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Date Mailed: August 21, 2020
MOAHR Docket No.: 20-000805
Agency No.: [redacted]
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Colleen Lack

DECISION AND ORDER

Following Petitioner's request for a hearing, this matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and 400.37; 7 CFR 273.15 to 273.18; 42 CFR 431.200 *et seq*; 42 CFR 438.400 *et seq*; and Mich Admin Code, R 792.11002.

After due notice, a telephone hearing commenced on April 29, 2020. Debra Chopp, Attorney; [redacted] Student Attorney; and [redacted] Student Attorney, represented the Petitioner. [redacted] Mother; and Dr. Michael Wood, Pediatric Endocrinology, University of Michigan, appeared as witnesses for Petitioner. The Department of Health and Human Services contracted Medicaid Health Plan (MHP), Priority Health, was represented by Ryan Kimble, Senior Appeal Coordinator. Kristin Piotrowicz, Senior Appeal Coordinator; and Jamie Lyberg, Clinical Pharmacist, appeared as witnesses for the MHP.

During the hearing proceeding, the MHP's documentation was admitted as Exhibit A, pp. 1-303.

ISSUE

Did the Medicaid Health Plan properly deny Petitioner's request for NovoLog PenFill Cartridges?

FINDINGS OF FACT

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

1. Petitioner is a Medicaid beneficiary enrolled in the MHP.

2. Petitioner is [redacted] years old, date of birth [redacted] 2002. (Exhibit A, p. 95)

3. On July 9, 2019, the MHP received a request for prior authorization for NovoLog PenFill Cartridges for Petitioner for a diagnosis of type 1 diabetes mellitus without complications. (Exhibit A, pp. 105-127)

4. On July 18, 2019, the MHP sent Petitioner written notice that the request for NovoLog PenFill Cartridges was denied. Novolog is not on the Michigan Medicaid Health Plan Common Formulary. There are other drugs on the approved list that would treat Petitioner's condition and the prescriber has not explained why those other drugs cannot be used. (Exhibit A, pp. 128-130)

5. On August 26, 2019, Petitioner requested an Internal Appeal. (Exhibit A, p. 293)

6. On October 2, 2019, the MHP issued a determination letter from the Internal Appeal upholding the original denial. The NovoLog PenFill is not on the Medicaid Common Formulary and it is not a covered medication due to the availability of many covered alternatives. It was noted that the basis for Petitioner's request for the NovoLog PenFill is that it allows for dosing in half unit increments. Admelog allows for whole unit dosing as a pen injector and half unit dosing by syringe ad vial. Additionally, the medical records reviewed did not provide sufficient medical rationale for why Petitioner is unable to try one of the covered alternatives. (Exhibit A pp. 292-294)

7. On February 5, 2020, the Michigan Office of Administrative Hearings and Rules received Petitioner's request for an administrative hearing. (Exhibit A, pp. 6-33)

CONCLUSIONS OF LAW

The Medical Assistance Program (MA) is established pursuant to Title XIX of the Social Security Act and is implemented by Title 42 of the Code of Federal Regulations (CFR). It is administered in accordance with state statute, the Social Welfare Act, the Administrative Code, and the State Plan under Title XIX of the Social Security Act Medical Assistance Program.

On May 30, 1997, the Department received approval from the Health Care Financing Administration, U.S. Department of Health and Human Services, allowing Michigan to restrict Medicaid beneficiaries' choice to obtain medical services only from specified Medicaid Health Plans.

The Respondent is one of those MHPs and, as provided in the Medicaid Provider Manual (MPM), is responsible for providing covered services pursuant to its contract with the Department:

> The Michigan Department of Health and Human Services (MDHHS) contracts with Medicaid Health Plans (MHPs), selected through a competitive bid process, to provide services to Medicaid beneficiaries. The selection process is

> described in a Request for Proposal (RFP) released by the Office of Purchasing, Michigan Department of Technology, Management & Budget. The MHP contract, referred to in this chapter as the Contract, specifies the beneficiaries to be served, scope of the benefits, and contract provisions with which the MHP must comply. Nothing in this chapter should be construed as requiring MHPs to cover services that are not included in the Contract. A copy of the MHP contract is available on the MDHHS website. (Refer to the Directory Appendix for website information.)
>
> MHPs must operate consistently with all applicable published Medicaid coverage and limitation policies. (Refer to the General Information for Providers and the Beneficiary Eligibility chapters of this manual for additional information.) Although MHPs must provide the full range of covered services listed below, MHPs may also choose to provide services over and above those specified. MHPs are allowed to develop prior authorization requirements and utilization management and review criteria that differ from Medicaid requirements. The following subsections describe covered services, excluded services, and prohibited services as set forth in the Contract.
>
> MPM, Medicaid Health Plans Chapter,
> July 1, 2019, p. 1.

In this case, Petitioner is seeking coverage of NovoLog PenFill Cartridges. Effective October 1, 2018, NovoLog 100/Unit/ml Cartridges have not been on the Michigan Medicaid Managed Care Common Formulary. (Medicaid Health Plan Common Formulary Changes Effective October 1, 2018, p. 18, https://www.michigan.gov/documents/mdhhs/History_of_Formulary_Changes_for_webV3_600233_7.pdf) The MHP denied a previous prior authorization request for NovoLog PenFill Cartridges for Petitioner. The MHP also sent a letter to Petitioner regarding this change in the Michigan Medicaid Managed Care Common Formulary and stated she would need to switch to an alternative medication by December 31, 2018. (Exhibit A, pp. 91-100 and 296-297) However, the action at issue for this case is the denial of the July 9, 2019, prior authorization request for NovoLog PenFill Cartridges for Petitioner.

The introduction portion of the Michigan Department of Health and Human Services Medicaid Health Plan Common Formulary (MHP Common Formulary) states:

> In order to streamline drug coverage policies for Medicaid and Healthy Michigan Plan members and providers, the Michigan Department of Health and Human Services (MDHHS) has created a formulary that is common across all

contracted Medicaid Health Plans (MHPs) for the current Comprehensive Health Plan Contract. The development of the Common Formulary is required under Section 1806 of Public Act 84 of 2015.

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Medicaid Health Plans May Be Less Restrictive

As part of the Common Formulary, minimum requirements will be established for drug utilization management policies such as quantity limits, age and gender edits, prior authorization criteria and step therapies. MHPs may be less restrictive, but not more restrictive, than the coverage parameters of the Common Formulary.

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Mandatory Generic Drug Policy

A mandatory generic drug policy encourages the generic version to be dispensed rather than a brand-name product. In most instances, a brand-name drug for which a generic product becomes available will become non-formulary, with the generic product covered in its place, upon release of the generic product onto the market.

Generic drugs are usually priced lower than their brand-name equivalents. Prescription generic drugs are approved by the US Food and Drug Administration for safety and effectiveness, and are manufactured under the same strict standards that apply to brand-name drugs. When a generic drug is substituted for a brand-name drug, you can expect the generic to produce the same clinical effect and safety profile as the brand-name drug (therapeutic equivalence).

Unit Dose Packaging

Products in Unit Dose packaging are not typically covered. Individual Medicaid Health Plans may be less restrictive and cover unit dose packaged products on a case by case basis.

> Medically Accepted Indications
> Medically accepted indications will also be considered for approval. Medically accepted indications include any use of a drug which is approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in the compendia listed in Section 1927(g)(I)(B)(i) of the Social Security Act.
>
> MDHHS Medicaid Health Plan
> Common Formulary,
> effective July 1, 2019
> (Exhibit A, pp. 280-281)

NovoLog PenFill Cartridges are not listed in the July 1, 2019, version of the MHP Common Formulary. (Exhibit A, pp. 282-283; See also Exhibit A, pp. 272) Accordingly, the MHP properly reviewed Petitioner's request through a non-formulary prior authorization process.

The MHP denied Petitioner's request for NovoLog PenFill Cartridges because it is not on the Medicaid Common Formulary and is not a covered medication due to the availability of many covered alternatives. Petitioner requested an exception because the NovoLog PenFill allows for dosing in half unit increments as a pen injector. The MHP determined that the medical records reviewed did not provide sufficient medical rationale for why Petitioner is unable to try one of the covered alternatives. Alternatives allow for whole unit dosing as a pen injector or half unit dosing with a syringe and vial. (Exhibit A, pp. 293-294) While it is common to use half units in young children, Petitioner was almost [redacted] years old. The medical records did not show that Petitioner's doctor prescribed half unit dosing, or that rounding had caused an issue for Petitioner. (Clinical Pharmacist Testimony; See also Exhibit A, p. 103)

Petitioner asserts that an insulin pen that allows for half unit administration is medically necessary for her. An insulin pen is a superior method of administration that provides greater accuracy, greater ease of use, better adherence, less pain, and a higher quality of life. At the time of the determination at issue, the one pen alternative the MHP listed as an alternative can only provide insulin in full unit doses. However, the half unit dosing increases choice, comfort, and overall health and wellbeing. While Petitioner is prescribed a maximum of 55 units of insulin per day, she typically uses between 10.5 and 14 units total on a normal day. On average, Petitioner injects herself with less than 5 units of insulin after every meal. For example, after breakfast Petitioner administers 2.5 units. With a pen that only allows for full unit dosing, Petitioner has to choose between 2 units (80% of the insulin she needs) and 3 units (120% of the insulin she needs). Petitioner asserts that she has a physical barrier that prevents her from using the preferred equivalent insulin products because of either the dosage form (non-pen) or dosage schedule (no option for half-units). (Exhibit A, pp. 8-10)

Petitioner's Endocrinologist testified that it is not common to use insulin via vials and syringes anymore. It is accepted in pediatric endocrinology that insulin pens are superior. Pens are less likely to be wrong and the dosing is more consistent and reliable. Some pens are digital, which make it easier to select the correct dose. Patients all say the pen needles are more comfortable. Some pens also have a memory feature that assist with recalling the last dose given. Further, a half unit dose can make a big difference for patients that take very small amounts of insulin and/or are fairly sensitive to insulin. Petitioner has not had any trouble using the Novolog pen. When Petitioner tried Admelog there was concern that she was not having the same level of control. The Novolog pen is better for Petitioner than syringes. Regarding when half unit dosing is really necessary, the Pediatric Endocrinologist testified that he did not know. Half unit dosing is used in all of the very young patients, ages 6 months to two years. Full unit pens are often used in adults. It is unknown when the half unit dosing is no longer necessary. Additionally, there is often high anxiety in juvenile patients regarding keeping their numbers in control. (Pediatric Endocrinologist Testimony)

Petitioner's mother testified that Petitioner was diagnosed with type I diabetes at age [redacted]. From ages [redacted] the MHP covered the Novolog pen for Petitioner, which allowed for precise half unit dosing. Now that Petitioner has had to use insulin that only comes in full unit dosing, she has to choose between high and low blood sugar outcomes. This has affected her physical and mental health. Petitioner checks her blood sugar a minimum of 6 times per day. Petitioner administers insulin at least 5 times per day on a sliding scale that considers multiple factors, such as her blood sugar, carbs, exercise, and illness. The pen has the smallest needle Petitioner has ever used and is much less painful. Petitioner's pen has a memory feature to track her last dose. Petitioner tried the alternative Admelog pen that administers full unit doses when the Novolog pen was no longer covered. Petitioner became very frustrated within a week with her inability to control her blood sugar without the half unit dosing. The Novolog pen has always been very effective with controlling her blood sugar and has prevented any health complications to date. (Mother Testimony)

Overall, the evidence supports the MHP's determination to deny the July 9, 2019, request for the NovoLog PenFill Cartridges for Petitioner as a non-formulary medication based on the information available at that time. The MHP explained that the medical records they received did not provide sufficient medical rationale for why Petitioner is unable to try one of the covered alternatives. The medical records did not show that Petitioner's doctor prescribed half unit dosing, or that rounding had caused an issue for Petitioner. (Clinical Pharmacist Testimony; See also Exhibit A, p. 103)

Additionally, the list of services that MHP's must cover includes Well child/EPSDT for individuals under age 21. *MPM, Medicaid Health Plans Chapter, July 1, 2019, pp. 1-2.*

The EPSDT chapter of the MPM states:

> Medically necessary services include habilitative or rehabilitative services that are expected to attain, maintain,

or regain functional capacity and to achieve maximum health and function. A service need not cure a condition in order to be covered under EPSDT, and maintenance services or services that improve the child's current health condition are also covered in EPSDT because they ameliorate a condition. The common definition of ameliorate is "to make more tolerable." Thus, services such as physical and occupational therapy are covered when they have an ameliorative, maintenance purpose. Maintenance services are defined as services that sustain or support rather than those that cure or improve health problems. It is important to identify illnesses and conditions early and to treat any health problems discovered in children before they become worse and more costly. Services are covered when they prevent a condition from worsening or prevent development of additional health problems. Refer to the Special Coverage Provisions section of the Healthy Michigan Plan chapter for the definition of “habilitative services”.

EPSDT includes a broad range of services that can be covered and includes:

- licensed practitioners services;
- speech, occupational, and physical therapies;
- physician services;
- private duty nursing;
- personal care services;
- home health;
- medical equipment and supplies;
- habilitative and rehabilitative services;
- vision services;
- hearing services; and
- dental services.

In addition, the coverage of other diagnostic, screening, preventive and rehabilitative services is required, and includes any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under state law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level. The coverage of EPSDT services is particularly important for children with disabilities, because such services can prevent conditions from worsening, reduce pain, and avert the development of more costly illnesses and conditions. Other less common examples include items of

durable medical equipment, such as decubitus cushions, bed rails and augmentative communication devices. Such services are a crucial component of a good, comprehensive child-focused health benefit.

The determination of whether a service is medically necessary must be made on a case-by-case basis, taking into account the particular physical, behavioral, mental, or dental health needs of the child. While the treating provider is responsible for determining or recommending that a particular service is needed to correct the child's condition, both the Michigan Department of Health and Human Services (MDHHS) and a child's treating provider play a role in determining whether a service is medically necessary. If there is a disagreement between the treating provider, health plan, and/or Medicaid as to whether a service is medically necessary for a particular child, Medicaid is responsible for making a decision for the individual child based on information presented to departmental staff. The MDHHS Office of Medical Affairs consists of a panel of physicians, including pediatricians, who will review the medical necessity of a particular service when there is a disagreement between the treating provider, health plan or Medicaid. These physicians review, on a case-by-case basis, the particular needs of the child based on the medical standards and literature, and in consultation with subspecialists when appropriate in accordance with Michigan Medicaid policy.

A medically necessary treatment service should not be denied to a child based on cost alone, but the relative cost effectiveness of alternative services may be considered as part of the prior authorization process. Services may be covered in the most cost effective mode as long as the less expensive service is equally effective and actually available. Prior authorization must be conducted on a case-by-case basis, evaluating each child's needs individually. Prior authorization is not required for medically necessary screenings.

MPM, Early and Periodic Screening, Diagnosis, and Treatment Chapter, July 1, 2019, pp. 1-2

The evidence indicates that the MHP did not consider the applicable EPSDT policy. The Clinical Pharmacist was not familiar with EPSDT, but was able to pull up the MPM policy during the hearing. The Clinical Pharmacist noted that pharmacy was not

specifically included in the list for EPSDT covered services, but indicated it may still fall within the covered services. (Clinical Pharmacist Testimony) The MPM policy indicates this list is not a complete list of all of the services included in EPSDT coverage. The policy goes on to specify that coverage "includes any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under state law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level."

Overall, the evidence shows that the MHP and the treating provider disagree as to whether the Novolog PenFill Cartridges are medically necessary for Petitioner. Under the above cited MPM policy from the EPSDT Chapter, if there is a disagreement between the treating provider and MHP as to whether a service is medically necessary for a particular child, Medicaid is responsible for making a decision for the individual child based on information presented to departmental staff. Specifically, the MDHHS Office of Medical Affairs will review the medical necessity of a particular service when there is a disagreement between the treating provider and the MHP. The process of having the MDHHS Office of Medical Affairs review the request for Novolog PenFill Cartridges for Petitioner has not occurred.

However, the testimony of all parties indicated that a generic equivalent for Novolog Penfill Cartridges, with half unit dosing, recently became available and is included in the current formulary. Petitioner had difficulty in trying to obtain this medication from the pharmacy when it was first approved but is willing to try it when she can actually get it from the pharmacy. Accordingly, if Petitioner has since been able to obtain and utilize the new generic equivalent for Novolog Penfill Cartridges with half unit dosing, it may no longer be necessary to re-process Petitioner's July 9, 2019, prior authorization request for Novolog Penfill Cartridges in accordance with the MPM EPSDT policy, which would include review of medical necessity by the MDHHS Office of Medical Affairs.

DECISION AND ORDER

The Administrative Law Judge, based on the above Findings of Fact and Conclusions of Law, decides that the MHP improperly denied Petitioner's request for Novolog Penfill Cartridges based on the available information.

IT IS, THEREFORE, ORDERED that:

The Medicaid Health Plan's, determinations regarding Petitioner's July 9, 2019, prior authorization requests cannot be upheld at this time. If still needed, the MHP shall initiate re-processing Petitioner's July 9, 2019, prior authorization request for Novolog Penfill Cartridges in accordance with the MPM EPSDT policy, which would include review of medical necessity by the MDHHS Office of Medical Affairs.

CL/dh

Colleen Lack
Administrative Law Judge
for Robert Gordon, Director
Department of Health and Human Services

NOTICE OF APPEAL: A party may appeal this Order in circuit court within 30 days of the receipt date. A copy of the circuit court appeal must be filed with the Michigan Office of Administrative Hearings and Rules (MOAHR).

A party may request a rehearing or reconsideration of this Order if the request is received by MOAHR within 30 days of the date the Order was issued. The party requesting a rehearing or reconsideration must provide the specific reasons for the request. MOAHR will not review any response to a request for rehearing/reconsideration.

A written request may be mailed or faxed to MOAHR. If submitted by fax, the written request must be faxed to (517) 763-0155; Attention: MOAHR Rehearing/Reconsideration Request.

If submitted by mail, the written request must be addressed as follows:

Michigan Office of Administrative Hearings and Rules
Reconsideration/Rehearing Request
P.O. Box 30763
Lansing, Michigan 48909-8139

DHHS -Dept Contact	Managed Care Plan Division CCC, 7th Floor Lansing, MI 48919
Counsel for Petitioner	Debra Chopp 2076 South Hall 701 South State Street Ann Arbor, MI 48109
Petitioner	[redacted] [redacted] MI [redacted]
Community Health Rep	Priority Source LLC 9650 Grand River PO Box 04819 Detroit, MI 48204
Authorized Hearing Rep.	[redacted] [redacted], MI [redacted]