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:

[redacted]

Docket No. 2014-31595 REM
Case No. [redacted]

Appellant
_____/

DECISION AND ORDER ON REMAND

This matter is before the undersigned Administrative Law Judge following a Remand Order entered on [redacted] by the Hon. [redacted]., [redacted] Circuit Court. The Remand Order was entered following Appellant's appeal of a Decision and Order issued by Administrative Law Judge Colleen Lack on [redacted] in Docket No. 2013-53617-PA.

After due notice, a hearing was held on [redacted] and continued on [redacted]. Attorney [redacted] represented Appellant, [redacted]. Appellant's witnesses were Dr. [redacted], Appellant's Physician; [redacted], mother and Guardian; and [redacted], Senior Territory Manager.

Assistant Attorney General [redacted] represented the Department. Dr. [redacted], Chief Medical Director, Michigan Department of Community Health, appeared as a witness for the Respondent (Respondent, Department or MDCH).

At the commencement of the hearing, the parties agreed that one recording would be made for the instant matter and the related case on remand, Docket No. 2014-30383 REM, even though separate Decisions and Orders would be issued for each case.

EXHIBITS

Petitioner's Exhibits:

Exhibit A:	Excerpt from Medicaid Provider Manual (MPM), Medical Supplier Chapter, page 1
Exhibit B:	Excerpt from MPM, Mental Health and Substance Abuse Chapter, page 88
Exhibits C-D:	Excerpt from MPM, Medical Supplier Chapter, pages 4-5

Exhibits E-F: Excerpt from MPM, Mental Health and Substance Abuse Chapter, pages 90-91

Exhibit G: Attachment 3.1 of the State Plan under Title XIX of the Social Security Act

Exhibits H, I, J, K, L, M and N: Not admitted

Exhibits O-P Excerpt from MPM, Medical Supplier Chapter, pages i and ii

Exhibits Q-U Excerpt from MPM, Medical Supplier Chapter, pages 42-46

Respondent's Exhibits:

Exhibit 1: Decision and Order by Administrative Law Judge Colleen Lack, dated [redacted]

Exhibit 2: Transcript of Hearing held before Administrative Law Judge Colleen Lack on [redacted]

Exhibit 3: Hearing Summary, dated [redacted]

Exhibit 4: Transcript of Oral Argument on Appeal before the Honorable [redacted]., dated [redacted]

Exhibit 5: Excerpt from MPM, Nursing Facility Coverages Chapter, pages 32-40

ISSUE

Did the Department properly deny 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. Appellant is a [redacted]-year-old Medicaid beneficiary who has multiple diagnoses, including neurogenic bladder, Aicardi Goutieres syndrome, and urinary tract infections. (Exhibit 3, pages 16-22)

2. On or about [redacted], the Department received a prior authorization request for a bladder scanner for Appellant. (Exhibit 3, pages 7 and 16-41)

3. On [redacted], the Department issued a Notification of Denial to 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 3, pages 8-9)

4. On [redacted], the Michigan Administrative Hearing System received the hearing request filed on Appellant's behalf. (Exhibit 3, page 4)

5. On [redacted], a Hearing was held before Administrative Law Judge Colleen Lack (ALJ Lack). (Exhibit 2)

6. On [redacted], ALJ Lack issued a Decision and Order, in which she concluded:

> 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 Senior Territory 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. (Senior Territory 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. (Exhibit 1, p 6)

7. Appellant appealed ALJ Lack's Decision and Order to the Circuit Court for the County of [redacted]. Following Oral Arguments on [redacted], the Honorable [redacted] remanded the matter for "further development of the record [to] see if on remand we can articulate

a medical basis that makes sense." (Exhibit 4, p 32)

8. According to both the Department's Chief Medical Officer and Appellant's own physician, intermittent catheterization is the standard of care for someone like Appellant with a neurogenic bladder. (Testimony)

9. Even if Appellant was institutionalized, the institution would not use a bladder scanner to determine every time he needed to urinate. (Testimony)

10. Evidence submitted with the prior authorization request showed that Appellant frequently had wet diapers and sometimes went up to a week without being catheterized. (Testimony)

11. Evidence submitted with the prior authorization request did not show that any other options, besides intermittent catheterization, had been tried for Appellant. Other options include insertion of a Foley catheter, insertion of a super pubic catheter, or examining Appellant clinically to determine when he needs to urinate by checking his vital signs and looking for signs of distress or by palpitating the bladder, all of which could possibly address Appellant's issues. (Exhibit 3; Testimony)

12. A bladder scanner is typically found in institutional settings and some physicians' offices, but rarely in private homes. Literature received from the manufacturer with the prior authorization request says nothing about home use of the bladder scanner. (Exhibit 3; Testimony)

13. A bladder scanner will not remove the need for catheterization and could actually lead to Appellant being catheterized more often. (Testimony)

14. Evidence submitted with the prior authorization request did not show any evidence of kidney reflux or renal failure. (Exhibit 3; Testimony)

15. Appellant would still be at risk for hospitalization for urinary tract infections even if he had the use of a bladder scanner in the home and a bladder scanner would not reduce the risk of kidney reflux any more than intermittent catheterization would. (Testimony)

16. Medicaid does not purchase bladder scanners for institutions; rather, those institutions chose to purchase the bladder scanner on their own as the cost of doing business. (Exhibit 5; Testimony)

17. Other health insurance companies, as well as Medicare, have not paid for a bladder scanner in the home setting. An auto insurance company paid for one bladder scanner sold for home use in Michigan. (Testimony)

18. Kidney damage is cumulative and minimizing the risk of kidney damage is

important for someone with Appellant's condition. (Testimony)

19. There is no medical reason why a bladder scanner cannot be used in a home and a person of average intelligence could be taught to use a bladder scanner very easily. (Testimony)

20. Appellant is dependent on his caregivers for all of his Activities of Daily Living (ADL's). (Exhibit 3; Testimony)

21. According to Appellant's own physician, typically a patient like Appellant, who can go up to a week without needing to be catheterized, would not receive a bladder scanner. (Testimony)

22. Medicaid has never paid for a bladder scanner sold by the Senior Territory Manager from Vericon Medical for home use. (Testimony)

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 Appellant's prior authorization request for a bladder scanner should be denied because medical necessity was not established.

Following the hearing on [redacted], ALJ Lack summarized the testimony in her Decision and Order as follows:

> 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.
>
> The Chief Medical Director testified that she has reviewed the information submitted for Appellant's prior authorization request. From the documentation it is clear that 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. 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 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.
>
> Appellant's mother disagrees with the denial and testified that intermittent catheterization is not working for Appellant. Appellant is not catheterized every day, but some days it may be needed twice per day. The current order from Appellant's doctor is to catheterize every 6 hours from either the last catheterization or from when Appellant last urinated without catheterization. The doctor has indicated that catheterization should occur when there is 500 ml of urine in the bladder. However, 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 Appellant's bladder is easy with the requested bladder scanner and will allow for more appropriate catheterization based on volume.
>
> 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.
>
> Because of 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. 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.
>
> 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, 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.
>
> The Senior Territory 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 Senior Territory Representative has extensive training from employer, the manufacturer, but not traditional medical credentials. (Exhibit 1, pp 4-6)

ALJ Lack then concluded:

> 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 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, Appellant did not meet the Medicaid Provider Manual criteria to establish the medical necessity of the requested bladder scanner. This ALJ understands Appellant's position that Appellant's urine production varies and therefore, scanning 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 Senior Territory 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. (Senior Territory 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 Appellant's mother's testimony indicates that at this point, catheterization is not even needed on a daily basis for Appellant. (Mother Testimony) Accordingly, the Department's denial must be upheld because medical necessity has not been established for the requested bladder scanner. (Exhibit 1, pp 6-7)

At the hearing on [redacted] and continued on [redacted], the Department's Chief Medical Director testified that she has been a physician since [redacted], with the Department of Community Health in some capacity since [redacted], and has been Chief Medical Director for the past three years. The Department's Chief Medical Director indicated that she reviewed Appellant's prior authorization request in this case. The Department's Chief Medical Director testified that Appellant does have a very rare genetic condition that has led to a neurogenic bladder, which is a complication from neurological issues, which basically leads to the bladder not voiding properly. The Department's Chief Medical Director testified that intermittent catheterization is the standard of care for someone with a neurogenic bladder. In Appellant's case, the Department's Chief Medical Director indicated that Appellant's mother weighs Appellant's diapers and, if the volume is low, catheterizes Appellant. The Department's Chief Medical Director testified that the evidence submitted with the prior authorization request showed that Appellant frequently had wet diapers and sometimes went up to a week without being catheterized.

The Department's Chief Medical Director testified that to determine the scope of medical practice, she takes into account her own experience and training, outside literature, what other insurance carriers are covering, policy, and confers with staff and other physicians in the office. In Appellant's case, the Department's Chief Medical Director testified that it did not appear that any other options, besides intermittent

catheterization, had been tried. The Department's Chief Medical Director indicated that other options included insertion of a Foley catheter or insertion of a super pubic catheter, both of which would address Appellant's issues. The Department's Chief Medical Director testified that she has treated patients with neurogenic bladder and has tried the other indicated alternatives.

The Department's Chief Medical Director testified that a bladder scanner is typically found in an institutional setting as well as in some physicians' offices. The Department's Chief Medical Director testified that a bladder scanner is used post operatively, on a short term basis, until the patient is able to void the bladder independently. The Department's Chief Medical Director also testified that other options that could be tried in Appellant's case would be to look at Appellant clinically to determine when he needs to urinate by checking his vital signs and looking for signs of distress or by palpitating the bladder. The Department's Chief Medical Director testified that she has never recommended a bladder scanner for home use and that the literature received with the prior authorization request said nothing about home use. (Exhibit 3, pp 34-39). The Department's Chief Medical Director testified that a bladder scanner will not remove the need for catheterization and could actually lead to Appellant being catheterized more often. The Department's Chief Medical Director reviewed the risks of neurogenic bladder and indicated that she did not see any evidence of kidney reflux or renal failure in the documentation submitted with the prior authorization request. The Department's Chief Medical Director testified that Appellant would still be at risk for hospitalization for urinary tract infections even if he had the use of a bladder scanner in the home. The Department's Chief Medical Director also testified that a bladder scanner would not reduce the risk of kidney reflux any more than intermittent catheterization would.

The Department's Chief Medical Director testified that Medicaid does not purchase bladder scanners for institutions; rather, those institutions chose to purchase the bladder scanner on their own as the cost of doing business. The Department's Chief Medical Director testified that there is no Medicaid procedure code for using a bladder scanner either. The Department's Chief Medical Director testified that Medicaid pays institutions a per diem rate to cover all costs of care that are not billed separately. The Department's Chief Medical Director testified that she checked with other insurance companies, as well as Medicare, and they have not covered a bladder scanner in the home setting. The Department's Chief Medical Director testified that people can be trained to use a bladder scanner. The Department's Chief Medical Director also indicated that even if Appellant were approved for a bladder scanner, he would still need to be catheterized, so Medicaid would actually then be paying for both.

The Department's Chief Medical Director testified that bladder scanners being available in institutions and physicians' offices is consistent with the manufacturer's literature because the service is supposed to be provided under a physician's order and supervision. The Department's Chief Medical Director also testified that whether a bladder scanner might be helpful to a patient is not taken into consideration under Medicaid policy.

On cross-examination, the Department's Chief Medical Director testified that a bladder scanner could be helpful to Appellant's caregivers to determine when he needs to be catheterized. The Department's Chief Medical Director indicated that bladder scanners are commonly used in institutions and are not experimental. The Department's Chief Medical Director testified that a bladder scanner would provide more information, and more accurate information, than palpitating the bladder, checking vital signs, or trying to determine a patient's pain levels. The Department's Chief Medical Director explained that a Foley catheter and a super-pubic catheter are permanent insertions of catheters in the body and can lead to an increased risk of urinary tract infections. The Department's Chief Medical Director testified that a super-pubic catheter would be inserted during an outpatient surgical procedure not requiring an overnight stay, while insertion of a Foley catheter would not require any surgery. The Department's Chief Medical Director discussed the pros and cons of both a Foley and super-pubic catheter and the considerations patients would take into account when deciding whether to have a permanent catheter inserted. The Department's Chief Medical Director testified that she has never trained a family member to use a bladder scanner and her only concern would be whether the family member was actually scanning the bladder. The Department's Chief Medical Director indicated that Appellant would have access to a bladder scanner in a facility, but that a facility would not use a bladder scanner to determine each time when Appellant would need to be catheterized.

The Department's Chief Medical Director also testified on cross examination that kidney damage is cumulative and minimizing the risk of kidney damage is important. The Department's Chief Medical Director indicated that Medicaid would no pay for a bladder scanner in an institutional setting, but an institution is allowed to purchase a bladder scanner if they wish to. The Department's Chief Medical Director testified that if a bladder scanner is used in a physician's office, the procedure is covered through the physician visit, but Medicaid does not pay for it separately. The Department's Chief Medical Director testified that even though a bladder scanner is not listed as a covered device in the Medicaid Provider Manual, the list of covered items is not exhaustive.

Appellant's physician testified that Appellant has been a patient of hers for approximately [redacted] years. Appellant's physician indicated that a bladder scanner would promote better care for Appellant because it would allow his mother to assess when his bladder was over filled and needed to be catheterized. Appellant's physician testified that a bladder scanner is commonly used in rehabilitation practice and post-surgical settings, but is uncommon in a private home. Appellant's physician indicated that a bladder scanner is not experimental and has been in use in the medical profession for over [redacted] years. Appellant's physician testified that a bladder scanner is a standard of care in the medical practice setting. Appellant's physician indicated that there is no medical reason why a bladder scanner cannot be used in a home and that a person could be taught to use a bladder scanner very easily. Appellant's physician testified that the process involves placing gel on the patient's abdomen, placing the scanner, and then pressing a button. Appellant's physician indicated that when someone is admitted to a rehabilitation facility, their bladder is scanned every time they urinate to ensure that the bladder is emptying completely.

Appellant's physician testified that intermittent catheterization is the standard of care for Appellant's condition of neurogenic bladder. Appellant's physician indicated, however, that because Appellant's urine output is so variable, he can go days without having to be catheterized. Appellant's physician testified that catheterization introduces a risk of infection, which could lead to serious medical complications for Appellant. Appellant's physician indicated that a bladder scanner would be more appropriate than intermittent catheterization for Appellant because Appellant does not need to be catheterized all the time; sometimes he needs to be catheterized several times per day, sometimes not at all. Appellant's physician testified that overfilling of the bladder can lead to serious problems for Appellant, including kidney infections. Appellant's physician testified that catheterization at home will also lead to more urinary tract infections. Appellant's physician indicated that a bladder scanner could be the most cost effective treatment for Appellant because it could lessen the cost of catheterization supplies, lessen the burden on Appellant's providers, and could prevent hospitalizations for urinary tract infections and kidney failure. Appellant's physician testified that Appellant has been hospitalized once in the past for kidney failure. Appellant's physician testified that Appellant is dependent on his caregivers for all of his Activities of Daily Living (ADL's). Appellant's physician indicated that a bladder scanner would improve Appellant's comfort level and help him avoid pain, which would lead to him enjoying life more. Appellant's physician indicated that Appellant is at greater risk for urinary tract infections and kidney damage because of his condition. Appellant's physician testified that in an institution, bladder scanners are used routinely even for patients with less problems than Appellant.

On cross-examination, Appellant's physician testified that she has no other patients who have a bladder scanner in the home. Appellant's physician indicated that Appellant's condition is rare and that there are only approximately 100 people in the world with his condition. Appellant's physician testified that the options for someone with Appellant's condition are intermittent catheterization, insertion of a Foley catheter, insertion of a super pubic catheter, or a bladder scanner with intermittent catheterization. Appellant's physician testified that it would be very risky for Appellant to have either a Foley catheter or a super pubic catheter inserted because he does not need to be catheterized all the time. Appellant's physician indicated that currently, Appellant's mother weighs Appellant's diaper and if the diaper is dry, or the volume is low after 6 hours, Appellant is catheterized. Appellant's physician testified that typically a patient, like Appellant, who can go up to a week without needing to be catheterized, would not receive a bladder scanner. Appellant's physician testified that bladder scanners are uncommon in the home because they are expensive and because someone has to be trained to use the device. Appellant's physician testified that Appellant is non-verbal and cannot give feedback as to when he needs to urinate. Appellant's physician indicated that there was no evidence of kidney reflux with Appellant as of [redacted], when the Department's denial was issued. Appellant's physician testified that if Appellant was institutionalized, the institution, not Medicaid, would pay for the bladder scanner. Appellant's physician indicated that if Appellant received a bladder scanner, he would still need catheterization supplies, but would likely need fewer such supplies.

The Senior Territory Manager testified that he sells bladder scanners for Vericon Medical. The Senior Territory Manager indicated that bladder scanners are regularly and customarily used in medical practice. The Senior Territory Manager testified that his company sells approximately 50 bladder scanners per year in Michigan. The Senior Territory Manager also indicated that he has sold bladder scanners for use in private homes for persons with neurogenic bladders. The Senior Territory Manager testified that the benefit of a bladder scanner is that it reduces infections caused by catheterization and it is also more comfortable for the patient and the caregiver. The Senior Territory Manager testified that bladder scanners are very easy to use and that the device will direct the user to the bladder via arrows on the wand and a picture on the base of the unity. The Senior Territory Manager testified that he has trained many lay persons in the use of bladder scanners and that it is a relatively easy process. The Senior Territory Manager indicated that bladder scanners are not prohibited for use in homes.

On cross-examination, the Senior Territory Manager testified that he is paid by a combination of salary and commission, so his salary does increase if he sells more bladder scanners. The Senior Territory Manager testified that he has sold 3-5 bladder scanners for use in homes in Michigan and 1 for use in a home in Michigan since [redacted]. The Senior Territory Manager testified that Medicaid has never paid for one of the bladder scanners he has sold for home use. The Senior Territory Manager indicated that he is not a doctor or a nurse, although he is certified to train others to use the bladder scanner. The Senior Territory Manager testified that a catheter would still be required for Appellant, even if a bladder scanner were authorized, but he opined that if used properly, the bladder scanner would reduce the number of catheterizations needed.

Appellant's mother testified that before Appellant was born [redacted] years ago she was a teacher and she has a Bachelor's degree in Biology with minors in Chemistry and Physics. Appellant's mother testified that she taught biology, chemistry and physics to junior and senior high school students. Appellant's mother testified that for the last [redacted] years she has been a stay at home mother caring for Appellant and his sibling, who also has special needs. Appellant's mother testified that Appellant's daily care needs include diapering, catheterizations, respiratory care, respiratory care at night, and oxygen level monitoring. Appellant's mother testified that her care is an extreme level of nursing care that others have compared to the care someone would receive in an intensive care unit.

Appellant's mother testified that Appellant has a neurogenic bladder and the long term effect of that condition is kidney failure and then death. Appellant's mother testified that she thinks a bladder scanner will prevent kidney failure and death by allowing her to monitor Appellant's bladder so that it does not become over extended and risk reflux into the kidneys. Appellant's mother testified that she has been trained on the use of a bladder scanner and has used a bladder scanner during Appellant's frequent hospitalizations. Appellant's mother indicated that Appellant has been hospitalized 10-12 times in the last [redacted] years. Appellant's mother testified that the bladder scanner helps her to know when to catheterize Appellant because she can scan him every 1-3 hours.

Appellant's mother testified that the training to use the bladder scanner was very simple and took probably 2-3 minutes. Appellant's mother indicated that the device has arrows and a picture to make sure that you are actually scanning the bladder and the device is rather idiot-proof.

Appellant's mother testified that regular urine dips of Appellant's urine show signs of protein in the urine, which is an early sign of kidney issues. Appellant's mother testified that it is these signs that led her down this path to obtain a bladder scanner. Appellant's mother testified that Appellant overfills his bladder every day and has had diapers which, when weighed, showed 1000 ml of urine, or 4 times as much as a normal person would hold before feeling the need to urinate. Appellant's mother testified that she has kept records on diaper weight for over [redacted] years. Appellant's mother indicated that a bladder scanner would tell her exactly when Appellant reached the maximum volume limit of his bladder and would allow her to catheterize him right then, instead of waiting for the bladder to overfill and back up into the kidneys.

Appellant's mother testified that she has discussed a Foley catheter and a super-pubic catheter with her physicians and they all agree that they would not be appropriate for Appellant because he can urinate on his own much of the time. Appellant's mother also indicated that a permanent catheter also would lead to chronic urinary tract infections which could also lead to kidney failure. With regard to the super-pubic catheter, Appellant's mother testified that no surgeon would do the procedure on Appellant because of his respiratory difficulties, which make anesthesia extremely risky. Appellant's mother testified that intermittent catheterization, which they use now, has not worked because Appellant's urine production is so variable. Appellant's mother testified that with intermittent catheterization, Appellant is going over the 500 ml bladder limit every day and he has had diapers with over 1000 ml of urine. Appellant's mother indicated that Appellant has had numerous trips to the emergency room due to infections and is almost constantly taking antibiotics.

With regard to trying other options, Appellant's mother testified that she thinks it is objectionable for her to wait until Appellant appears to be in pain as a method of determining when he needs to urinate. Appellant's mother indicated that no doctors have ever recommended that she try this approach and Appellant becomes unstable many times throughout the day anyway, so there would be no way to know if his actions were related to having to urinate. Appellant's mother testified that she does not know how to determine if Appellant needs to urinate through palpitating his bladder and that by the time his belly is big enough for her to notice, it is too late. With regard to intermittent catheterization and diaper weighing, Appellant's mother indicated that because Appellant's urine output is so variable, that method is not working. Appellant's mother testified that she has a quandary every morning when she weighs Appellant's diaper because she does not know if he urinated soon after going to bed and might need to urinate again or if he has urinated closer to the morning. Appellant's mother testified that she will not catheterize Appellant more often because it is uncomfortable for him and introduces bacteria into the bladder.

Appellant's mother testified that no doctor has ever told her that there would be a problem with her using a bladder scanner at home. Appellant's mother testified that Appellant's urologist office is right next door and Medicaid pays for those visits. Appellant's mother indicated that she thinks the bladder scanner is the most cost-effective method because if it could prevent one hospitalization, it would pay for itself. Appellant's mother testified that Appellant's 10-day hospital stays in [redacted] cost $[redacted], while a bladder scanner only costs $[redacted] to $[redacted]. Appellant's mother pointed to the list of Durable Medical Equipment provided by Medicaid in nursing homes and indicated that many of the devices are already in her home and have been approved by Medicaid. (The list is found in Exhibit 5, p 37). Appellant's mother testified that if Appellant were not being cared for at home he would have to be institutionalized and he would have access to a bladder scanner.

On cross-examination, Appellant's mother testified that she is not a medical professional. Appellant's mother indicated that Appellant can often urinate on his own and there have been weeks when he has not been catheterized at all. Appellant's mother testified that if Appellant urinates on his own within 6 hours, then she does not catheterize him under the intermittent catheterization protocol. Appellant's mother testified that she has not discussed catheterizing Appellant more often with his doctor. Appellant's mother admitted that use of a bladder scanner could lead to Appellant being catheterized more often. Appellant's mother reviewed Appellant's diaper weighing logs, which begin on page 23 of Exhibit 3, and admitted that Appellant often went days or up to a week without needing catheterization. Appellant's mother indicated that if she received the bladder scanner, she would still need catheterization supplies.

Much of the analysis on remand is consistent with the analysis performed by ALJ Lack at the first hearing. 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; it is life sustaining; it is the most cost effective treatment available and it is within the scope of current medical practice. Here, a bladder scanner is not medically or functionally necessary to meet the needs of Appellant because intermittent catheterization, the standard of care for persons like Appellant with neurogenic bladder, can meet Appellant's needs. While a bladder scanner might, in some ways, *better* meet Appellant's needs, it cannot be said that intermittent catheterization does not meet his needs. And, while a bladder scanner may prevent frequent hospitalization or institutionalization, and could be life sustaining for Appellant, there was no evidence submitted with Appellant's prior authorization request showing that Appellant had been frequently hospitalized for urinary tract infections or kidney failure at that time. Given that this decision can only determine whether the Department's decision was correct at the time it was made in [redacted], the undersigned cannot consider the fact that Appellant was hospitalized in [redacted] for kidney failure or more recently for urinary tract infections. Furthermore, a bladder scanner is not the most cost-effective treatment available because it is much more expensive than intermittent catheterization and Appellant's needs can be met with intermittent catheterization. Finally, use of a bladder scanner at home is not currently within the scope of medical practice. Only 3-5 bladder scanners have ever been sold

for home use in the State of Michigan, only 1 of those scanners has been sold for home use since [redacted], no commercial health insurance companies have ever paid for a bladder scanner for home use, and Medicaid has never paid for a bladder scanner for home use.

One issue that was raised during the appeal that was not addressed at the initial hearing was a concern that if Medicaid would pay for a bladder scanner in an institutional setting, and if a bladder scanner is the standard of care in an institutional setting, why would Medicaid not pay for a bladder scanner for in-home use and why would a bladder scanner not be the standard of care for in-home use? At the hearing, both the Department's Chief Medical Director and Appellant's own physician testified that intermittent catheterization is the standard of care for someone like Appellant with neurogenic bladder, whether they are at home or in an institution. The Department's Chief Medical Director also testified that even if Appellant was institutionalized, the institution would not use a bladder scanner to determine every time he needed to urinate. In addition, evidence at the hearing demonstrated that Medicaid does not purchase bladder scanners for institutions; rather, those institutions chose to purchase a bladder scanner on their own as the cost of doing business. While some of the funds to purchase a bladder scanner in an institution could be traced back to Medicaid, those funds would also come from patients with private insurance, Medicare, and patients who pay for their own care privately. This issue also relates to the cost-effectiveness of a bladder scanner for in-home use: in an institutional setting, a bladder scanner is cost effective for facilities because the facilities can purchase one or more bladder scanners with funds from Medicaid, Medicare, private insurance, and private-pay patients, and then use that bladder scanner on dozens, or even hundreds, of patients. Here, it would not be cost effective for Medicaid to purchase one bladder scanner for the use of one patient in his home.

Another issue raised during the appeal was the argument that since the State is saving thousands of dollars per year by allowing Appellant's mother to care for Appellant, as opposed to him being cared for in an institutional setting, the State should cover the cost of a bladder scanner. This is not necessarily true. Evidence in the related case involving Northern Lakes Community Mental Health (CMH), Docket No. 2014-30383 REM, demonstrates that at the time of Appellant's appeal, the CMH alone estimated the cost of services it was providing to Appellant and his family at $[redacted] annually. (See Exhibit A, Attachment D, p 5 in Docket No. 2014-30383 REM). And, this amount does not include the health insurance Appellant also receives through Medicaid.

Based on the foregoing, Appellant has failed to prove, by a preponderance of the evidence, that a bladder scanner for in-home use is medically necessary.

It does appear that additional factors have arisen since the original denial in this matter way back in [redacted]. Since that time, Appellant has been hospitalized for kidney failure at a cost of close to $[redacted]. The Department's Chief Medical Director testified that the Department could take into consideration such a cost when determining whether a bladder scanner would be cost effective for Appellant. In addition,

Appellant's mother presented evidence during this hearing regarding the inappropriateness or failure of other alternatives to a bladder scanner suggested by the Department that were not presented with the prior authorization request and were, therefore, not considered during the initial denial. For example, testimony at the hearing demonstrated that it would be difficult or impossible for Appellant to have a super-pubic catheter inserted because he cannot tolerate anesthesia. Appellant's mother may wish to consider resubmitting a new prior authorization request to include these factors for consideration by the Department.

DECISION AND ORDER

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

IT IS THEREFORE ORDERED that:

The Department's decision is AFFIRMED.

Robert J. Meade
Administrative Law Judge
for James K. Haveman, Director
Michigan Department of Community Health

RJM[redacted]

Date Signed: [redacted]

Date Mailed: [redacted]

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. 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.