**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],

Docket No. 2010-40571 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 [redacted]. The [redacted] appeared on behalf of the Appellant. [redacted], represented [redacted] the Medicaid Health Plan (MHP). [redacted] and [redacted], appeared as witnesses for the MHP.

## ISSUE

Did the MHP properly deny the Appellant's request for Desmopressin Nasal Spray?

## FINDINGS OF FACT

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

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

2. The Appellant has been diagnosed with nocturnal enuresis. (Exhibit 1, page 9)

3. On [redacted], the MHP received a request from the Appellant's pediatrician for prior authorization of Desmopressin Nasal Spray to treat the Appellant's nocturnal enuresis. (Exhibit 1, page 9)

4. The Appellant has also used the pill form of Desmopressin, but it is not as effective as the nasal spray. (Mother's Testimony)

5. On [redacted], the Food and Drug Administration (FDA) issued an alert regarding Desmopressin Acetate. Specifically, there is a risk of developing severe hyponatremia that can result in seizures and death. Children treated with the intranasal formulations are particularly susceptible to severe hyponatremia and seizures. The intranasal formulations of Desmopressin Acetate are no longer indicated for the treatment of primary nocturnal enuresis. (Exhibit 2)

6. On [redacted], the MHP sent the Appellant a denial notice, stating because the Desmopressin Nasal Spray is not approved by the FDA for urine incontinence, the request would be considered an off label use of the mediation. The MHP determined that the submitted clinical information does not support the off label use of the drug. (Exhibit 1, pages 10-13)

7. The Appellant's mother requested a formal, administrative hearing contesting the denial on [redacted].

## 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 MHPs.

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, Contract,*
*October 1, 2009.*

The DCH-MHP contract provisions allow prior approval procedures for utilization management purposes. The MHP's Manager of Acute In Patient Services testified that the Appellant's prior-authorization request for Desmopressin Nasal Spray were denied because

of the FDA alert indicating the intranasal formulation is no longer indicated for the primary treatment of nocturnal enuresis. Accordingly, the prior authorization request would be considered off label use of the drug, which was not supported by the submitted clinical information.

The Appellant's mother testified that nocturnal enuresis runs in the family and her other son had to use the nasal spray when he was younger. She explained that the Appellant has tried the pill formulation of Desmopressin, but it does not work as well. Further, she stated the Appellant's prior insurance covered the nasal spray formulation and that the Appellant's doctor indicated the MHP likely was not covering this because it is more expensive than the pill formulation.

As noted in the above cited contract provisions, the MHP "may limit services to those which . . . conform to professionally accepted standards of care." Here, the 2007 FDA alert indicates that due to the risk of hyponatremia and seizures, the nasal formulation of Desmopressin is not indicated as the primary treatment of nocturnal enuresis. (Exhibit 2) The cost of the nasal formulation compared to the pill formulation was not a consideration. Given the FDA alert, the MHP's denial of the Appellant's prior-authorization request was proper.

## 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 Desmopressin Nasal Spray.

**IT IS THEREFORE ORDERED** that:

The MHP's decision is AFFIRMED.

Colleen Lack
Administrative Law Judge
for Janet Olszewski, Director
Michigan Department of Community Health

cc: [redacted]

Date Mailed: 9/15/2010

***** 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.