STATE OF MICHIGAN
STATE OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
FOR THE DEPARTMENT OF COMMUNITY HEALTH
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IN THE MATTER OF:

[redacted]

Appellant
_____/

Docket No. 2010-44988 QHP
Case No. [redacted]

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 Appellant's request for a hearing.

After due notice, a hearing was held on [redacted]. The Appellant, [redacted], appeared on her own behalf. [redacted] Director of Member Services, represented the Medicaid Health Plan (MHP), Health Plan of Michigan. [redacted], Medical Director for Utilization Management (UM), [redacted], Director of Care Management, and [redacted], Pharmacist, appeared as witnesses for the MHP.

ISSUE

Did the MHP properly deny Appellant's request for Rituxan?

FINDINGS OF FACT

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

1. Appellant is a [redacted] Medicaid beneficiary enrolled in the MHP.

2. The Appellant has been diagnosed with Myasthenia Gravis. (Exhibit 1, page 6). She received two cycles of Rituxan—one in [redacted] and one in [redacted] which were paid for by a care foundation, and which were successful in treating her condition. (Testimony of [redacted])

3. On [redacted], the MHP received a prior-authorization request from Appellant's doctor for the approval of two cycles of Rituxan injections. (Exhibit 1, page 6)

4. On [redacted], the MHP sent the Appellant and her doctor notice that her request for Rituxan injections could not be authorized because the medication is not been approved by the FDA[1] for use in treating Myasthenia Gravis and there are other FDA-approved medications available to treat that condition. (Exhibit 1, pages 11-13)

5. The Appellant filed an internal grievance/appeal of the denial, which was denied on [redacted]. (Exhibit 1, pages 14-15)

6. On [redacted], the State Office of Administrative Hearings and Rules received Appellant's hearing request, protesting the denial of Rituxan injections. (Exhibit 1, page 5)

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 [redacted], 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 Medicaid Health Plans.

> 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

[1] Food and Drug Administration

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)(1) and (2), Utilization Management, Contract, October 1, 2009.*

The DCH-MHP contract provisions require the MHP to establish prior-approval procedures for UM purposes. The MHP witnesses testified that the prior-authorization request in this case was denied because Rituxan is not FDA-approved for the treatment of the Appellant's condition (Myasthenia Gravis), and the Appellant did not satisfy the criteria for an exception, i.e., approval of an off-label use of the medication. That exception criteria is as follows:

Pharmaceutical coverage includes coverage for an off-label use of a federal food and drug administration approved drug and the reasonable cost of supplies medically necessary to administer the drug will apply if all of the following conditions are met:

(a) The drug is approved by the federal food and drug administration.

(b) The drug is prescribed by an allopathic or osteopathic physician for the treatment of either of the following:

i. A life-threatening condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan's formulary procedures.

ii. A chronic and seriously debilitating condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan's formulary procedures.

(c) The drug has been recognized for treatment for the condition for which it is prescribed by 1 of the following:

i. The American medical association drug evaluations.

ii. The American hospital formulary service drug information.

iii. The United States Pharmacopoeia Dispensing Information.

iv. Two articles utilizes [sic] prospective, randomized trials comparing the drug to a placebo and the drug considered standard of care from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective if there is clear and convincing

> contradictory evidence presented in a major peer-reviewed medical journal the drug will not be approved.
>
> (Exhibit 1, page 16)

The MHP's Medical Director explained that in this case there was no evidence that Rituxan has been recognized by the medical community for treatment of Myasthenia Gravis. (Exhibit 1, page 16) Indeed, an independent medical reviewer determined that that use of Rituxab for treatment of Myasthenia Gravis would be both experimental and investigational. (Testimony of [redacted])

The Appellant testified that she has tried other medications, including Plasmapherisis, Cellcept, oral steroids, and IVIG, but they have not been successful in managing her condition. She explained that the form of Myasthenia Gravis that she suffers from is relatively new and that different things are being tried around the country to treat it. However, she stated that the Rixutab has been successful in controlling her symptoms, which include a raspy voice, blurred vision, and shaking episodes.

While this Administrative Law Judge sympathizes with the Appellant's circumstances, I must uphold the MHP's denial. The MHP's prior-approval process is consistent with Medicaid policy and allowable under the DCH-MHP contract provisions. And the Appellant failed to refute the MHP's evidence that Rituxan is not FDA-approved for treatment of her condition or that it has been accepted by the medical community for treatment of that condition. However, the Appellant may re-apply for prior approval at any time should she obtain the required documentation to support an exception for off-label use of the drug.

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 request for Rituxan injections.

IT IS THEREFORE ORDERED that:

The Medicaid Health Plan's decision is AFFIRMED.

_____

Kristin M. Heyse
Administrative Law Judge
for Janet Olszewski, Director
Michigan Department of Community Health

[redacted]
Docket No. 2010-44988 QHP
Decision and Order

cc: [redacted]

Date Mailed: 10/22/2010

***** NOTICE *****

The State Office of Administrative Hearings and Rules 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 State Office of Administrative Hearings and Rules 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.