

STATE OF MICHIGAN
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
FOR THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
P.O. Box 30763, Lansing, MI 48909
(517) 335-2484; Fax: (517) 373-4147

IN THE MATTER OF:

Docket No. 15-016230 MHP

████████████████████

██████████

██████████

Appellant

_____ /

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 Appellant's request for hearing.

After due notice, a telephone hearing was held on ██████████. Appellant appeared and testified on his own behalf. ██████████, Director of Customer Service, represented ██████████, the Respondent Medicaid Health Plan (MHP). ██████████ ██████████, Pharmacy Specialist, appeared as a witness for the Respondent.

ISSUE

Did the MHP properly deny Appellant's prior authorization request for Clomiphene Citrate 50 mg?

FINDINGS OF FACT

The Administrative Law Judge, based upon the competent, material and substantial evidence on the whole record, finds as material fact:

1. Appellant is a █████ year-old Medicaid beneficiary, born ██████████ who is enrolled in the Respondent MHP. (Exhibit A, p 1).
2. On or about ██████████, the MHP received a prior authorization request submitted by Appellant's physician requesting Clomiphene Citrate 50 mg tablets for Appellant. (Exhibit A, pp 10-18; Testimony).
3. On ██████████, the MHP sent Appellant and his physician written notice that the prior authorization request was denied. The denial indicated that Clomiphene Citrate 50 mg was specifically excluded from coverage by Medicaid per the Medicaid Provider Manual and that agents used for the treatment of infertility are not a covered benefit. (Exhibit A, p 8-9; 20-22; Testimony).

4. On ████████████████████, the Michigan Administrative Hearing System (MAHS) received the request for hearing filed in this matter. (Exhibit 1).

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.

In 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 Community Health (MDCH) 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 MDCH 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.

Medicaid Provider Manual
Medicaid Health Plan Chapter
July 1, 2015, p 1

The *Medicaid Provider Manual, Pharmacy Chapter, Section 6, July 1, 2015*, references services that are covered by the MDCH under Medicaid. This section states:

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 or weight loss
- 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

*Medicaid Provider Manual,
Pharmacy Chapter, p 12
July 1, 2015*

Pursuant to the above policy and its contract with the Department, the MHP has developed a drug management program that includes a drug formulary and provides that its covered services are subject to the limitations and restrictions described in the MHP's Medicaid agreement, the MPM, Medicaid bulletins, and other directives.

In this case, the denial of the prior authorization request was based on the fact that Clomiphene Citrate 50 mg tablets are not covered under either the MHP's drug formulary or the MPPL and are specifically excluded from coverage as a medication used to promote fertility. The MHP's Pharmacy Specialist pointed out that Appellant's doctor indicated in the prior authorization request that the medication was being requested for "infertility due to azoospermia (606.0)".

Appellant testified that he went to the doctor about a year ago to have his testosterone levels checked and discovered that his testosterone levels were very low due to varicoceles. Appellant indicated that his doctor told him that he would not recommend traditional treatment for low testosterone because those treatments cause infertility and Appellant, as a young man, did not want to be infertile. Appellant indicated that he then changed doctors and the new doctor mistakenly submitted the prior authorization request for Clomiphene Citrate 50 mg for infertility, even though Appellant is not taking the medication for fertility. Appellant also indicated that he searched the internet after receiving the denial and found several articles indicating that Clomiphene Citrate 50 mg could be prescribed for low testosterone.

In response, the MHP's Pharmacy Specialist indicated that he was unaware of any medical articles indicating that the medication could be used off-label for low testosterone. And, at any rate, there were no articles submitted with the prior authorization request, as would be required if the doctor was requesting the medication for an off-label use.

Given the above policy and evidence, Appellant has failed to satisfy his burden of proving by a preponderance of the evidence that the MHP erred in denying the prior authorization request for Clomiphene Citrate 50 mg. The requested medication is not included on the MHP's formulary or the State of Michigan's MPP and is specifically excluded from coverage as an agent to promote fertility. Here, Appellant's doctor indicated that the medication was being requested for infertility. If Appellant's doctor is requesting the medication for an off-label use, he would need to resubmit the prior authorization request and include documentation supporting said use. Accordingly, the Clomiphene Citrate 50 mg tablets did not meet the coverage criteria under policy and it could not be approved for Medicaid coverage based on the information submitted.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, decides that the MHP properly denied Appellant's prior authorization request for Clomiphene Citrate 50 mg tablets.

IT IS THEREFORE ORDERED that:

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



Robert J. Meade
Administrative Law Judge
for Nick Lyon, Director
Michigan Department of
Health and Human Services

Date Signed: [REDACTED]

Date Mailed: [REDACTED]

RJM/db

cc: [REDACTED]
[REDACTED]
[REDACTED]

***** NOTICE *****

The Michigan Administrative Hearing System order a rehearing on either its own motion or at the request of a party within 30 days of the mailing date of this Decision and Order. The Michigan Administrative Hearing System will not order a rehearing on the Department's motion where the final decision or rehearing cannot be implemented within 90 days of the filing of the original request. The Appellant may appeal the Decision and Order to Circuit Court within 30 days of the receipt of the Decision and Order or, if a timely request for rehearing was made, within 30 days of the receipt of the rehearing decision.