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. 2013-53617 PA

[redacted]

Appellant
_____/

DECISION AND ORDER

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

After due notice, a hearing was held on [redacted], [redacted] mother and Guardian, represented the Appellant. [redacted] Manager, appeared as a witness for the Appellant. [redacted], CMH Case Manager, was also present. [redacted], Appeals Review Officer, represented the Department. [redacted], RN, Program Review Division, and [redacted], Chief Medical Director, appeared as witnesses for the Department.

ISSUE

Did the Department properly deny the Appellant's prior authorization request for a bladder scanner?

FINDINGS OF FACT

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

1. The Appellant is a [redacted]-year-old Medicaid beneficiary who has multiple diagnoses, including neurogenic bladder, Aicardi Goutieres syndrome, and urinary tract infections. (Exhibit 1, pages 16-22)

2. On or about [redacted] the Department received a prior authorization request for a bladder scanner for the Appellant. (Exhibit 1, pages 7 and 16-41)

3. On [redacted], the Department issued a Notification of Denial to the Appellant stating the prior authorization request was denied under

Section 1.5 of the Medical Supplier Chapter of the Medicaid Provider Manual and specifically because the device is not intended for home use, it is intended for inpatient use under the supervision of a physician.. (Exhibit 1, pages 8-9)

4. On [redacted], the Michigan Administrative Hearing System received the hearing request filed on the Appellant's behalf. (Exhibit 1, page 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.

The Medicaid Provider Manual provides, in pertinent part, as follows:

> **SECTION 1 – PROGRAM OVERVIEW**
>
> This chapter applies to Medical Suppliers/Durable Medical Equipment and Orthotists/Prosthetists.
>
> Providers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) must be enrolled as a Medicare provider effective September 30, 2009. (Refer to the General Information for Providers chapter for additional information.)
>
> The primary objective of the Medicaid Program is to ensure that medically necessary services are made available to those who would not otherwise have the financial resources to purchase them.
>
> The primary objective of the Children's Special Health Care Services (CSHCS) Program is to ensure that CSHCS beneficiaries receive medically necessary services that relate to the CSHCS qualifying diagnosis.
>
> This chapter describes policy coverage for the Medicaid Fee-for-Service (FFS) population and the CSHCS population. Throughout the chapter, use of the terms Medicaid and MDCH includes both the Medicaid and CSHCS Programs unless otherwise noted.

Medicaid covers the least costly alternative that meets the beneficiary's medical need for medical supplies, durable medical equipment or orthotics/prosthetics.

* * *

Durable Medical Equipment (DME)

DME are those items that are Food and Drug Administration (FDA) approved, can stand repeated use, are primarily and customarily used to serve a medical purpose, are not useful to a person in the absence of illness or injury, and can be used in the beneficiary's home. Examples are: hospital beds, wheelchairs, and ventilators. DME is a benefit for beneficiaries when:

- It is medically and functionally necessary to meet the needs of the beneficiary.
- It may prevent frequent hospitalization or institutionalization.
- It is life sustaining.

* * *

1.5 MEDICAL NECESSITY

Medical devices are covered if they are the most cost-effective treatment available and meet the Standards of Coverage stated in the Coverage Conditions and Requirements Section of this chapter.

The medical record must contain sufficient documentation of the beneficiary's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement. The information should include the beneficiary's diagnosis, medical condition, and other pertinent information including, but not limited to, duration of the condition, clinical course, prognosis, nature and extent of functional limitations, other therapeutic interventions and results, and past experience with related items. Neither a physician's order nor a certificate of medical necessity by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician. Information in the medical record must support the item's medical necessity and substantiate that the medical device needed is the most

appropriate economic alternative that meets MDCH standards of coverage.

Medical equipment may be determined to be medically necessary when all of the following apply:

- The service/device meets applicable federal and state laws, rules, regulations, and MDCH promulgated policies.
- It is medically appropriate and necessary to treat a specific medical diagnosis, medical condition, or functional need, and is an integral part of the nursing facility daily plan of care or is required for the community residential setting.
- The function of the service/device:
  - meets accepted medical standards;
  - practices guidelines related to type, frequency, and duration of treatment; and
  - is within scope of current medical practice.
- It is inappropriate to use a nonmedical item.
- It is the most cost effective treatment available.
- The service/device is ordered by the treating physician, and clinical documentation from the medical record supports the medical necessity for the request (as described above) and substantiates the physician's order.
- The service/device meets the standards of coverage published by MDCH.
- It meets the definition of Durable Medical Equipment (DME), as defined in the Program Overview section of this chapter.
- Its use meets FDA and manufacturer indications.

MDCH Medicaid Provider Manual,
Medical Supplier Section
April 1, 2013 pages 1 and 3-5

In the present case, the Department determined that the Appellant's prior authorization request for a bladder scanner should be denied because medical necessity was not established.

The RN with the Program Review division testified that the requested bladder scanner is not a standard for homecare. The Department policy addresses both economic alternatives and medical necessity, which includes the device being within the scope

of current medical practice. The RN with the Program Review Division noted that none of the articles that have been submitted regarding bladder scanners relate to home use. (RN Program Review Division Testimony)

The Chief Medical Director testified that she has reviewed the information submitted for the Appellant's prior authorization request. From the documentation it is clear that the Appellant has a neurogenic bladder. However, home use of a bladder scanner is not within the scope of current medical practice. Rather, in the home setting, intermittent time based catheterization is the current standard medical practice. The Appellant has asked that this request be looked at as an exception to decrease the risk of urinary tract infections. However, the data and studies that have been submitted did not describe a patient like the Appellant or not reflecting home use of a bladder scanner. For example, use of a bladder scanner for post-operative care. For home care, intermittent catheterization is the current standard of care and is an economic alternative to the requested bladder scanner. (Chief Medical Director Testimony)

The Appellant's mother disagrees with the denial and testified that intermittent catheterization is not working for the Appellant. The Appellant is not catheterized every day, but some days it may be needed twice per day. The current order form the Appellant's doctor is to catheterize every 6 hours from either the last catheterization or from when the Appellant last urinated without catheterization. The doctor has indicated that catheterization should occur when there is 500 ml of urine in the bladder. However, the Appellant's urine production varies. Sometimes at 6 hours there is far less than 500 ml and sometimes within less than 6 hours there can be far greater than 500 ml. Scanning the Appellant's bladder is easy with the requested bladder scanner and will allow for more appropriate catheterization based on volume. (Mother Testimony; Exhibit 1, pages 18-28; Exhibit A)

The Appellant's mother explained that there are risks with both unnecessary catheterization and not frequent enough catheterization. Every catheterization carries some risk for developing infection because a foreign body is inserted. Therefore, unnecessary catheterizations, i.e. when there is not much urine in the bladder, should be avoided. However, waiting too long between catheterizations, which may allow large volumes of urine to be retained, also carries risks for developing infections and for additional complications. These complications can be progressive and include valve reflux, kidney infections, kidney failure, congestive heart failure and eventually death. (Mother Testimony; Exhibit A)

Because of the Appellant's variable urine production, just following the doctor's order to catheterize at the 6 hour interval has resulted in both unnecessary catheterizations and volumes of urine far greater than 500 ml occurring, sometimes even within significantly less than 6 hours. The Appellant has had recurrent urinary tract infections, some of which were treated in the emergency room or during hospitalizations. Utilizing the bladder scanner is quick and easy, the Appellant's mother was trained in less than two

minutes during a previous hospitalization. The bladder scanner would help ensure that catheterization only occurs when needed, based on volume of urine. (Mother Testimony; Exhibit A)

Simply increasing the frequency of catheterizations based on time, such as to every 2 hours, does not address both sets of risks. While this would help prevent the larger volumes of urine, it would also increase the unnecessary catheterizations when there has not been much urine production. In addressing economic alternatives, the Appellant's mother asserts that the costs of treating infections or complications will far exceed the cost of the bladder scanner. Preventing even one hospitalization for a urinary tract infection will cover cost of bladder scanner. (Mother Testimony; Exhibit A)

The [redacted] Representative testified that the requested bladder scanner is intended for and has been sold for home use. It was explained that the data, studies and other materials submitted focus on institutional or professional office setting use because this is the primary market for the device. It was estimated that three units were sold for home use last year. The [redacted] Representative has extensive training from employer, the manufacturer, but not traditional medical credentials. ([redacted] Manager Testimony)

This ALJ understands the argument that the cost of the bladder scanner will be less than treating recurrent urinary tract infections or complications that may develop. However, this ALJ does not have any authority to change or make an exception to the Medicaid policy or any equitable authority to grant the relief the Appellant seeks.

The above cited policy indicates durable medical equipment is a benefit when: it is medically and functionally necessary to meet the needs of the beneficiary; it may prevent frequent hospitalization or institutionalization; and it is life sustaining. However, the Medicaid Provider Manual policy sets out the medical necessity criteria, which include the device being the most cost effective treatment available and being within the scope of current medical practice.

Based on the documentation submitted, the Appellant did not meet the Medicaid Provider Manual criteria to establish the medical necessity of the requested bladder scanner. This ALJ understands the Appellant's position that the Appellant's urine production varies and therefore, scanning the Appellant's bladder will allow for the more appropriate catheterization based on volume and aid in preventing infections and the complications that can develop from retention of the larger volumes of urine. However, even the [redacted] Representative's testimony indicated only about three units were sold for home use last year and acknowledged the primary market for device is in the institutional or office setting. ([redacted] Representative Testimony) The Chief Medical Director testified intermittent catheterization is the current standard of care and is an economic alternative to the requested bladder scanner. (Chief Medical Director Testimony) The evidence does not establish that home use of a bladder scanner is within the scope of current medical practice. It is also noted that the Appellant's

mother's testimony indicates that at this point, catheterization is not even needed on a daily basis for the Appellant. (Mother Testimony) Accordingly, the Department's denial must be upheld because medical necessity has not been established for the requested bladder scanner.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, decides that the Department properly denied the Appellant's request for a bladder scanner based on the submitted documentation.

IT IS THEREFORE ORDERED that:

The Department's decision is AFFIRMED.

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

Date Signed: [redacted]

Date Mailed: [redacted]

CL/db

cc: [redacted]

***** 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.