STATE OF VERMONT

HUMAN SERVICES BOARD

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| In re | ) | Fair Hearing No. B-04/10-198 |
| | ) | |
| Appeal of | ) | |

INTRODUCTION

The petitioner appeals a decision by the Department of Vermont Health Access (DVHA)[1] denying her request for compounded medications for her children under the exception criteria set out in W.A.M. § 7104.

DVHA stopped reimbursement for medications compounded with bulk ingredients on July 15, 2009.[2] DVHA did so after notification from the Centers for Medicare and Medicaid Services that such medications would no longer be covered as outpatient medications because medications compounded with bulk ingredients are not approved by the Federal Food and Drug Administration (FDA).

Petitioner applied for prior authorization under the exemptions found at W.A.M. § 7104 (formerly M108) and under the medical necessity standard found in the Early Periodic Screening, Diagnosis and Treatment (EPSDT) provisions of the Medicaid Act. The issue is whether the petitioner can

[1] DVHA was formerly known as the Office of Vermont Health Access (OVHA).

[2] Prior to this date, DVHA covered the cost of medications compounded with bulk ingredients for L.K. (pharmacy records submitted by petitioner).

demonstrate that DVHA abused its discretion under W.A.M. § 7104 or whether the petitioner can demonstrate the medical necessity for the medications under the EPSDT program.

Preliminary Matters

A. Brooklyn King

The appeal on behalf of B.K. is untimely as it was filed more than ninety days after an adverse decision. The parties acknowledge that this appeal is untimely. As a result, this appeal is dismissed.

B. Department's Motion to Dismiss

DVHA filed a Motion to Dismiss. DVHA argued that the requested medications could not be covered under Medicaid because the Food and Drug Administration does not approve medications compounded with bulk ingredients.

The petitioner opposed the Motion to Dismiss and requested a hearing on medical necessity. The petitioner based her arguments upon the EPSDT provisions of the Medicaid Act to support her claim that she should be allowed to show the medical necessity for her son, L.K., to use medications compounded with bulk ingredients. DVHA was given an opportunity to respond to the EPSDT argument.

As will be more fully set out in the reasons, the Motion to Dismiss was denied and the case continued to look at the issue of medical necessity.

Medical Necessity

During the briefing of the issues, the Hearing Officer asked DVHA to augment the record by filing copies of all the applications, supporting medical documentation, and denials. On July 19, 2010, the Hearing Officer wrote the parties to schedule a status conference because of the paucity of the medical record supporting the basis for petitioner's request.

A series of telephone status conferences were held. The petitioner was given an opportunity to augment the medical record. The petitioner provided additional materials. The medical director of DVHA and the child's doctor consulted. DVHA did not change its decision. The record was closed so that the Hearing Officer could write a recommendation based on the evidence in the record.

## FINDINGS OF FACT

1. The petitioner lives with her husband and their three minor children. This appeal concerns their oldest child, L.K., who is now nine years old.

2. L.K. is disabled and receives Medicaid. L.K. has a complex medical history. Among his problems, L.K. is on the autism spectrum and has problems with his immune, endocrine, and intestinal systems. He has exhibited allergic reactions to foods, especially products including gluten[3], and sensitivity to dyes and other substances put in food. Details will be more fully set out below to better mirror the medical information as it was received by DVHA.

3. Petitioner is seeking medications compounded by bulk ingredients because manufactured medications[4] may contain gluten or other substances to which L.K. is allergic.

M108 Applications (now 7104)

4. On September 9, 2009, petitioner submitted four applications for M108 exceptions (now W.A.M. § 7104). She requested the following medications in a form where they are compounded by bulk ingredients:

a. fluconazole
b. clindamycin
c. minocyclin
d. azithromycin/zithromax

[3] Testing from August 2004 included high IgG and high IgE; these tests document sensitivity to gluten and wheat allergies.

[4] Drug companies use binding ingredients as part of their manufacturing process.

5. All four of these medications in their manufactured form are covered under the Medicaid program without the need for prior authorization. They are FDA approved medications.

6. Fluconazole is an antifungal medication. Clindamycin is an antibiotic to treat infections. Azithromycin/zithromax are antibiotics of the same class as clindamycin. Minocyclin is a tetracycline antibiotic to treat infections.

7. Fluconazole compounded with bulk ingredients. Petitioner's request explained that L.K. has allergies that require compounding of medications. She stated that L.K. would be harmed because his yeast infection would worsen, his intestinal symptoms would worsen, and his behavior would worsen.

In support of petitioner's request, Dr. J.F. submitted a statement dated November 2, 2009 that L.K. has a history of gluten-induced seizures and a history of neurologic and respiratory allergic reactions to other additives. Dr. J.F. is L.K.'s treating doctor. He did not indicate why the medication was needed.

Dr. M.F., DVHA's medical director, reviewed the request. He issued a Coverage Exception Request/Medical Basis Statement (MBS) on October 19, 2009 finding there was no

documentation of a fungal infection and no medical indication to support the need for the medication.

On January 25, 2010, DVHA issued a denial finding that the request did not meet the 7104 criteria because the FDA does not approve medications compounded by bulk products.

8. Clindamycin compounded with bulk ingredients. Petitioner's request gave more information. She wrote that L.K. has PANDAS (pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections). She wrote that antibiotics were necessary to fight the infections and that L.K.'s symptoms and behaviors regress when he is not on antibiotics including loss of emotional control, unsafe behaviors to himself and others, obsessive behaviors, problems with learning, diarrhea and weight loss. Petitioner noted there was documentation of these changes by L.K.'s providers of physical therapy, occupational therapy, and psychological counseling; she did not provide copies of this documentation.

Dr. J.W. submitted a report that L.K. needed medications compounded by bulk products to prevent severe allergic reactions. He noted that L.K. has documented grand mal and absence seizures when exposed to gluten and absence seizures

when exposed to food preservatives. He did not indicate why this medication was prescribed.

There are two MBS by Dr. M.F. On November 5, 2009, Dr. M.F. wrote that clindamycin was denied but another prior authorization could be submitted if a medical condition arose where the medication was the preferred treatment. On January 27, 2010, he wrote, based on the record, that no medical condition requires the medication.

On January 27, 2010, DVHA issued a denial based for the same reasons as the denial for fluconazole. DVHA also added that the petitioner had not supplied additional documentation from mental health, physical therapists, and occupational therapists working with L.K.

9. Minocyclin compounded with bulk ingredients.[5] Both the petitioner's and Dr. J.W.'s written statements present the same information as the request for clindamycin.

On October 29, 2009, Dr. M.F. issued a MBS that there was no evidence of infections that would respond to the medication. He added that the drug has significant side effects.

DVHA issued a denial on January 25, 2010.

[5] During argument before the Board, petitioner stated that the minocyclin was not effective and they were no longer seeking Medicaid coverage for this medication.

10. Azizthromycin/zithromax compounded with bulk ingredients. The information from petitioner and Dr. J.W. prevents the same information as the above requests. The MBS by Dr. M.F. presents the same information as the first two request medications.

DVHA issued a denial on January 25, 2010.

11. Petitioner appealed the denials of the four requested medications on or about April 20, 2010. Petitioner has been paying out of pocket for medications.

Additional Documentation

12. Petitioner attached materials to her response to DVHA's Motion to Dismiss. Materials from 2004 through 2008 include:

a. August 27, 2004 letter from Dr. J.B. (Allergy Link, P.A.) stating that L.K. tested high in IgG to gluten and tested high in IgE. L.K. was placed on a gluten free diet and his growth as measured by weight and height changed from 0-5% to 50-75%.

b. October 25, 2005 letter from Dr. E.P. stating L.K. is autistic with a history of petit mal seizures.

c. May 19, 2006 letter from Dr. E.P. stating that L.K. has many "behavioral abnormalities" in support of a request for a behavioral assessment.

d. August 31, 2007 report of gastrointestinal consultation by Dr. T.B. of LADDERS (Learning and Developmental Disabilities Evaluation and Rehabilitation Services). He noted the diagnosis of autism spectrum disorder/pervasive developmental disorder complicated by food sensitivities and the possibility of metabolic

disease. He recommended follow-up with a pediatric gastroenterologist with expertise in autism.

e. October 15, 2007 summary of autism diagnostic evaluation by the Spurwink Clinic with a recommendation to continue services for L.K.'s PDD-NOS.

f. May 21, 2008 letter from Dr. J.B. He noted L.K.'s history of failure to thrive and then current diagnosis of malabsorption with possible metabolic disorder. He wrote that L.K. was found to have mercury and lead poisoning and mild arsenic poisoning as well as liver problems. He noted that PANDAS became an issue since 2006.

Petitioner included progress notes from Dr. J.W. for July 15, 2009; August 31, 2009; November 13, 2009; and January 4, 2010. These notes do not indicate an active strep infection. They note petitioner's observations about L.K.'s behavior regressing when not on antibiotics. The use of the antibiotics is tied to the treatment of autism.

13. Petitioner set out her concerns in a written statement dated September 3, 2010. She explained that L.K. has complications from PANDAS that she associates with L.K. having OCD (obsessive/compulsive disorder) and having ODD (oppositional defiance disorder). L.K. is gluten and lactose intolerant and allergic to beef (gelatin). She states the treatment for PANDAS is antibiotics. L.K. has flares when they run out of clindomycin. They have not seen a change when they run out of minocycline. Petitioner wrote they are

using the azithromycin prophelaticly to ward off flares. An antifungal medication is needed to offset the impact of antibiotic use on the gut.

Petitioner is asking that L.K. be maintained on antibiotics to avoid flares of physical symptoms and to avoid behavioral difficulties associated with PANDAS and autism.

14. Petitioner submitted a letter dated August 27, 2010 from Dr. J.W. that is set out below:

> [L.K.] is a child with multiple immune, endocrine and intestinal system dysfunctions. Including probable chronic Streptococcal infection with PANDAS, probable chronic intestinal fungal infection and other abnormalities leading to the therapeutic decision of trials of various medications to try and provide symptomatic relief for him. He has underlying multiple severe immune system reactions/allergic reactions to multiple food-based constituents that range from mild/moderate to severe and life threatening anaphylaxis. As well, he has had severe reactions to certain dyes and preservatives.
>
> For instance a medication such as Clindamycin contains "gelatin" that is from a beef source and [L.K.] has marked reaction/allergy to beef. Others such as Nystatin may contain gluten-derived constituents and [L.K.] has life-threatening reactions to gluten. Other medications such as fluconazole and azithromycin contain red#40, again [L.K.'s] abnormal immune system reacts severely to this chemical. He is allergic to soy and many medications can have "vegetable oil" which is often soy-based.
>
> Due to [L.K.'s] multiple severe allergies of constituents in standard industry-produced medications and the attendant potentially life-threatening allergic reactions he could have if exposed-I feel it is medically indicated for his safety to have his

> prescribed medications carefully formulated via compounding using known constituents and to assure his safety via the compounding pharmacist's careful avoidance of potentially allergic substances.

The letter does not identify the use of a particular medication, why multiple medications are needed, and does not address the prophylactic use of ongoing antibiotic treatment for L.K.

15. Petitioner presented materials including materials from the National Institute of Mental Health (NIMH) explaining PANDAS, its diagnosis, and treatment. PANDAS is a relatively new diagnosis and research is ongoing. PANDAS is a pediatric disease whose onset is prior to age three years, is episodic, and associated with strep infections. Symptoms can include OCD, tics, ADHD symptoms, mood changes, motor changes and joint pains. The NIMH materials indicate that antibiotics are to be used when there is an active strep infection. Long-term use of antibiotics for prophylaxis is being studied but NIMH indicates there is insufficient evidence to recommend long-term use of antibiotics for prophylaxis.

16. Dr. M.F. consulted with the child's doctor, Dr. J.W. on October 1, 2010; Dr. M.F. reviewed the materials. Dr. M.F. issued an updated MBS on October 18, 2010 upholding

DVHA's denial. The pertinent parts of the MBS are as follows:

> The azithromycin and clindamycin were for recurrent Beta hemolytic Group A streptococcus (strep throat). It was unclear why minocycline had been prescribed. Subsequently, Dr. [J.W.] provided a non-peer-reviewed article recommending minocycline to treat Autism. . .
>
> . . .minocycline is a tetracycline and should not be used in children and has significant side effects of vertigo and has much safer alternatives.
>
> The fluconazole was prescribed because of chronic abdominal discomfort and diarrhea felt to be secondary to bowel invasion by Candida. …there is weak evidence that this is the cause of the patient's symptoms. Of greater concern is the use of fluconazole which has significant liver toxicity.
>
> . . .DVHA has not received any convincing evidence based documentation that there is a specific allergy to additives to these medications although the specific medications themselves would have significant potential for adverse reactions of their own right. . . .I find no medical documentation to justify the use of minocycline. . .or fluconazole.
>
> The issue of a compounded medication is a separate issue. . . .the case for need for compounded medications. . .is not strong and I would recommend specific referral to a pediatric allergist for 2nd opinion and support for this request.

Attached to the MBS is a statement from a pharmacist employed by DVHA that medications compounded with bulk products are not FDA approved, and as a result, are not covered by Medicaid.

## ORDER

The appeal on behalf of B.K. is dismissed as untimely. The Department's decision to deny Medicaid coverage for L.K. for the compounded medications is affirmed.

## REASONS

The petitioner made prior authorization medication requests on behalf of two of her children, L.K. and B.K. B.K.'s appeal was filed beyond the ninety day limit allowed for requests to the Human Services Board and is dismissed. The issues facing the Board deal with the prior authorization requests on behalf of L.K.

L.K. is impacted by a combination of complex medical issues including autism and autoimmune disorders. L.K. has significant behavioral issues that vary in intensity. His severe allergies to gluten, certain foods and additives complicate his treatment options. Petitioner described the challenges of dealing with L.K.'s physical and behavioral symptoms.

This case focuses on the prescribed fluconazole, minocycline, azithromycin/zithromax and clindamycin, all to be made with compounded bulk ingredients.

Prescribed medications are generally covered under Medicaid. W.A.M. § 7502 states:

> Payment may be made for any preparation, except those unfavorably evaluated, either included or approved for inclusion in the latest edition of official drug compendia; the U.S. Pharmacopoeia, the National Formulary, the U.S. Homeopathic Pharmacopoeia, AMA drug evaluations, or Accepted Dental Therapeutics. These consist of both "legend" drugs, for which a prescription is required by State or Federal law, and "over-the-counter" medicinals. . .

As manufactured, the above medications would be covered under Medicaid because they are included in the official drug compendia.

The manufacturers bind or compound these medications with inert substances to produce the medications in their usable form. These inert substances may contain gluten or other substances to which L.K. is allergic. By having a pharmacist add the binding agent, the petitioner can be assured that the binding agent does not contain a substance to which L.K. is allergic.

The problem is that DVHA stopped paying for medications compounded by bulk ingredients on July 15, 2009 in response to information from the Centers for Medicare and Medicaid

Systems (CMS).[6] In fact, Medicaid covered medications compounded by bulk substances prior to July 15, 2009.

DVHA promulgated rules that allow a Medicaid recipient to seek coverage for a service, procedure, or medication not covered by the Vermont Medicaid regulations. Petitioner sought DVHA approval by filing for exceptions under W.A.M. § 7104. DVHA denied petitioner's requests for medications with bulk ingredients. A secondary reason for the denial is the lack of medical documentation.

W.A.M. § 7104 is the successor to M108 and allows payment when there are extenuating circumstances unique to the individual that would cause serious harm to the individual if the cost is not covered. W.A.M. § 7104 states, in part:

> If, under this section, an individual requests that a service or item be covered, the following criteria will be considered, in combination,. . .with the following

[6] DVHA (then OVHA) sent notice dated June 23, 2009 to Vermont pharmacies, prescribers and beneficiaries of the State funded pharmacy programs of changes to reimbursement including notice that medications compounded by bulk ingredients would no longer be covered starting July 15, 2009. The letter stated "CMS has clarified that bulk products are not considered outpatient drugs because they are not prescription drug products approved under Section 505, 505(j), or 507 of the Federal Food Drug and Cosmetic Act." DVHA attached CMS memos to their Motion; but, the CMS memos dealt with the Medicare Part D program, not Medicaid. However, the Federal Medicaid Act speaks to the use of rebate agreements with manufacturers for drugs to qualify for Medicaid reimbursement and specifies that medications subject to Medicaid payment be approved for safety and effectiveness by the FDA. 42 U.S.C. § 1396r-8. Although not addressed by the parties, there were difficulties under the rebate system when pharmacists compounded medications with bulk ingredients.

exception. If the service or item is subject to FDA approval and has not been approved (criterion (I) below), the request for coverage of the service or item will be denied.

A. Are there extenuating circumstances that are unique to the beneficiary such that there would be serious detrimental health consequences if the service or item were not provided?

B. Does the service or item fit within a category or subcategory of services offered by the Vermont Medicaid program for adults?

C. Has the service or item been identified in rule as not covered, and has new evidence about the efficacy been presented or discovered?

D. Is the service or item consistent with the objective of Title XIX?

E. Is there a rational basis for excluding coverage of the service or item? The purpose of this criterion is to ensure that the department does not arbitrarily deny coverage for a service or item. The department may not deny an individual coverage of a service solely based on its cost.

F. Is the service or item experimental or investigational?

G. Have the medical appropriateness and efficacy of the service or item been demonstrated in the literature or by experts in the field?

H. Are there less expensive, medically appropriate alternatives not covered or not generally available?

I. Is FDA approval required, and if so, has the service or item been approved?

J. Is the service or item primarily and customarily used to serve a medical purpose, and is it generally not useful to an individual in the absence of an illness, injury, or disability?

DVHA filed a Motion to Dismiss arguing that the lack of FDA approval for bulk ingredients used in compounding medications forecloses consideration under the 7104 exception. DVHA points to Board decisions that affirmed the Department when they denied adults coverage for medications not approved by the FDA. Fair Hearing Nos. M-09/09-509 (W.A.M. § 7502 excluded syteste because the drug was unfairly evaluated by the FDA. Dicta stated that a drug that had not been approved by the FDA would be excluded from the 7104 exception.), No. 19,111 (upholding denial of a migraine medication due to lack of FDA approval for the particular medication).

Petitioner argues that medications compounded with bulk ingredients had been covered by Medicaid for years[7] and that the change created a problem for children with severe food allergies who would not be able to safely access medically necessary medications. The petitioner argues that doing so leads to the anomalous result of a subgroup of children who can show the medical necessity for a particular medication compounded by bulk ingredients going without needed

[7] It is not clear from the submitted materials whether the bulk ingredients used in compounding have been evaluated by the FDA or if the concern is the degree to which a pharmacist can consistently compound medications to have the same ratio of active ingredient to filler or if concern is with compliance with the rebate program.

medication. Petitioner's legal argument is based upon the EPSDT program in which Congress provided an expanded and more liberal definition of medical necessity than for adults.

The Medicaid program is a remedial act meant to be liberally construed. Congress took especial care of children be providing more expansive coverage. 42 U.S.C. §§ 1396d(a)(13) and 1396d®(5); Rosie D. v. Romney, 410 F.Supp.2d 18 (D.Mass. 2006 at page 25, "[a]s broad as the overall Medicaid umbrella is generally, the initiatives aimed at children are far more expansive.")

This expanded definition is mirrored in Vermont's regulations. W.A.M. § 7103 states that medical necessity for EPSDT recipients "includes a determination that a service is needed to achieve proper growth and development or prevent the onset or worsening of a health condition." Fair Hearing No. 21,077.

The MBSs by DVHA's medical director are instructive. In the November 5, 2009 MBS, Dr. M.F. notes that clindamycin in the form requested by petitioner can be considered if there is documentation of a medical condition where the drug is the preferred treatment. In the October 8, 2010 MBS, Dr. M.F. recommends referring L.K. to a pediatric allergist because he finds there is a lack of medical documentation regarding the

current state of L.K.'s allergies. The door is open to a medical necessity determination. By opening the door, DVHA cannot say the door is barred.

Under the EPSDT program, petitioner can use the 7104 exception to request coverage for the medications compounded by bulk ingredients. In doing so, the petitioner has the burden of providing medical documentation to support the request. If a 7104 request is denied, the decision is given deference by the Board absent an abuse of discretion.

The underlying problem in this case is the lack of medical documentation justifying petitioner's requests. In the initial applications, the medical documentation is sparse. The treating physician does not indicate why a specific medication is needed at that time, what documentation (lab results, etc.) support the request, and why denial of the request would harm L.K.

Petitioner was given the opportunity to supplement the record with additional medical documentation to buttress her requests. Petitioner is seeking ongoing antibiotic treatment with an additional antifungal medication to balance the effects of the antibiotics on L.K.'s intestinal system; the antibiotics are used prophylacticly to deal with L.K.'s PANDAS and autism. Antibiotics are indicated to treat

infections. Petitioner is asking for a use that does not appear to be medically indicated. The materials from NIMH show that the prophylactic use of antibiotics is currently being tested for PANDAS, but this use has not been approved.

Based on the documentation, DVHA did not abuse their discretion in this case. Petitioner can apply in the future for a 7104 exception, but, is she does so, she should work with L.K.'s healthcare providers to put together comprehensive materials to support a request.

Accordingly, DVHA's decision to deny Medication coverage for the requested medications compounded with bulk ingredients is affirmed. 3 V.S.A. § 3091(d), Fair Hearing Rule No. 1000.4D.

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