

**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:

Docket No. 15-011468 MHP

████████████████████

██████████

██████████

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 ██████████. The Appellant's mother ██████████ appeared on the Appellant's behalf and offered testimony. ██████████, Grievances and Appeals Lead, represented ██████████, the Medicaid Health Plan (hereinafter MHP).

ISSUE

Did the MHP properly deny Appellant's request for the drug Namenda 10 mg Tab?

FINDINGS OF FACT

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

1. The Appellant is a ██████-year-old male Medicaid beneficiary born ██████████ suffering from Autism who is currently enrolled in the MHP. (Exhibit A, p. 1; Testimony.)
2. On ██████████ submitted to the MHP a prior authorization request on behalf of the Appellant requesting the drug Namenda 10 mg Tab to treat the Appellant's autism. (Exhibit A, p 12.)
3. On ██████████ submitted to the MHP a prior authorization request on behalf of the Appellant requesting reconsideration of the ██████████ request. (Exhibit A, pp 6-37; Testimony.)
4. On ██████████, the MHP sent the Appellant and ██████████ a letter denying the ██████████ prior authorization request. The letter indicated the drug Namenda was not approved by the FDA to treat autism, did not

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meet the MHP's drug policy coverage criteria and did not meet their off label use requirements. (Exhibit A, pp 13-15.)

5. On or around [REDACTED], the MHP reviewed [REDACTED] request and on [REDACTED] sent the Appellant and [REDACTED] a letter indicating [REDACTED] request was denied. (Exhibit A, p 39; Testimony.)
6. At all times relevant to the hearing, the FDA had not approved the drug Namenda to treat autism. (Exhibit A, pp 45-50; Testimony.)
7. On [REDACTED], MAHS received a Request for Hearing from the Appellant. (Exhibit A, p 4.)

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. Contractors must operate consistent with all applicable Medicaid provider manuals and publications for coverage(s) and limitations. (Emphasis added by ALJ)* 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 1-Z.

*Article II-G, Scope of Comprehensive Benefit Package.
MDCH contract (Contract) with the Medicaid Health Plans,
September 30, 2004.*

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The major components of the Contractor's utilization management plan must encompass, at a minimum, the following:

- Written policies with review decision criteria and procedures that conform to managed health care industry standards and processes.
- A formal utilization review committee directed by the Contractor's medical director to oversee the utilization review process.
- Sufficient resources to regularly review the effectiveness of the utilization review process and to make changes to the process as needed.
- An annual review and reporting of utilization review activities and outcomes/interventions from the review.

The Contractor must establish and use a written prior approval policy and procedure for utilization management purposes. The Contractor may not use such policies and procedures to avoid providing medically necessary services within the coverage(s) 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 utilization management decisions be made by a health care professional who has appropriate clinical expertise regarding the service under review.

*Article II-P, Utilization Management, Contract,
September 30, 2004.*

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 section of the Michigan Medicaid Provider Manual (MPM) states "[m]edicaid covers medically necessary surgical procedures."

*MPM, October 1, 2014
Practitioner, page 60*

The MHP provides coverage for off-label use of a FDA approved drug when there is evidence the drug has been recognized for the treatment for which it has been prescribed. Acceptable evidence includes information from:

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- The American Hospital formulary Service Drug Information
- Thomson Micromedex DrugDex or DrugPoints
- The National comprehensive cancer Network (NCCN) Guidelines.
- Clinical Pharmacology
- Two articles from peer-reviewed medical literature:
 - Whose primary purpose is to evaluate the use of the drug for the off-label diagnosis for which it is requested, and
 - That support the proposed off-label use as generally safe and effective for the patient's diagnosis.

The MHP witness testified the information supplied with the prior-authorization requests did not satisfy the off-label requirements and did not meet their MHP drug policy coverage criteria.

The Appellant's mother argued the drug Namenda provided the most benefit and worked better than other drugs that were tried. Specifically, the Appellant's mother indicated the number of meltdowns were significantly reduced when taking Namenda and that without Namenda the Appellant was at risk of self-injuring himself.

The MHP provided sufficient evidence that its formulary and medication prior approval process is consistent with Medicaid policy and allowable under the DCH-MHP contract provisions. The MHP demonstrated that at the time the denial decision was made, the Appellant did not meet criteria for approval of Namenda because the available information did not satisfy the off-label use.

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 the medication Namenda based on the available information.



Corey A. Arendt
Administrative Law Judge
for Director, Nick Lyon

Michigan Department of Health and Human Services

Date Signed: [REDACTED]

Date Mailed: [REDACTED]

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CAA/db

cc:



***** 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.