



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: March 16, 2016
MAHS Docket No.: 15-022209
Agency No.: [REDACTED]
Petitioner: [REDACTED]

ADMINISTRATIVE LAW JUDGE: Landis Y. 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.*, following the Petitioner's request for a hearing.

After due notice, a telephone hearing was held on [REDACTED]. Petitioner appeared and testified. [REDACTED], Assistant General Counsel, appeared to represent [REDACTED] (MHP or Respondent). [REDACTED], Manager of Specialty Pharmacy, appeared to testify on behalf of Respondent.

Respondent's Exhibit A pages 1-98 were admitted as evidence.

ISSUE

Did the MHP properly deny the Petitioner's request for the medication Sovaldi?

FINDINGS OF FACT

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

1. [REDACTED] (MHP) is contracted with the State of Michigan to arrange for the delivery of health services to Medicaid recipients.
2. At all times relevant to this case, Petitioner was enrolled in the MHP.
3. On [REDACTED], Respondent received a Prior Authorization request from Petitioner's physician, requesting the medication Sovaldi for treatment of Hepatitis C.
4. On [REDACTED], Respondent reviewed the request and sent Petitioner a Notice of denial stating: Sovaldi has not yet been determined

by the State of Michigan to be a covered benefit for Medicaid Members.

5. On [REDACTED], the MHP received a provider appeal.
6. On [REDACTED], the provider appeal was evaluated for medical necessity and the decision to deny was upheld.
7. On [REDACTED], Petitioner filed a Request for Hearing with the Michigan Administrative Hearing System (MAHS) to contest the negative action.
8. On [REDACTED], a provider appeal Notice was sent to Petitioner stating that the MHP again denied the authorization request because the Medication was not on the Medicaid Formulary and it did not meet a Formulary exception criteria. (Respondent's Exhibit A page 7)
9. As of [REDACTED], the medication Sovaldi has been placed on a 'carve out' list on a fee for service basis through Magellan. (testimony)

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. 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
- 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
- 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/EPSTD for persons under age 21 [Article 1.020 Scope of [Services], at §1.022 E (1) contract, 2010, p. 22].

(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. 49].

As stated in the Department-MHP contract language above, a MHP "must operate consistent with all applicable Medicaid Provider Manuals and publications for coverages and limitations."

The Michigan Medicaid Formulary does not include the medication Sovaldi as a covered benefit. Sovaldi was not a Medicaid covered benefit at the time of the request. In addition, Petitioner's doctor did not provide a request for an exception to policy that waiting for approval of the drug would put Petitioner's health in jeopardy. Petitioner's physician may ask for an exception, but the prescriber needs to explain the medical reasons why Petitioner needs an exception approved; why other covered drugs are not

medically appropriate for Petitioner's condition, and why waiting to start this drug until after the review process is complete may seriously jeopardize Petitioner's health. If the drug is medically appropriate and waiting to start treatment will cause significant complications to Petitioner's health, the prescriber should provide a new prior authorization request to Magellan for the medication Sovaldi as it has been placed on a 'carve out' list as of [REDACTED] and is now covered by Medicaid through the fee for service program for treatment of Hepatitis C.

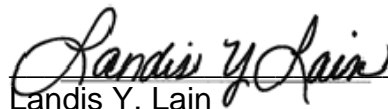
Petitioner has failed to satisfy the burden of proving by a preponderance of the evidence that the MHP improperly denied the requested medication. The denial is based upon Medicaid benefit exclusion. The Medicaid Health Plan (MHP) does not have discretion to approve Petitioner's request for items which are not covered Medicaid benefits. The decision to deny the request for authorization must be upheld.

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 medication Sovaldi was proper under the circumstances.

IT IS THEREFORE ORDERED that:

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



Landis Y. Lain
Administrative Law Judge
for Nick Lyon, Director
Michigan Department of Health and Human
Services

LYL [REDACTED]

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

Petitioner

[REDACTED]

DHHS -Dept Contact

[REDACTED]

Community Health Rep

[REDACTED]