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Date Mailed: November 19, 2020
MOAHR Docket No.: 20-006302
Agency No.: [redacted]
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Robert J. Meade

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and 42 CFR 431.200 *et seq.*, upon Petitioner's request for a hearing.

After due notice, a hearing was held on November 18, 2020. [redacted], Petitioner's father, appeared and testified on Petitioner's behalf. [redacted], Petitioner's mother; [redacted], Occupational Therapist, Huron Learning Center (HLC); [redacted], HLC Principle; [redacted], HLC Special Education Teacher; [redacted], HLC Speech Language Pathologist; [redacted] HLC Physical Therapist; and [redacted], Evaluating Speech Pathologist, Central Michigan University, appeared as witnesses for Petitioner.

Emily Piggott, Appeals Review Officer, represented Respondent, Michigan Department of Health and Human Services (MDHHS or Department). Jan White, Consultant Reviewer appeared as a witness for the Department.

ISSUE

Did the Department properly deny Petitioner's prior authorization request for a Speech Generating Device (SGD)?

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, born [redacted], who has been diagnosed with spastic diplegic cerebral palsy, nonverbal, Rett's syndrome, and scoliosis. (Exhibit A, pp 33, 35; Testimony).

2. On May 12, 2020, the Department received a prior authorization request for a Speech Generating Device (SGD) and accessories for Petitioner. (Exhibit A, pp 13, 20-51; Testimony)

3. On May 20, 2020, the Department sent Petitioner and Petitioner's provider a Request for Additional Information. (Exhibit A, pp 13-15; Testimony)

4. On August 20, 2020, after receiving the same information from the provider, the Department sent the Petitioner and Petitioner's provider a Notice of No Action Required, which again outlined the information required to approve an SGD for Petitioner. A similar notice was resent to Petitioner and Petitioner's provider on September 2, 2020. (Exhibit A, pp 16-19; Testimony)

5. On September 14, 2020, the Department received a prior authorization request for an SGD and accessories for Petitioner, which included the original documentation plus some additional information from Petitioner's Speech Pathologist. (Exhibit A, pp 52-57; Testimony).

6. On September 22, 2020, the Department sent Petitioner and her provider a Notification of Denial, indicating that the request for an SGD had been denied. The Department denied the prior authorization request because it did not include the occupational and/or physical therapy evaluation addressing posture, positioning and access during device use required by policy. The Notice informed Petitioner and Petitioner's provider that the evaluation must be completed within 180 days of the submission. The Notice also indicated that documentation showing that all economical/cost effective alternatives had been considered would need to be included. (Exhibit A, pp 9-12; Testimony).

7. On October 9, 2020, the Michigan Office of Administrative Hearings and Rules (MOAHR) received Petitioner's request for hearing. (Exhibit 1).

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 statutes, the Social Welfare Act, the Administrative Code, and the State Plan under Title XIX of the Social Security Act Medical Assistance Program.

Medicaid covered benefits are addressed for the practitioners and beneficiaries in the Medicaid Provider Manual (MPM). Regarding the specific request in this case, the applicable version of the MPM states in part:

SECTION 1 – PROGRAM OVERVIEW

This chapter applies to Medical Suppliers/Durable Medical Equipment and Orthotists/Prosthetists.

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 Michigan Department of Health and Human Services (MDHHS) 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.

* * *

1.6 MEDICAL NECESSITY

Medicaid covers medically necessary durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) for beneficiaries of all ages. DMEPOS are covered if they are the least costly alternative that meets the beneficiary’s medical/functional need 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, clinical nurse specialist (CNS) nurse practitioner (NP) or physician assistant (PA) order nor a certificate of medical necessity by itself provides sufficient documentation of medical necessity, even though it is signed by the treating/ordering physician, NP or PA. 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, NP or PA (for CSHCS beneficiaries, the order must be from the pediatric subspecialist) and clinical documentation from the medical record supports the medical necessity for the request (as described above) and substantiates the practitioner's order.
- The service/device meets the standards of coverage published by MDHHS.
- 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.

MDHHS does not cover the service when Medicare determines that the service is not medically necessary.

Medicaid will not authorize coverage of items because the item(s) is the most recent advancement in technology when the beneficiary's current equipment can meet the beneficiary's basic medical/functional needs.

* * *

2.38 SPEECH GENERATING DEVICES

Definition Speech generating devices (SGD) are defined as durable medical equipment (electric or nonelectric) that provide an individual with a severe speech impairment, who is unable to communicate using natural means (e.g., spoken, written, gestures, sign language), the ability to meet his or her daily communication needs.

Other terms used interchangeably with SGD include augmentative and alternative communication (AAC) device or augmentative communication device (ACD).

Standards of Coverage

To be considered for coverage, documentation must substantiate medical need for beneficiaries whose needs cannot be met using natural communication methods and demonstrate the comprehension and physical skills necessary to communicate using the requested device. An SGD will be considered medically necessary when supporting documentation demonstrates all of the following:

- The prognosis for developing and using oral speech as a primary method of communication is considered guarded;
- The requested SGD is an integral part of the communication plan of care; and
- The beneficiary will be able to use the device in all environments he/she frequents (e.g., home, school, job, etc.).

Software intended for augmentative communication purposes may be considered upon review of documentation supporting medical necessity. If the beneficiary intends to download augmentative communication software onto his/her personal laptop, computer, or iPad, it is the responsibility of the beneficiary and/or his/her legal guardian to check with the vendor of the personal device for licensing, compatibility, repair, warranty and proprietary information.

Standards of Coverage – Eye Control

An eye control is a type of mechanism that helps the beneficiary access the SGD. The eye control may or may not be integrated within the speech generating device. Eye control mechanisms will be covered when all of the following apply:

- All other methods to operate the SGD have been evaluated and ruled out and the eye control is the most appropriate method that

provides a functional level of communication (speed, accuracy, etc.);

- Documentation specifies medical, functional and physical necessity that supports the need for the eye control; and

- The evaluation(s) has documented evidence of the beneficiary's ability to physically activate the system and demonstrate meaningful use of the device with minimal assistance from others.

Non-covered The following are non-covered:

- Items that do not meet the definition of durable medical equipment and are not dedicated speech devices.

- Software to play games, create spreadsheets or documents or is not specific to augmentative communication.

- Environmental control units.

- More than one SGD per beneficiary.

- Registering the device.

- Extended warranties.

- SGDs used solely for education, vocational or recreational purposes. It is expected that the beneficiary will be able to use the device in all environments he/she frequents (e.g., home, school, job, etc.).

- Replacements based on manufacturer recommended replacement schedules.

- SGD requests for devices that do not match the beneficiary's current and reasonably foreseeable communication abilities and needs.

- Separate billing for interfaces, cables, adapters or interconnects and switches (with the exception of accessing switches) necessary to interface with the SGD.

- Requests for replacement due to new technology when the beneficiary's current SGD continues to meet his/her medical and functional needs.

- Items that are not defined by the American Medical Association, the Food and Drug Administration, and the Pricing, Data Analysis, and Coding (PDAC) contractor as medical devices or dedicated durable medical equipment (e.g., personal tablets, computers, iPads, iPhones, etc.).

Evaluation Components

A speech-language pathologist, in conjunction with other disciplines such as occupational therapists, physical therapists, psychologists, and seating specialists as needed, must provide a thorough and systematic evaluation of the beneficiary's receptive and expressive communication abilities.

Ancillary professionals must possess proper credentials (certification, license and registration, etc.) as appropriate.

SGD vendors (manufacturers, distributors) may not submit assessment information or justification for any requested SGD.

An objective evaluation (using objective functional baseline measures and/or standardized testing) of the beneficiary’s receptive and expressive communication abilities by a speech-language pathologist (SLP), in conjunction with other applicable disciplines (e.g., occupational therapist, physical therapist, psychologists, and seating specialists, etc.) as needed, has been performed and the SLP has documented the following:

- The beneficiary’s functional ability to use the device throughout their daily activities.

- The consideration of alternative access and positioning devices, as appropriate.

- The device is appropriate to the beneficiary’s current comprehension, abilities and skills.

- The beneficiary demonstrates the cognitive, physical, visual and hearing skills necessary to communicate using the requested device.

- The SGD is the least costly device that meets the beneficiary’s basic communication needs (in the home and in their community). Include in the evaluation supporting documentation substantiating the requested device as the least costly alternative that meets the beneficiary’s current functional needs.

- Assessment of the beneficiary on more than one device, by more than one manufacturer, and documenting why the requested device

is more appropriate than the other device(s). Include the following in the evaluation:

- Device(s) evaluated;
- The beneficiary's performance on each device evaluated;
- The device requested (brand, make/model and type); and
- Reasons why other evaluated devices did not meet the beneficiary's needs.

- A trial period using the requested device must be provided for initial device authorization requests. The trial period must be a least one month in length (the SLP may submit a prior authorization request for up to three months). The SLP must document a description of the trial period with the requested device, including length of trial, settings, outcome, and additional training needs identified.

Documentation

Documentation must be within 180 days and include:

- the physician's order with the diagnosis directly related to the beneficiary's communication deficit. The order must be based on the SLP's evaluation of the beneficiary's communication abilities and medical needs.
- the date of onset, progress made and a comprehensive summary of the beneficiary's communication goals. (Refer to criteria outlined in the Therapy Services Chapter, Speech-Language Therapy subsection.)
- the assessment by a physical therapist (PT) or occupational therapist (OT) to address functional mobility and postural control.
- the SLP's documentation of hearing and vision status.
- a copy, if available, of the hearing (audiologist) or vision (ophthalmologist or optometrist) test if the beneficiary has had a hearing or vision test within the past 12 months.
- a plan of care (POC) identifying other disciplines involved in the care and goals for therapy and training. For beneficiaries under the age of 21 attending school, the POC must include other disciplines and parents/legal guardian as appropriate (i.e., OT, PT, psychologist, school therapist, etc.).

- specifications for the SGD. (Refer to the Therapy Services Chapter).

- necessary therapy and training to allow the beneficiary to meet functional needs.

- the speech and language evaluation results.

All SGD evaluation documentation must be submitted following the established criteria stated within the Evaluations and Follow-up for Speech Generating Devices/Voice Prostheses subsection of the Therapy Services Chapter.

Documentation for modifications/upgrades must describe the changes in the beneficiary's physical, medical, cognitive, vision or hearing status that necessitates the need for the requested modifications/upgrades for the system or parts.

A video of the beneficiary using the SGD and/or eye control is a useful tool in establishing the beneficiary's ability to use either item, but is not required. The SLP may submit a video with the prior authorization request if all of the following are met:

- The beneficiary or beneficiary's legal guardian has dated and signed an authorization for the video documentation as additional documentation of the beneficiary's ability to use the device;

- The video is current (within the past 12 months); and

- The provider encrypts the video prior to sending it in with the prior authorization request (following HIPAA compliance regulations).

PA Requirements

The speech-language pathologist performs the functional communication assessment and SGD evaluation and initiates the prior authorization request with a medical supplier that has a specialty enrollment with MDHHS to provide SGDs. To improve beneficiary access to low-end devices, a medical supplier without a SGD specialty enrollment with MDHHS may provide SGDs with eight minutes or less of speech capability, basic SGD accessories such as switches, buttons, etc., or SGD wheelchair mounting systems. A SGD vendor must enroll through the MDHHS CHAMPS PE on-line system as a medical supplier with a subspecialty of Speech Generating Devices in order to provide the full range of SGDs. (Refer to the Directory Appendix for contact information.)

PA is required for all SGDs, eye control mechanisms, upgrades, modifications, accessories, repairs, replacements and device trials. Required documentation must accompany the Special Services Prior Approval—Request/Authorization (MSA-1653-B) when requesting authorization for all original and replacement/upgrade SGD requests.

A copy of the physician prescription must be submitted with the request for an SGD.

The prescription must be based on the evaluation of an individual's communication abilities and medical needs made by a speech-language pathologist and other evaluation team members (as appropriate).

Modifications/Upgrades

Indicate the procedure code that defines the modification(s) or upgrades.

Providers have six months from the prior authorization approval date to provide all approved items, including the SGD, mount and accessories. After six months, a new prior authorization request must be submitted.

Repairs - For a repair, report HCPCS code K0739 (for the labor charge) and HCPCS code E1399 (for the replacement part). PA is required for all repairs. If repair charges exceed $150, a speech-language pathologist, occupational therapist, or physical therapist must conduct an evaluation. A statement must be included in the evaluation indicating whether the current SGD continues to meet the beneficiary's functional needs. If the beneficiary's needs are being met with the current system, PA may be granted.

Each repair must consist of a thorough assessment of the general working condition of the entire system so that frequent repairs may be avoided. If additional repairs to the system are needed, PA for those additional services must be obtained.

In some cases, it may be more costly to repair the SGD than to replace it. When requesting PA for a repair, provide the cost of the repair and the cost of the replacement so that determination can be made by MDHHS whether to repair or replace the device.

Replacements - All replacements (identical, upgrades, downgrades) of an SGD require PA.

Follow-Up Services The provision of speech therapy services for training following the purchase of an SGD is expected to occur within the 12 months following the beneficiary’s receipt of the device. (Refer to the

Therapy Services Chapter and the Medicaid Code and Rate Reference tool for PA and coverage parameters.) During this time, the SLP and SGD provider are required to ensure that a support team is in place to assist the beneficiary and/or their family with all follow-up SGD needs and therapy.

Frequency The program will purchase new equipment only. Only one SGD will be purchased within a three-year period for beneficiaries under age 21. Only one SGD will be purchased within five years for beneficiaries age 21 and older. Exceptions may be considered in situations where there has been a recent and significant change in the beneficiary's medical or functional status relative to the beneficiary's communication skills.

Warranty The warranty period begins at the point when the device is in the beneficiary's home and the beneficiary has received adequate training to use the system for functional communication.

Repairs Repairs for speech generating devices (SGD) are covered after the warranty expires for no more than one SGD per beneficiary. Additionally, repair of an SGD not purchased by MDHHS is covered only if the SGD is determined to be necessary to meet basic functional communication needs in accordance with the criteria for SGD coverage.

For a repair, report HCPCS code K0739 (for the labor charge) and HCPCS code E1399 (for the replacement part). PA is required for all repairs. If repair charges exceed $150, a speech-language pathologist, occupational therapist, or physical therapist must conduct an evaluation. A statement must be included in the evaluation indicating whether the current SGD continues to meet the beneficiary's functional needs. If the beneficiary's needs are being met with the current system, PA may be granted.

Each repair must consist of a thorough assessment of the general working condition of the entire system so that frequent repairs may be avoided. If additional repairs to the system are needed, PA for those additional services must be obtained.

In some cases, it may be more costly to repair the SGD than to replace it. When requesting PA for a repair, provide the cost of the repair and the cost of the replacement so that determination can be made by MDHHS whether to repair or replace the device.

Technological improvements and upgrades are not considered repairs and must not be requested as such.

The prior authorization request for repair must include:

- Documentation from the SLP (or if not currently receiving speech services, a physician, a PT or OT, or teacher) confirming the current device is used by the beneficiary on a regular basis and continues to meet the beneficiary's needs;

- Part number(s), description(s), manufacturer name, Healthcare Common Procedure Coding System (HCPCS) codes; and

- Warranty information and catalog number(s) for the part number(s) to be used for the repair.

Repairs must extend the useful lifetime of the SGD by at least one year from the date of the repair request.

Replacements All replacements (identical, different, upgrades, downgrades) of an SGD require PA.

Replacements may be covered when there has been a significant medical/functional change in the beneficiary's ability to use the SGD, the device is no longer repairable, or the cost of repairs exceeds the cost of replacement. Limits for replacement are based on medical/functional need and the operating condition of the beneficiary's current device.

Manufacturer suggested replacement schedules are not considered a reason for replacement.

When a current SGD needs replacement and the replacement is **identical** to the SGD previously purchased by MDHHS, the documentation required to be submitted with the prior authorization request is:

- Clinical confirmation by the speech-language pathologist the device continues to be suitable for the beneficiary's needs;

- The SLP, OT or PT confirmation of the beneficiary's functional ability to use the SGD; and

- Cost to repair and cost to replace.

If an identical SGD is no longer available, a new unit that is equivalent to the original in function, utility and user adaptability will be furnished.

When a current SGD needs replacement with an SGD that is **different** than the SGD previously purchased by the program, the documentation to be submitted with the prior authorization is:

- A new speech and language evaluation; and

- A statement (to be included with the evaluation) indicating why and how the current SGD no longer meets the beneficiary's functional communication needs.

All other standards of coverage requirements must be met for coverage consideration.

Replacement requests due to loss, damage or theft must include the policy or fire marshal report, as applicable, and a plan to prevent recurrence. MDHHS does not cover replacement of SGDs due to misuse or abuse.

Payment Rules Purchase - MDHHS will purchase new equipment only. The serial number of the device purchased must be maintained on file by the vendor for audit purposes.

Shipping and handling fees relating to the SGD equipment are not separately reimbursed.

Reimbursement includes the charges for the SGD and all approved components.

The provider's charge for an SGD must be based on the usual and customary charge.

Reimbursement will be the lesser of the provider's charge and/or the Medicaid fee screen.

Rental – Equipment will not be rented for a period of less than 30 days and may be rented for a maximum period of 90 days. The monthly rental reimbursement rate will be 1/10 of the maximum purchase reimbursement. The amount reimbursed for rental will be deducted from the total purchase price.

MDHHS will apply the trial period rental to the purchase of the SGD. For an SGD device(s) approved for a trial period and ruled out (by the SLP, the beneficiary and/or legal guardian, DME provider, etc.) at some point during the trial period (first, second or third month), MDHHS will reimburse the SGD provider for the period of time the device was trialed. (Refer to the Medical Supplier Database and the Medicaid Code and Rate Reference tool for specific HCPCS codes and rental rates.)

Medicaid Provider Manual
Medical Supplier Chapter
April 1, 2020, pp 1, 9, 90-96
Emphasis added

The Department's Consultant testified that the Department does not evaluate whether an SGD is appropriate for a beneficiary but rather just whether the documentation received with the PA request meets policy requirements. The Department's Consultant testified that in the instant case, the Department received documentation with the PA request, but that documentation did not meet policy requirements. The Department's Consultant indicated that Petitioner and her provider can resubmit a PA request at any time with the proper documentation. The Department's Consultant testified that she did not disagree that Petitioner needed a replacement SGD.

The Department's Consultant reviewed the history of Petitioner's submissions and the documentation that was lacking in the PA request. First, the Department's Consultant indicated that all documentation needs to be dated within 180 days of the PA request and that the request must include a current evaluation conducted by an OT or PT. The Department's Consultant noted that the Department would be happy to rent an SGD for Petitioner to use so that the evaluations can be completed. The Department's Consultant also noted that the PA request must include documentation showing that other economic alternatives have been ruled out. For example, the Department's Consultant indicated that Petitioner would have to demonstrate why her prior mounting device could not be used with the new SGD. The Department's Consultant also indicated that the documentation submitted with a PA request must meet policy requirements so that the authorization is audit ready should the Department be audited by Medicaid.

Petitioner's Evaluating Speech Pathologist testified that she did not receive a copy of the Department's evidence packet so has not had a chance to review it. Petitioner's Evaluating Speech Pathologist also indicated that she did not receive any phone calls from the Department regarding this request and if she had she would have returned those calls. Petitioner's Evaluating Speech Pathologist admitted that she may have misinterpreted the policy in the MPM as she thought that since this was a replacement device all the criteria did not need to be met. Petitioner's Evaluating Speech Pathologist indicated that she would work with Petitioner's OT and PT from her school to obtain the needed evaluation.

Based on the evidence presented, the undersigned Administrative Law Judge finds that Petitioner has failed to prove, by a preponderance of the evidence, that the Department erred in denying the requested SGD. As indicated above, policy requires that the PA request for an SGD contains a current (within 180 days) evaluation by an OT and/or PT to address functional mobility and postural control. The parties admit that this documentation was not included with the instant PA request. In addition, the PA request must include documentation that the request is the most economical alternative available and that other accessories, such as the prior mount, cannot be used. Therefore, the Department's decision to deny the requested SGD must be upheld. Petitioner may submit a new PA request at any time.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, finds that the Department properly denied Petitioner's prior authorization request for a Speech Generating Device (SGD).

IT IS THEREFORE ORDERED THAT:

The Department's decision is AFFIRMED.

RM/sb

Robert J. Meade
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

Gretchen Backer
400 S. Pine, 6th Floor
PO Box 30479
Lansing, MI 48909

DHHS Department Rep.

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