STATE OF MICHIGAN
MICHIGAN ADMINISTRATIVE HEARING SYSTEM
FOR THE DEPARTMENT OF COMMUNITY HEALTH
P.O. Box 30763, Lansing, MI 48909
(877) 833-0870; Fax: (517) 373-4147

IN THE MATTER OF:

[redacted],

Docket No. 2013-10335 QHP
Case No. [redacted]

Appellant
_____/

DECISION AND ORDER

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

After due notice, a hearing was held on [redacted]. [redacted], the Appellant, appeared on her own behalf. [redacted], husband, appeared as a witness for the Appellant. [redacted], Inquiry Dispute Appeals Resolution Coordinator, represented [redacted] of Michigan, the Medicaid Health Plan (hereinafter MHP). [redacted], Medical Director, appeared as a witness for the MHP.

ISSUE

Did the MHP properly deny the Appellant's request for Requip (Ropinirole) 0.5mg tablets?

FINDINGS OF FACT

Based upon the competent, material, and substantial evidence presented, I find, as material fact:

1. The Appellant is a Medicaid beneficiary who is enrolled in the Respondent MHP, Molina Healthcare of Michigan.

2. On [redacted], the MHP received a prior authorization request for a Requip 0.5 mg tablets from the Appellant's doctor. The request and the attached medical documentation indicated diagnoses of myalgia and myositis. (Exhibit 1, pages 4-7)

3. The FDA has approved Requip (Ropinirole) for the treatment of Parkinson's disease and Restless Leg Syndrome. (Exhibit 1, page 2)

4. On [redacted], the MHP sent the Appellant and her doctor's office a denial notice, stating that the request for Ropinirole 0.5mg tablets was not authorized based on Drug Facts and Comparisons criteria. (Exhibit 1, pages 9-12)

5. On [redacted], the Appellant's Request for Hearing was received by the Michigan Administrative Hearing System.

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 Medicaid Health Plans.

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 (List omitted by Administrative Law Judge). 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.
>
> *Section 1.022(E)(1), Covered Services.*
> *MDCH contract (Contract) with the Medicaid Health Plans,*
> *October 1, 2009.*

> (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.

Section 1.022(AA), Utilization Management,
MDCH contract (Contract) with the Medicaid Health Plans*,*
October 1, 2009.

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 pertinent sections of the Michigan Medicaid Provider Manual (MPM) 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

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On [redacted], the MHP received a prior authorization request for a Requip 0.5 mg tablets from the Appellant's doctor. The request and the attached medical documentation indicated diagnoses of myalgia and myositis. (Exhibit 1, pages 4-7) The FDA has approved Requip (Ropinirole) for the treatment of Parkinson's disease and Restless Leg Syndrome. (Exhibit 1, page 2) The Drug Facts and Comparisons for this medication only lists indications for Parkinson's disease and Restless Leg Syndrome. (Exhibit 1, page 8) The Medical Director testified that the Appellant's prior authorization request for Requip would be an off label use, which would also be considered to be experimental, and is not covered under the MDCH policy. (Medical Director Testimony) Accordingly, on [redacted], the MHP sent the Appellant and her doctor's office a denial notice, stating that the request for Ropinirole 0.5mg tablets was not authorized based on Drug Facts and Comparisons criteria. (Exhibit 1, pages 9-12)

The Appellant disagrees with the denial and explained that her condition is like Restless Leg Syndrome, but affects her whole body. The Appellant has involuntary movements. This includes her legs, arms, face and back. The Appellant shakes the whole day. The Appellant has previously been diagnosed with Parkinson's disease and MS, but her current diagnosis is fibromyalgia with severe chronic fatigue. The twitches can be so hard they wake her up at night with pain. This also wakes her husband. When the Appellant was taking Requip, she did not have the twitching and was able to sleep. (Appellant Testimony) The Appellant's husband confirmed his wife's testimony about the bad twitches at night, and that she did not have them when taking Requip. The Appellant's husband indicated the intense twitches hit the Appellant when she reaches REM sleep. (Husband Testimony)

The documentation provided with the prior authorization request only listed diagnoses of myalgia and myositis. (Exhibit 1, pages 5-7) While this ALJ understands the Appellant's condition is like Restless Leg Syndrome or Parkinson's disease, there is no evidence that Requip had been FDA approved for her condition nor that the prescribed off label use is a 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. Accordingly, the MHP's denial must be upheld based on the available information.

DECISION AND ORDER

The ALJ, based on the above findings of fact and conclusions of law, decides that the MHP properly denied the Appellant's request for Requip (Ropinirole) 0.5mg tablets based on the submitted information.

IT IS THEREFORE ORDERED that:

The MHP's decision is AFFIRMED.

\s\

Colleen Lack
Administrative Law Judge
for James K. Haveman, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: 1/22/2013

***** NOTICE *****

The Michigan Administrative Hearing System may 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.