STATE OF MICHIGAN
STATE OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
FOR THE DEPARTMENT OF COMMUNITY HEALTH
P.O. Box 30763, Lansing, MI 48909
(877) 833-0870; Fax: (517) 334-9505

IN THE MATTER OF:

[redacted]

Appellant
_____/

Docket No. 2010-54994 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], represented herself. [redacted], Director of Member Services, represented the [redacted]), Health Plan of Michigan, Inc. [redacted], Medical Director, and [redacted], Director of Pharmacy, appeared as witnesses for the MHP.

ISSUE

Did the MHP properly deny the Appellant's request for Lidoderm Patches?

FINDINGS OF FACT

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

1. The Appellant is a [redacted] Medicaid beneficiary, who has been enrolled in the MHP since [redacted].

2. The Appellant has a history of back pain. (Exhibit 1, page 5) She has tried other medications. However, the Lidoderm Patches have been successful in treating her condition. (Testimony of [redacted])

3. On [redacted], the [redacted] received a prior-authorization request from the Appellant's doctor for the approval of Lidoderm Patches. (Exhibit 1, page 5)

4. On [redacted], the [redacted] sent the Appellant and her doctor notice that her request for Lidoderm Patches could not be authorized because the medication has not been approved by the FDA[1] for use in treating back pain and there are other FDA-approved medications available to treat that condition. (Exhibit 1, pages 15-18)

5. On [redacted], the Appellant filed for an Internal Greivance/Appeal of the [redacted] denial. The [redacted] again upheld its original denial. (Exhibit 1, pages 20-23)

6. On [redacted], the State Office of Administrative Hearings and Rules received the Appellant's hearing request, contesting the denial of Lidoderm Patches.

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 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-[redacted] contract provisions require the [redacted] to establish prior-approval procedures for [redacted] purposes. The [redacted] witnesses testified that the prior-authorization request in this case was denied because Lidoderm Patches are not FDA-approved for the treatment of the Appellant's condition (chronic back pain), and the Appellant did not satisfy the criteria for an exception, i.e., approval of an off-label use of the medication.

The [redacted]'s Medical Director explained that Lidoderm Patches have been approved by the FDA only for treatment of post-herpetic neuralgia. He further stated that an exception may be granted in cases where the off-label use is widely employed or otherwise generally accepted by the medical community. But there is no evidence to support that the patches have been recognized as an acceptable treatment for chronic back pain. The [redacted] further stated that an exception form was forwarded to the Appellant's physician on [redacted]. But that form was never returned to the [redacted].

The Appellant testified that the Lidoderm Patches work for her, and she cannot understand why the patches were previously approved but are now not being approved. She further stated that she does not believe that her physician ever received the exception form in this case because he is very conscientious and would have returned it to the [redacted]

While this Administrative Law Judge sympathizes with the Appellant's circumstances, I must uphold the [redacted]s denial. The [redacted]s prior-approval process is consistent with Medicaid policy and allowable under the DCH[redacted] contract provisions. And the Appellant failed to refute the [redacted]s evidence that Lidoderm Patches are 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 [redacted] properly denied Appellant's request for Lidoderm Patches.

IT IS THEREFORE ORDERED that:

The MHP's decision is AFFIRMED.

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

cc: [redacted]

Date Mailed: 12/14/2010

***** 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.