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.: 16-001374
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], mother, represented the Petitioner. [redacted], the Petitioner, appeared and testified. [redacted], Chief Clinical Officer, represented [redacted], the Medicaid Health Plan (MHP). [redacted], Associate Medical Director; [redacted], Pharmacy Claim Supervisor; and [redacted], Grievance Coordinator, appeared as witnesses for the MHP.

During the hearing proceedings, the MHP's Hearing Summary packet was admitted as marked, Exhibits 1-4; and Petitioner's Hearing Request was admitted as Exhibit A, pp. 1-3.

ISSUE

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

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 who is enrolled in the Respondent MHP. (Exhibit 1)

2. On [redacted], the MHP received a prior authorization request for a Xifaxan from the Petitioner's gastroenterologist. The diagnoses listed on the prior authorization request was small bowel bacterial overgrowth. An encounter summary from a [redacted], office visit was included. (Exhibit 2)

3. On [redacted], the MHP sent Petitioner and his doctors' offices a denial notice, in part, stating that the prior authorization request was not authorized because the Food and Drug Administration (FDA) has not approved Xifaxan for the treatment of bacterial overgrowth of bowel. (Exhibit 3)

4. On [redacted], Petitioner's Request for Hearing was received by the Michigan Administrative Hearing System. (Exhibit A)

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 & 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, January 1, 2016, version*
> *Medicaid Health Plans Chapter, p. 1*

Regarding drug categories that are not covered as a benefit, the MPM provides:

> **SECTION 6 – GENERAL NONCOVERED SERVICES**
>
> This section specifies general coverage restrictions. However, drugs in other classes may not be covered. Pharmacies should review the MPPL for specific coverage. When possible, pharmacies are encouraged to suggest alternative covered therapy to the prescriber if a product is not covered.
>
> The following drug categories are **not covered** as a benefit:
>
> - Agents used for anorexia
> - Agents used for weight gain
> - Agents used for cosmetic purposes or hair growth
> - Agents used for symptomatic relief of cough and colds
> - Experimental or investigational drugs
> - Agents used to promote fertility
> - Agents used to promote smoking cessation not on the MPPL
> - Vitamin/Mineral combinations not for prenatal care, end stage renal disease or pediatric fluoride supplementation
> - Covered outpatient drugs that the Labeler seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the Labeler or their designee
> - Covered outpatient drugs where the Labeler limits distribution
> - Proposed less-than-effective (LTE) drugs identified by the Drug Efficacy Study Implementation (DESI) program

- Over-the-counter drugs not on the MPPL
- Drugs of Labelers not participating in the Rebate Program
- Drugs prescribed for "off label" use if there is no generally accepted medical indication in peer reviewed medical literature (Index Medicus), or listing of such use in standard pharmaceutical references such as Drug Facts and Comparisons, AMA Drug Evaluations, American Hospital Formulary Service Drug Information, or DRUGDEX Information Systems
- Drugs prescribed specifically for medical studies
- Drugs recalled by Labelers
- Drugs past CMS termination dates (Refer to the Directory Appendix for CMS website information.)
- Lifestyle agents
- Standard Infant Formulas
- Drugs used to treat gender identity conditions, such as hormone replacement
- Drugs covered by the Medicare Part D benefit
- Drugs not FDA approved or licensed for use in the United States
- Agents used for treatment of sexual or erectile dysfunction

MPM, January 1, 2016, version
Pharmacy Chapter, p. 12

On [redacted], the MHP received a prior authorization request for a Xifaxan from the Petitioner's gastroenterologist. The diagnoses listed on the prior authorization request was small bowel bacterial overgrowth. An encounter summary from a [redacted], office visit was included. (Exhibit 2) On [redacted], the MHP sent Petitioner and his doctors' offices a denial notice, in part, stating that the prior authorization request was not authorized because the FDA has not approved Xifaxan for the treatment of small bowel bacterial overgrowth. (Exhibit 3) The Medical Director testified that Xifaxan is an antibiotic approved for treating specific diseases and is not appropriate for the diagnosis listed on the [redacted] prior authorization request.

The Petitioner and his mother described Petitioner's condition and the minimal improvement there has been with another medication. Petitioner is sick all the time, goes to the bathroom every two hours, and has lots of diarrhea.

Petitioner bears the burden of proving by a preponderance of the evidence that the MHP erred in denying his request for services. While this ALJ sympathizes with the Petitioner's circumstances, the denial of the [redacted], request for Xifaxan must be upheld based on the information available at that time. The diagnoses listed on the prior authorization request was small bowel bacterial overgrowth. (Exhibit 2) There was no evidence presented establishing that the FDA has approved Xifaxan for the

treatment of small bowel bacterial overgrowth or that there is a generally accepted medical indication in peer reviewed medical literature or in standard pharmaceutical references for Xifaxan being prescribed for this "off label" use. Accordingly, the undersigned Administrative Law Judge finds that Petitioner has failed to meet his burden of proof and that the MHP's decision for the [redacted], prior authorization request must therefore be affirmed.

DECISION AND ORDER

The Administrative Law Judge, based on the above Findings of Fact and Conclusions of Law, decides that Medicaid Health Plan properly deny Petitioner's [redacted], prior authorization request for Xifaxan.

IT IS, THEREFORE, ORDERED that:

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

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]

Authorized Hearing Rep. [redacted]

Community Health Rep [redacted]