of executive power rather than judicial power, and restricts the granting of equitable remedies*. Michigan Mutual Liability Co. v Baker*, 295 Mich 237; 294 NW 168 (1940).

This Administrative Law judge lacks the authority to make equitable determinations. Therefore, the Administrative Law Judge must find that the Magellan Medicaid Administration has established by the necessary competent, material and substantial evidence on the record that it was acting in compliance with Department policy when it determined that Petitioner did not meet the criteria for eligibility to receive the medication Harvoni for treatment of Hepatitis C. The [redacted] Medicaid Administration's decision must be upheld under the circumstances.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, decides that the Magellan Medicaid Administration properly denied Petitioner's request for prior authorization of Harvoni.

IT IS THEREFORE ORDERED that:

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

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LL/[redacted]

Landis Lain
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

Authorized Hearing Rep. [redacted]

DHHS -Dept Contact [redacted]

Petitioner [redacted]

DHHS Department Rep. [redacted]