STATE OF FLORIDA
DEPARTMENT OF CHILDREN AND FAMILIES
OFFICE OF APPEAL HEARINGS

[redacted]

APPEAL NO. 15F-08555

PETITIONER,

Vs.

AGENCY FOR HEALTH CARE ADMINISTRATION
CIRCUIT: 09 Orange
UNIT: AHCA

RESPONDENT.
_____/

FINAL ORDER

Pursuant to notice, the undersigned convened a telephonic administrative hearing in the above-styled matter on December 4, 2015, at approximately 10:30 a.m.

APPEARANCES

For Petitioner: [redacted]
Petitioner's mother

For Respondent: Doretha Rouse
Registered Nurse Specialist
Agency for Health Care Administration

STATEMENT OF ISSUE

At issue is whether or not Respondent's termination of Petitioner's Dexcom Continuous Glucose Monitor ("CGM") is correct. The burden of proof is assigned to Respondent.

PRELIMINARY STATEMENT

Petitioner's mother represented him at the hearing. Petitioner presented the following witness:

- [redacted]

Respondent presented the following witnesses:

- Carlene Brock, Quality Operations Nurse, Amerigroup
- Dr. Amy Zitiello, Lead Medical Director, Amerigroup

Petitioner moved Exhibits 1 through 9 into evidence at the hearing. Respondent's Exhibits 1 through 10 were entered into evidence at the hearing. The record was held open for Respondent to submit additional evidence and for Petitioner to submit a response, if desired. Respondent submitted additional evidence, entered as Exhibits 11 through 14. Petitioner did not submit a response. The undersigned took administrative notice of the Florida Medicaid Provider General Handbook, July 2012.

FINDINGS OF FACT

1. Petitioner is a 10-year-old male.

2. Petitioner is enrolled with Amerigroup as his Managed Medical Assistance (MMA) plan.

3. Petitioner was diagnosed with [redacted] in June of 2011. Petitioner has [redacted] particularly at night.

4. On September 30, 2015, Petitioner's endocrinologist, [redacted] submitted a Detailed Written Order to Amerigroup for the CGM and associated accessories, CPT codes A9276, A9277, and A9278. He indicated Petitioner was running low on supplies for the CGM. (Respondent's Composite Exhibit 4).

5. Initially, Amerigroup denied the request as not being medically necessary, via a Notice of Action dated October 5, 2015 signed by [redacted] Associate Medical Director. (Respondent's Exhibit 5). On October 7, 2015, [redacted] had a peer-to-peer conference, where Mr. Leach was told the CGM is not a covered benefit, per Medicaid rules. (Respondent's Exhibit 6). On October 9, 2015, Amerigroup issued a letter upholding the denial of the CGM as not a covered benefit.

6. Dr. Zitiello testified Amerigroup's vendor was incorrectly providing Petitioner with the CGM without Amerigroup's authorization. She testified the CGM was denied as not being a covered benefit pursuant to the Florida Medicaid Durable Medical Equipment Fee Schedule. Codes A9276, A9277, and A9278 are not on the Fee Schedule. (Respondent's Exhibit 14).

7. Dr. Zitiello also said it is not medically necessary because it is a convenience item and in excess of Petitioner's needs. She said it has not been proven in the medical literature that a CGM reduces [redacted] events in the middle of the night. It is Amerigroup's position that Petitioner only needs to perform finger sticks to check his blood glucose and does not need a second way to monitor it.

8. A CGM does not measure blood glucose levels. It continuously measures interstitial glucose. A finger stick is a more accurate measure of blood glucose. However, a finger stick only measures blood glucose at that exact moment in time. CGMs are approved for use in individuals ages seven (7) to eighteen (18) years of age as of 2007. CGMs were approved for use in adults prior to being approved for use in children.

9. [redacted] testified the CGM does 288 readings per day. He further stated that using a CGM does not preclude the use of a finger stick. The CGM warns the patient via an alarm when they are becoming [redacted] or [redacted] He stated the CGM in not experimental in nature. He said that in Europe, CGMs are approved to be used for administering doses of insulin. In the United States, the CGM warns the patient, but a finger stick is still required to determine appropriate insulin dose.

10. [redacted] said CGMs are not provided to every patient. He said the patient must maintain a consistent hemoglobin A1c level over a two (2) to three (3) month period before it will be provided. He said Petitioner and his mother have done a terrific job at maintaining his A1c level. Dr. Zitiello agreed. The target for children in Petitioner's age group is 7.5% according to the American Diabetes Association ("ADA"), and Petitioner has averaged 7.6% over a three (3) month period. He referenced Petitioner's Exhibit 3, which concludes that even with excellent A1c levels, children often experience nocturnal hypoglycemia and hyperglycemia and that a CGM can provide a means of maintaining optimal blood glucose levels.

11. Dr. Zitiello said the ADA only recommends CGMs for Petitioner's age group if they have A1c levels below 7.0%. Respondent submitted Exhibit 12, which is an article from the New England Journal of Medicine that concludes "Continuous glucose monitoring can be associated with improved glycemic control in adults with type 1 diabetes. Further work is needed to identify barriers to effectiveness of continuous monitoring in children and adolescents." The article is dated October 2, 2008.

12. Respondent also submitted Exhibit 11, which is a Clinical Practice Guideline from the Endocrine Society, published in October of 2011. In support of Dr. Zitiello's assertion, the article states: "2.1 We recommend that RT-CGM with currently approved devices be used by children and adolescents with T1DM who have achieved HbA1c levels below 7.0% because it will assist in maintaining target HbA1c levels while limiting the risk of [redacted]." However, the article also states: "2.2 We recommend RT-CGM devices be used with children and adolescents with T1DM who have HbA1c levels [greater than or equal to] 7.0% who are able to use these devices on a nearly daily basis." Petitioner was using the device on a daily basis prior to termination.

13. [redacted] testified that an A1c level of 7.0% is ideal, but that 7.5% is the current target for children, per the ADA. Further, [redacted] submitted a letter stating: "The internationally recognized standard of care in pediatric [redacted], for [redacted] is 7.5% as established by the [ADA] and the International Society for Pediatric and [redacted] (ISPAD)." (Petitioner's Exhibit 1).

14. Petitioner's Exhibits 5 through 8 are logs of his CGM reports and finger sticks using different meters. A blood glucose level below 70 is considered [redacted] In Petitioner's Exhibit 7, [redacted] showed where Petitioner had a blood glucose level below 70 at three (3) different times during the short period of October 10, 2015 through October 23, 2015.

15. Petitioner's mother testified that prior to using the CGM, he would have frequent episodes of [redacted]. She said he would become faint and discolored, couldn't

eat or drink, and was weak. She testified that he did not have any [redacted] episodes when he was using the CGM. She said she is able to prevent the episodes because the CGM will alarm her when he becomes [redacted] and she can take appropriate action prior to him experiencing problems.

16. Petitioner also experiences benefits from the CGM beyond monitoring his blood sugar levels at night while sleeping. Petitioner's primary care physician, [redacted] drafted a letter dated October 8, 2015 (Respondent's Exhibit 7), which states, in pertinent part:

> [Petitioner's] mother contacted me informing me that Amerigroup would no longer cover his Dexcom machine. My understanding and experience with this child tells me that his lifestyle has so dramatically improved with this device that I find it hard to understand why it would not be covered.
>
> Before utilizing this device, it was my advice along with his endocrinologist, to check his blood sugar levels every few hours with test strips. His sleep, school and daily routines were constantly interrupted and inhibited with this type of monitoring, albeit necessary. The Dexcom machine allowed him to have a more routine, normal daily life…The exhaustion he previously experienced, which affected his attitude, behavior and focus in school, was relieved using this device.

CONCLUSIONS OF LAW

17. By agreement between AHCA and the Department of Children and Families, the Office of Appeal Hearings has jurisdiction to conduct this hearing pursuant to § 120.80, Fla. Stat.

18. This hearing was held as a *de novo* proceeding, in accordance with Florida Administrative Code Rule 65-2.056.

19. This is a Final Order, pursuant to Sections 120.569 and 120.57, Fla. Stat.

20. The standard of proof in an administrative hearing is a preponderance of the evidence. The preponderance of the evidence standard requires proof by "the greater weight of the evidence," (Black's Law Dictionary at 1201, 7th Ed.).

21. Legal authority governing the Florida Medicaid Program is found in Fla. Stat. Chapter 409, and in Chapter 59G of the Florida Administrative Code. Respondent, AHCA, is the single state agency that administers the Medicaid Program.

22. The July 2010 Florida Medicaid Durable Medical Equipment and Medical Supply Services Coverage and Limitations Handbook ("DME Handbook") is promulgated into law by Chapter 59G of the Florida Administrative Code.

23. Page 2-5 of the DME Handbook states the service criteria for DME as follows:

> All DME, medical supplies, and orthotics and prosthetic devices must be:
>
> - Medically necessary, and
> - Functionally appropriate for the individual recipient, and
> - Adequate for the intended medical purpose, and
> - For conventional use, and
> - For the exclusive use of the recipient.
>
> **DME items requested or supplied must not duplicate or perform the same function as other DME equipment or medical supplies currently in the recipient's possession.** (emphasis added).

24. It is Amerigroup's position that the CGM is not a covered benefit. It is also their position that, even if it is a covered benefit, it is not medically necessary because it is a convenience item and in excess of his needs. They contend finger sticks are sufficient to monitor his blood glucose, and that the CGM duplicates this function.

25. The definition of "medically necessary" is found in Fla. Admin. Code R.59G-1.010, which states, in part:

> (166) 'Medically necessary' or 'medical necessity' means that the medical or allied care, goods, or services furnished or ordered must:

> (a) Meet the following conditions:
> 1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
> 2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
> 3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
> 4. Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available; statewide; and
> 5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider…
>
> (c) The fact that a provider has prescribed, recommended, or approved medical or allied care, goods, or services does not, in itself, make such care, goods or services medically necessary or a medical necessity or a covered service.

26. Since Petitioner is under 21 years of age, a broader definition of medical necessity applies to include the Early and Periodic Screening, Diagnosis, and Treatment Services (EPDST) requirements. Section 409.905, Fla. Stat., Mandatory Medicaid services, provides that Medicaid services for children include:

> EARLY AND PERIODIC SCREENING, DIAGNOSIS, AND TREATMENT SERVICES.--The agency shall pay for early and periodic screening and diagnosis of a recipient under age 21 to ascertain physical and mental problems and conditions and provide treatment to correct or ameliorate these problems and conditions. These services include all services determined by the agency to be medically necessary for the treatment, correction, or amelioration of these problems, including personal care, private duty nursing, durable medical equipment, physical therapy, occupational therapy, speech therapy, respiratory therapy, and immunizations.

27. Under the above statute, the Agency must provide durable medical equipment that would correct or ameliorate Petitioner's condition.

28. The United States Court of Appeals for the Eleventh Circuit clarified the states' obligation for the provision of EPSDT services to Medicaid-eligible children in *Moore v. Reese*, 637 F.3d 1220, 1255 (11th Cir. 2011). The Court provided the following guiding principles in its opinion, which involved a dispute over private duty nursing:

> (1) [A state] is required to provide private duty nursing services to [a child Medicaid recipient] who meets the EPSDT eligibility requirements, when such services are medically necessary to correct or ameliorate [his or her] illness and condition.
> (2) A state Medicaid plan must include "reasonable standards … for determining eligibility for and the extent of medical assistance" … and such standards must be "consistent with the objectives of" the Medicaid Act, specifically its EPSDT program.
> (3) A state may adopt a definition of medical necessity that places limits on a physician's discretion. A state may also limit required Medicaid services based upon its judgment of degree of medical necessity so long as such limitations do not discriminate on the basis of the kind of medical condition. Furthermore, "a state may establish standards for individual physicians to use in determining what services are appropriate in a particular case" and a treating physician is "required to operate within such reasonable limitations as the state may impose."
> (4) The treating physician assumes "the primary responsibility of determining what treatment should be made available to his patients." Both the treating physician and the state have roles to play, however, and "[a] private physician's word on medical necessity is not dispositive."
> (5) A state may establish the amount, duration, and scope of private duty nursing services provided under the required EPSDT benefit. **The state is not required to provide medically unnecessary, albeit desirable, EPSDT services.** However, a state's provision of a required EPSDT benefit, such as private duty nursing services, "must be sufficient in amount, duration, and scope to reasonably achieve its purpose."
> (6) A state "may place appropriate limits on a service based on such criteria as medical necessity." In so doing, a state "can review the medical necessity of treatment prescribed by a doctor on a case-by-case basis" and may present its own evidence of medical necessity in disputes between the state and Medicaid patients. (see (citations omitted)) (emphasis added).

29. Consistent with these requirements, the state is obligated to provide services to recipients under 21 years of age, but only to the extent such services are medically necessary. The definition of medical necessity for services provided under the EPSDT

benefit is established by the state and the state is authorized to establish the amount, duration, and scope of such services.

30. In the instant matter, Amerigroup is incorrect that the CGM is not a covered benefit. Pursuant to EPSDT, Medicaid is required to pay for durable medical equipment that would correct or ameliorate Petitioner's condition. The totality of evidence shows the CGM is clearly helping to ameliorate Petitioner's condition. His mother testified he would have frequent [redacted] episodes while not using the CGM, and he did not have a single episode while using it. [redacted] indicated the CGM has improved Petitioner's attitude, behavior, and focus in school, among other benefits.

31. Amerigroup's next argument is that the CGM is not medically necessary because it is a convenience item, and that it is in excess of his needs because it duplicates the function of finger sticks. The DME Handbook prohibits providing equipment that duplicates the function of DME already in Petitioner's possession, and EPSDT does not require Medicaid to pay for medically unnecessary equipment, even if it is desirable. The states can review medical necessity on a case-by-case basis.

32. Regarding Petitioner's case, the greater weight of the evidence shows the CGM is not duplicating the function of the finger sticks, but is complementing it. Petitioner is unaware if he is [redacted] at night. The CGM alerts his mother that he is becoming hypoglycemic. A finger stick is then performed to determine his exact blood glucose level and the appropriate course of action.

33. The notion that the CGM is a convenience item is without merit in this case. The Florida Administrative Code prohibits items that are *primarily* intended for the convenience of the recipient, caretaker, or provider. It is true that not having to set

alarms at night, waking both Petitioner and his mother, in order to perform a finger stick just to make sure he's OK is more convenient than only having to wake up if the CGM sounds an alarm. But that is not the *primary* purpose of the CGM. The primary purpose of the CGM is to help optimize Petitioner's A1c levels and avoid hypoglycemic episodes like he has experienced in the past.

34. Respondent has not met its burden of proof that it was proper to terminate providing Petitioner's CGM and supplies.

DECISION

Based upon the foregoing, Petitioner's appeal is GRANTED. The Agency is directed to provide Petitioner with the Dexcom Continuous Glucose Monitor and associated supplies, CPT codes A9276, A9277, and A9278, consistent with [redacted] Detailed Written Order.

NOTICE OF RIGHT TO APPEAL

This decision is final and binding on the part of the agency. If the petitioner disagrees with this decision, the petitioner may seek a judicial review. To begin the judicial review, the petitioner must file one copy of a "Notice of Appeal" with the Agency Clerk, Agency for Health Care Administration, 2727 Mahan Drive, Tallahassee, FL 32308-5403. The petitioner must also file another copy of the "Notice of Appeal" with the appropriate District Court of Appeal. The Notices must be filed within thirty (30) days of the date stamped on the first page of the final order. The petitioner must either pay the court fees required by law or seek an order of indigency to waive those fees. The petitioner is responsible for any financial obligations incurred as the agency has no funds to assist in this review.

DONE and ORDERED this 27 day of January, 2016,

in Tallahassee, Florida.

Rick Zimmer

Rick Zimmer
Hearing Officer
Building 5, Room 255
1317 Winewood Boulevard
Tallahassee, FL 32399-0700
Office: 850-488-1429
Fax: 850-487-0662
Email: Appeal.Hearings@myflfamilies.com

Copies Furnished To: [redacted] Petitioner
Judy Jacobs, Area 7, AHCA Field Office