[redacted]
[redacted], MI [redacted]

Date Mailed: April 5, 2022
MOAHR Docket No.: 22-000680
Agency No.:
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Steven Kibit

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and upon the Petitioner's request for a hearing.

After due notice, a telephone hearing was held on March 24, 2022. Petitioner appeared and testified on her own behalf. Katie Feher, Senior Manager of Operations and Appeals, appeared and testified on behalf of MeridianHealth, the Respondent Medicaid Health Plan (MHP). Dr. Maria Hayes, Medical Director, also testified as a witness for Respondent.

During the hearing, Respondent submitted an evidence packet that was admitted into the record as Exhibit A, pages 1-50. Petitioner did not submit any exhibits.

ISSUE

Did Respondent properly deny Petitioner's prior authorization for a continuous glucose monitor and supplies?[1]

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 [redacted] year-old Medicaid beneficiary who is enrolled in the Respondent MHP. (Exhibit A, page 12; Testimony of Respondent's representative).

2. On September 29, 2021, Respondent received a prior authorization request for a continuous glucose monitor and supplies submitted on Petitioner's behalf by her provider. (Exhibit A, pages 12-24).

[1] Petitioner testified during the hearing that, as she had already received a continuous glucose monitor through a medical study she took part in, she did not request or need the monitor and only wanted supplies for it. However, as the actual request and denial at issue both involved the monitor and supplies, this Decision and Order will also address both.

3. The supporting medical documentation submitted along with that request indicated that Petitioner has been diagnosed with Type II diabetes mellitus, uncontrolled. (Exhibit A, pages 20-21).

4. On November 22, 2021, Respondent sent Petitioner written notice that the prior authorization request had been denied. (Exhibit A, pages 25-34).

5. With respect to the reason for the denial, the notice stated:

> The notes sent to us did not show:
>
> -You have type 1 diabetes while using insulin 3 or more times daily, or you are now using an insulin pump.
>
> *Exhibit A, page 26*

6. On November 30, 2021, Petitioner filed an Internal Appeal with Respondent regarding that decision. (Exhibit A, page 35).

7. As part of that request, Petitioner indicated that she has chronic Type II diabetes. (Exhibit A, page 35).

8. On December 17, 2021, Respondent sent Petitioner written notice that her Internal Appeal was denied. (Exhibit A, pages 36-45).

9. With respect to the reason for the denial, the notice stated:

> We received a request a device to help check your blood sugar around the clock (Continuous Glucose Monitoring Device and Supplies). The notes show you have a problem with the way your body regulates the sugar in your blood (type 2 diabetes mellitus). The notes show you use insulin three (3) times a day and check the level of sugar in your blood four (4) times day. The notes show you have pain and numbness in your hands. Per the Michigan Centene Medical Policy: MI.CP.MP.501 Continuous Glucose, the notes must show:
>
> - You have type 1 diabetes while using insulin three (3) or more times daily, or you are now using an insulin pump

> The notes did not show this. Therefore, the request remains denied.
>
> Your appeal and all clinical information were reviewed by a Meridian Medical Director. The reviewer is a(n) M.D. who is board certified in Family Medicine and Pediatrics. The reviewer was not involved in the original decision. Meridian is keeping the first denial decision after this review.

Exhibit A, pages 37-38

10. On February 10, 2022, the Michigan Office of Administrative Hearings and Rules (MOAHR) received the request for hearing filed by Petitioner in this matter regarding Respondent's decision. (Exhibit A, pages 1-3).

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.

In 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, October 1, 2021 version*
> *Medicaid Health Plan Chapter, page 1*
> *(underline added for emphasis)*

As allowed by the above policy and its contract with the Department, Respondent has developed specific prior authorization requirements, utilization and management, and review criteria.

With respect to the continuous glucose monitor and supplies like the ones requested by Petitioner, that review criteria states in part:

> **Policy/Criteria**
> It is the policy of MeridianHealth affiliated with Centene Corporation® that continuous glucose monotoring(CGM) [sic] is **medically necessary** when the below criteria are met.
>
> I. Prior authorization
> A. **Age 5 and under** – PA not required for infants and toddlers if standards of coverage and documentation requirements are met. It is assumed that hypoglycemic unawareness is common within this age group.
> B. **All other ages** – PA is required for all other ages and conditions.
> II. **All of** the following criteria must be met:
> A. The member is under the care of:
> i. An endocrinologist; **OR**
> ii. A physician or non-physician practitioner (nurse practitioner) [NP], physician

assistant [PA], or clinical nurse specialist [CNS] who is managing the beneficiary's diabetes.

1. This provider must provide documentation that the beneficiary completed a Medicaid-covered certified diabetes self-management education [DSME] training program within one year prior to the written order.

B. For CSHCS members, a prescription from a pediatric endocrinologist is required from CGMs.
C. Member has a diagnosis of **Type 1 diabetes** mellitus requiring the use of insulin 3 or more times a day or is currently using an insulin pump and at least one of the following is documented:
   i. Is unable to consistently and reliably identify hypoglycemic events (e.g. hypoglycemic unawareness);
   ii. A recent history of hospitalization or emergency room visits for seizures or other conditions that attributed to a hypoglycemic event;
   iii. Coexistent morbidity that poses an unusual challenge with concomitant hypoglycemia (e.g., uncontrolled epilepsy);
   iv. The presence of:
      1. Microvascular complication (e.g., hbA1c); **Or**
      2. 2. Ketoacidosis or uncontrolled glucose
D. Ability to comply with at least 4x daily blood glucose monitoring is documented
E. The member has poor diabetic control despite attempts to maximally optimize care (e.g. compliance) with hypoglycemic unawareness, seizures, unexplained hypoglycemic episodes, recurrent ketoacidosis, and/or hbA1c not in an acceptable range;
F. The member's current treatment plan requires frequent adjustments to insulin dosage throughout the day;

G. The member or his/her caregiver is educated on the use of the device and is willing and able to use the CGM;
H. The requested device must be FDA-approved for the purpose and patient requested.

Exhibit A, pages 46-48

Respondent's clinical policy is also consistent with the applicable published Medicaid coverage and limitation policies for continuous glucose monitors and supplies set forth in the Medicaid Provider Manual (MPM):

2.10.B. CONTINUOUS GLUCOSE MONITORING EQUIPMENT AND SUPPLIES

Definition	Continuous glucose monitoring systems (CGMS) are devices that measure glucose levels taken from interstitial fluid continually throughout the day and night, providing real-time data to the beneficiary or physician. The CGMS is comprised of three parts: 1) A disposable sensor (attaches to the skin and inserts a tiny wire into the subcutaneous tissue to measure glucose levels), 2) The transmitter (attaches to the sensor and sends the data to a wireless receiver/monitor), and 3) A receiver/monitor (records and stores the data and alerts the beneficiary when glucose levels are too high or too low).
Standards of Coverage	A personal use CGMS and supplies are covered for persons with Type I diabetes when all the following are met: ▪ The beneficiary is under the care of one of the following: ➢ An endocrinologist; or ➢ A physician or non-physician practitioner (nurse practitioner, physician assistant or clinical nurse specialist) who is managing the beneficiary's diabetes. (The provider

	must provide documentation that the beneficiary completed a Medicaid-covered diabetes self-management education [DSME] training within one year prior to the written order); ▪ The beneficiary has Type I diabetes requiring the administering of insulin three or more times per day or is currently using an insulin pump, and at least one of the following: ➢ Is unable to consistently and reliably identify hypoglycemic events (e.g., hypoglycemic unawareness); ➢ A recent history of hospitalization or emergency room visits for seizures or other conditions attributed to a hypoglycemic event; ➢ Coexistent morbidity that poses an unusual challenge with concomitant hypoglycemia (e.g., uncontrolled epilepsy); ➢ The presence of microvascular complication (e.g., vasculopathy, retinopathy); or ➢ Ketoacidosis or uncontrolled glucose. At least one of the above conditions must be documented (e.g., hypoglycemic unawareness). ▪ The beneficiary's treatment plan recommends testing blood glucose a minimum of four times per day; ▪ The beneficiary has poor diabetic control despite attempts to maximally optimize care (e.g., compliance) with hypoglycemic unawareness, seizures, unexplained hypoglycemic episodes, recurrent ketoacidosis, and/or HbA1c not in an acceptable range; ▪ The beneficiary's current treatment plan requires frequent adjustments to insulin

	dosage throughout the day; ▪ The endocrinologist/physician/non-physician practitioner documents beneficiary compliance with their treatment plan; and ▪ The beneficiary or his/her caregiver is educated on the use of the device and is willing and able to use the CGMS.
Documentation	Documentation must be less than 90 days old and include all the following: ▪ A written order by the treating physician/non-physician practitioner; ▪ Diagnosis related to the need for the CGMS; ▪ Length of need; ▪ Number of finger-stick tests beneficiary performs per day; ▪ Frequency of insulin administered per day or if the beneficiary is using an insulin pump; ▪ Records of hypoglycemic events, HbA1c levels, uncontrolled ketoacidosis, hypoglycemic events, coexistent morbidity having occurred with hypoglycemia or the presence of a microvascular complication(s), as applicable; ▪ Current treatment plan and beneficiary's compliance with the plan; and ▪ Documentation of beneficiary completion of a Medicaid-covered certified DSME training program (if provider other than an endocrinologist is treating the beneficiary's diabetes). The DSME training program must have been completed within one year prior to the written order for the CGMS and include education on the use of CGMS

	(refer to the Hospital Chapter in this manual for additional information). The initial order must be written for six months. If the beneficiary continues to be compliant with use of the CGMS and treatment plan, the practitioner may write an order for an additional six months. After the first year, an order(s) for replacement sensors, transmitters and receivers (following frequency rules) may be written for a 12-month period. **Note:** Children's Special Heath Care Services (CSHCS) beneficiaries require a prescription from a pediatric endocrinologist.
PA Requirements	Prior authorization is not required for infants and toddlers (age 5 and under*) if standards of coverage and documentation requirements are met. Prior authorization is required for all other ages and conditions. *It is assumed that hypoglycemic unawareness is common within this age group.
External Insulin Pump Combined with CGMSs	An external insulin pump combined with a CGMS is covered when the external insulin pump and the CGMS policy standards of coverage are met. To be considered for coverage, the device must be approved by the Food and Drug Administration (FDA) as a combined insulin pump/CGMS.
Non-Covered	Smart devices (e.g., smart phones, iPads, tablets, personal computers) used with a CGMS are not classified as durable medical equipment and are not covered by Medicaid.
Payment Rules	The sensor, transmitter and receiver are purchase-only items, except for K0554 (may be purchased, rented or used item). The following HCPCS codes are included in the allowance for K0553 and may not be billed separately: A4233, A4234, A4236, A4244, A4245, A4246, A4247, A4250, A4253, A4255, A4256, A4257, A4258, A4259, E0607, E2100 and E2101.

	The product warranty must be expired prior to replacement of the transmitter and/or receiver. Providers must use the most appropriate HCPCS code for each brand/make/model of CGMS by reviewing the Food and Drug Administration (FDA) product approvals and the Pricing, Data Analysis and Coding (PDAC) contractor website for coding assignment. Upcoding a product to receive higher reimbursement is incorrect billing and could result in post-payment recovery of funds or provider audit. Refer to the Medicaid Code and Rate Reference tool for HCPCS code coverage parameters.

MPM, October 1, 2021 version
Medical Supplier Chapter, pages 41-44

Here, Respondent denied Petitioner's request pursuant to the above policies and on the basis that Petitioner has Type II diabetes while the requested continuous glucose monitor and supplies can only be approved for beneficiaries with Type I diabetes.

In support of that decision, Respondent's Medical Director testified that the decision was based solely on policy, and that Petitioner's request was not reviewed for medical necessity. She also testified that she cannot speak to the reason for the distinction between Type I and Type II diabetes in policy, but that Respondent is bound by it.

In response, Petitioner testified that she does not understand the policy or why the type of diabetes she has should make a difference. She also testified that she has a chronic condition, and that the requested supplies would greatly help her. She further testified that she may have been diagnosed and may have Type I diabetes.

Respondent's Medical Director then urged Petitioner to speak with Petitioner's doctor about the diagnosis, and that there is a possibility of an error in Petitioner's diagnosis given the age Petitioner was diagnosed or other reasons. She also testified that, if the diagnosis is changed to Type I diabetes, then the requested items could be covered.

Petitioner has the burden of proving by a preponderance of the evidence that Respondent erred in denying her authorization request. Moreover, the undersigned Administrative Law Judge is limited to reviewing Respondent's decision in light of the information that was available at the time the decision was made.

Given the above policy and evidence in this case, Petitioner has failed to satisfy her burden of proof and Respondent's decision must be affirmed. Respondent, as permitted by its contract and the MPM, has developed specific utilization review criteria, consistent with all applicable published Medicaid coverage and limitation policies, regarding the continuous glucose monitor and supplies requested in this case, and Petitioner does not meet the required criteria. Specifically, that applicable criteria provide in part that continuous glucose monitors and supplies are only covered for beneficiaries who have Type I diabetes, and it is undisputed in this case that Petitioner has Type II diabetes. Moreover, while Petitioner may disagree with the policy, it is clear, it is consistent with published Medicaid policies, and the undersigned Administrative Law Judge is bound by it in making this decision.

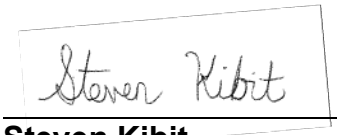
Petitioner and Respondent's Medical Director discussed Petitioner having her diagnosis reexamined and, to the extent Petitioner has updated information to provide in the future, she and her doctor can always submit a new authorization request along with that information. With respect to the issue in this case; however, Respondent's decision must be affirmed given the available information and applicable policy.

DECISION AND ORDER

The Administrative Law Judge, based on the above Findings of Fact and Conclusions of Law, decides that Respondent properly denied Petitioner's prior authorization request.

IT IS, THEREFORE, ORDERED that:

Respondent's decision is **AFFIRMED.**



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Steven Kibit
Administrative Law Judge

NOTICE OF APPEAL: Petitioner 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 MDHHS-MCPD@michigan.gov
Community Health Rep	Katie Feher c/o Meridian Health Plan of Michigan Inc. Kaitlynn Schwab 1 Campus Martius, Suite 700 Detroit, MI 48244 katie.feher@mhplan.com
Petitioner	[redacted], MI [redacted]