CLINICAL MEDICAL POLICY	
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Responsible Department(s):	Medical Management
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Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
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Policy History

Date	Activity
05/01/2025	Provider Effective date
02/26/2025	PARP Approval
11/20/2024	QI/UM Committee review
11/20/2024	Annual Review: Reformatted speech generating device clinical criteria. Added 'Eye Glaze/Eye Glance Technology' criteria.
05/01/2024	Provider Effective date
03/05/2024	PARP Approval
11/15/2023	QI/UM Committee review
11/15/2023	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' section.
03/01/2023	Provider Effective date
01/10/2023	PARP Approval
11/16/2022	QI/UM Committee review
11/16/2022	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
06/01/2022	Provider Effective date
04/06/2022	PARP Approval
11/17/2021	QI/UM Committee review

11/17/2021	Annual Review: Formatting changes made to Procedures section, no changes made to clinical criteria. Updated Summary of Literature and Reference Sources sections. Removed deleted ICD-10 code F80.8.
04/19/2021	Provider Effective Date
02/24/2021	PARP Approval
11/18/2020	QI/UM Committee review
11/18/2020	Annual Review: Formatting changes. Updated Summary of Literature and References.
03/16/2020	Provider effective date
01/29/2020	PARP approval
11/20/2019	QI/UM Committee Review
10/23/2019	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ may provide coverage under the DME benefits of the Company's Medicaid products for medically necessary speech generating devices.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) – A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Speech Therapy – The treatment of speech and communication disorders. The approach used varies depending on the disorder. It may include physical exercises to strengthen the muscles used in speech, speech drills to improve clarity, or sound production practice to improve articulation.

Aphasia/Dysphasia – A condition that involves the impairment of speech and language resulting from a brain lesion, stroke, head injury, or neurodevelopmental disorder.

Apraxia/Dyspraxia – A neurological disorder that involves the inability to sequence sounds or difficulty formulating words to speak, despite the ability to use the oral and facial muscles to make sounds.

Aphonia – A disorder that involves the total loss of speech sounds.

Dysarthria – A disorder that involves the difficulty producing sounds and words due to diseases that affect the oral, lingual, or pharyngeal muscles; speech may be difficult to understand, but the ability to communicate is present.

Speech-Generating Devices (SGDs) – Also known as voice output communication aids, are electronic augmentative and alternative communication (AAC) systems used to supplement or replace speech or writing for individuals with severe speech impairments, enabling them to verbally communicate.

Speech-Language Pathologists (SLPs) – Licensed health professionals educated at the graduate level in the study of human communication and development, as well as communication disorders. An SLP holds a Certificate of Clinical Competence (CCC) in speech-language pathology from the American Speech-Language-Hearing Association (ASHA).

Accessories for Speech-Generating Devices – Consist of access devices that enable selection of letters, words, or symbols via direct or indirect selection techniques. Examples of access devices include optical head pointers, joysticks, switches, wheelchair integration devices, and SGD scanning devices. In addition, replacement accessories such as batteries, battery chargers, and AC adapters are also included as accessories.

Severe excessive language disorder – a condition in which the individual has a lower than normal ability in vocabulary, forming complex sentences, and remembering words. An individual with this disorder may still possess the normal language skills needed to understand verbal or written communication.

Natural communication methods – the method most people exchange information and happens without aids or tools. Examples include speaking with the mouth or signing with the hands. This method may also include other unaided means of communication, including gestures and facial expression. Natural communication may often require adequate motor control and communication partners who can interpret the intended message.

Procedures

1. Speech-Generating Devices (SGDs) may be considered medically necessary durable medical equipment (DME) when ALL of the following criteria are met:

    A. A formal evaluation of the individual's cognitive and communication abilities have been performed by a Speech Language Pathologist (SLP). The findings of this evaluation must be documented as a formal written evaluation and forwarded to the individual's treating physician prior to the device being ordered. The written evaluation must include ALL of the following elements:
        1) Current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment; AND
        2) An assessment of whether the individual's daily communication needs could be met using other natural modes of communication; AND
        3) A description of the functional communication goals expected to be achieved and treatment options; AND
        4) Rationale for selection of a specific device and any accessories; AND
        5) Demonstration that the individual possesses the cognitive and physical abilities to effectively use the selected device and any accessories to communicate; AND
        6) A treatment plan that includes a training schedule for the selected device; AND
        7) For a subsequent upgrade to a previously issued SGD, information regarding the functional benefit to the individual of the upgrade compared to the initially provided SGD; AND
    B. The individual's medical condition is a result of a severe expressive speech impairment; AND
    C. The individual's speaking needs cannot be met using natural communication methods; AND
    D. Other forms of treatment have been considered and ruled out; AND
    E. The individual's speech impairment will benefit from the device ordered.

2. Eye Gaze/Eye Glance Technology
   Eye gaze or eye glance technology (e.g., DynaVox EyeMax System) may be considered medically necessary for an individual who meets the requirements for a SGD listed above, as well as ALL of the following criteria:
    A. The individual has limited use of their extremities which renders them unable to control or sustain fine/gross body movements; AND
    B. The individual must have direct vision in one or both eyes, and for full control of the system, should have the ability to look up, down, left and right; AND
    C. The individual must have adequate vision to view the screen; AND
    D. Must have ability to focus on one spot for a brief period of time; AND
    E. The provider must submit medical records and/or additional documentation to determine coverage for eye gaze access devices.
       Note: Contraindications for eye gaze/eye glance technology include, but may not be limited to, those individuals with the following conditions: continuous, uncontrolled head movement; nystagmus.

3. Related Components and Accessories for SGDs
    - Accessories may be considered medically necessary if the medical necessity criteria for the base device are met and the medical necessity for each accessory is clearly documented in the formal written evaluation by the SLP. Speech pathology services pertaining to the individual's evaluation and training in use of these devices may also be considered medically necessary.

- When the SGD is not covered, accessories are also not covered.
- The SGD and its components may not be billed separately.
- Speech generating software programs enabling a laptop computer, desktop computer or PDA to function as an SGD may be considered medically necessary as a SGD within the terms of this policy. Installation of the program or technical support is not separately reimbursable.
- Separate billing should not be made for any software, interfaces, cables, adapters, interconnects, or switches for the accessory to interface with the SGD.

4. Limitations
   Coverage is made for the most cost-effective item which meets basic communication needs commensurate with the patient's cognitive and language abilities.

5. When speech generating devices services are not considered medically necessary:
   - Devices that are considered experimental or investigational, such as brain-based interfaces
   - Personal laptop computers, desktop computers, personal digital assistants (PDAs), electronic tablets, and any other devices that are not dedicated SGDs are not considered communication devices and are not medically necessary.
   - Multiple or duplicate devices are not medically necessary.
   - Communication aids that are not SGDs (e.g., communication boards) are considered not medically necessary. In addition, services related to non-speech generating devices are also considered not medically necessary.

6. DME requirements
   - SGDs require a prior authorization under the DME benefit
   - The DME item must solely be dedicated to SGDs, accessories, and/or software. Installation of software or technical support are not separately reimbursable.
   - A formal, written report of a face-to-face evaluation of the individual's communication abilities performed by a SLP (mentioned in criteria above) must be available
   - There is a 30-day trial period. SGD devices are not approved unless the individual has used the requested SGD for a trial period in their everyday speaking environment of at least 30 days. During this time, the individual should have access to the device daily and use it in a variety of communication situations. Medicaid can provide reimbursement for the SGD rental during the trial period. The state assistive technology program as well as the manufacturer of the SGD can also assist with providing devices for a trial period. The trial periods are instructive in determining the most appropriate device. There can be multiple devices and multiple trial periods to determine the most appropriate device for the individual.

7. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

8. Place of Service
   The proper place of service for SGD is outpatient.

Governing Bodies Approval

FDA
The U.S. Food and Drug Administration (FDA) classifies SGDs as Class II devices and they are exempt from the premarket notification procedures. The FDA describes these devices as: "system, communication, powered devices." The FDA identifies a powered communication system as an alternating current (AC) or battery-powered device intended for medical purposes that is used to transmit or receive information.

The Centers for Medicare and Medicaid Services (CMS) has published the following guidance:

- National Coverage Determination (NCD) Speech Generating Devices (50.1)
- Local Coverage Determination (LCD) Speech Generating Devices (SGD) (L33739)
- Local Coverage Article (LCA) Speech Generating Devices (SGD) (A52469)

Summary of Literature

Augmentative and alternative communication (AAC) is an area of clinical practice that supplements or compensates for impairments in speech-language production and/or comprehension, including spoken and written modes of communication. AAC can include assistive technology, or the use of any equipment, tool, or strategy to improve functional daily living in individuals with disabilities or limitations. In the United States among students who need support when communicating, a national survey of special educators across all 50 states reported that 18.2% of their students use a form of AAC for their communication mode: 6.9% use gestural modes, 6.5% employ pictorial supports, and 4.8% use a speech-generating device (SGD) (ASHA, 2023).

AAC are typically grouped into two distinct sections:

- No-tech/Low-tech options include:
    - Gestures and facial expressions
    - Writing
    - Drawing
    - Spelling words by pointing to letters
    - Pointing to photos, pictures, or written words
- High-tech options include:
    - Using an app or an iPad or tablet to communicate
    - Using an SGD (ASHA, 2023).

SGDs produce speech using one of the following:

- Digitized audible/verbal speech output with prerecorded messages
- Synthesized audible/verbal speech output which requires message formulation by spelling and device access with the physical touch and device-direct selection techniques
- Synthesized audible/verbal speech output using multiple methods of message formulation and multiple methods of device access
- Software that is downloaded on a computer or other electronic device to generate synthesized audible/verbal speech output.

The following do not meet the definition of an SGD:

- Internet or phone providers, services, or any other modification to a patient's home to allow use of the SGD because such services or modifications could be used for non-medical equipment
- Personal phones or computers
- Specific features of an SGD that are not used by an individual who has a severe speech impairment to meet their functional speaking needs
- Any technology not necessary to allow for generation of audible/verbal speech, email or text, such as hardware or software used to create documents/spreadsheets, play games, play music, and any other technology that performs functions that do not directly meet the functional communication needs of an individual, such as video communications or conferencing.

SGDs can be packaged differently by a variety of manufacturers but must be solely dedicated to functional communication. They are always stand-alone units and may run dedicated proprietary software or commercially available communication apps. The devices may also have features that are capable of generating email, text, or phone messages to allow the patient to "speak" or communicate remotely, as well as the capability to download updates to the covered features of the device from the manufacturer or supplier of the device.

Rationale

In 2016, Chen et al. analyzed the efficacy of the interface design of SGDs on three non-verbal adolescents with Autism Spectrum Disorder (ASD), in hopes of improving their on-campus communication and cognitive disability. The intervention program was created based on their social and communication needs in school. Two operating interfaces were designed and compared: the Hierarchical Relating Menu and the Pie Abbreviation-Expansion Menu. The experiment used the ABCACB multiple treatment reversal design. The test items included:

- Accuracy of operating identification;
- Interface operation in response to questions;
- Degree of independent completion.

Each test listed above improved with the Hierarchical Relating Menu and the Pie Abbreviation-Expansion Menu. The children were able to operate the interfaces skillfully and respond to questions accurately, which evidenced the effectiveness of the interfaces. It was concluded that both interfaces were effective enough to help non-verbal children with ASD at different levels without any limitations. Initially, there was a small pool of nonverbal adolescents with ASD in Taiwan, only three highly heterogeneous participants were recruited. Second, Mirenda and Erickson (2000) hypothesized that the development of communication and adolescent mental function are strongly related, and the present study did not stratify the participants in IQ-level groups, which would have been statistically meaningless because there were only three participants; thus, those IQs might have affected the results.

The results of a 2018 study reveal the positive effects on communication and balanced exchanges that can occur with explicit instruction to peer partners on how to use the same SGD system to initiate, respond, and stay engaged in play. Successful participation across school environments for children with ASD who have complex communication needs is dependent upon ensuring that evidence-based AAC practices are put in place. Communication interventions that ensure others in the environment have skills and knowledge to be able to support individuals learning to use AAC systems can increase opportunities for social participation and possible friendship development (McNaughton & Light, 2013). More research is needed that focuses on support and training for early education service providers working with this population in inclusive settings (Romski et al., 2015). Given the recent advances in the use of iPads as

SGDs in classrooms and in clinical practice without evidence of effectiveness, it will be essential for future research to incorporate what we already know as effective SGD and peer-mediated instructional strategies to support staff using this technology (Thiemann-Bourque, 2018).

Barton-Hulsey and colleagues reported studying three children ages 3 years and 6 months to 5 years and 3 months with developmental and language delays were provided experience with a traditional grid-based display and a contextually organized visual scene display on a speech-generating device to illustrate considerations for practice and future research in augmentative and alternative communication assessment and intervention. Twelve symbols were taught in a grid display and visual scene display using aided input during dramatic play routines. Teaching sessions were 30 minutes a day, 5 days a week for 3 weeks. Symbol comprehension and use was assessed pre and post 3 weeks of experience. Comprehension of symbol vocabulary on both displays increased after 3 weeks of experience. Participants 1 and 2 used both displays largely for initiation. Participant 3 had limited expressive use of either display. The methods used in this study demonstrate one way to inform individual differences in learning and preference for speech-generating device displays when making clinical decisions regarding augmentative and alternative communication supports for a child and their family (2017).

Almirall et al noted that there are limited data on the effects of adaptive social communication interventions with a SGD in autism. These researchers compared growth in communications outcomes among 3 adaptive interventions in school-age children with ASD who are minimally verbal. A total of 61 children, aged 5 to 8 years, participated in a sequential, multiple-assignment randomized trial (SMART). All children received a developmental behavioral communication intervention: joint attention, symbolic play, engagement and regulation (JASP) with enhanced milieu teaching (EMT). The SMART included 3 2-stage, 24-week adaptive interventions with different provisions of a SGD in the context of JASP+EMT. The first adaptive intervention, with no SGD, initially assigned JASP+EMT alone, then intensified JASP+EMT for slow responders. In the second adaptive intervention, slow responders to JASP+EMT were assigned JASP+EMT+SGD. The third adaptive intervention initially assigned JASP+EMT+SGD; then intensified JASP+EMT+SGD for slow responders. Analyses examined between-group differences in change in outcomes from baseline to week 36. Verbal outcomes included spontaneous communicative utterances and novel words. Non-linguistic communication outcomes included initiating joint attention and behavior regulation, and play. The adaptive intervention beginning with JASP+EMT+SGD was estimated as superior. There were significant ($p < 0.05$) between-group differences in change in spontaneous communicative utterances and initiating joint attention. The author concluded that school-age children with ASD who are minimally verbal made significant gains in communication outcomes with an adaptive intervention beginning with JASP+EMT+SGD. They stated that future research should explore mediators and moderators of the adaptive intervention effects and second-stage intervention options that further capitalize on early gains in treatment. These findings were also confounded by the use of multiple modalities (Almirall et al, 2016).

Coding Requirements

Procedure Codes

CPT/ HCPCS Code	Description
E2500	Speech generating device, digitized speech, using prerecorded messages, less than or equal to eight minutes recording time
E2502	Speech generating device, digitized speech, using prerecorded messages, greater than eight minutes but less than or equal to 20 minutes recording time
E2504	Speech generating device, digitized speech, using prerecorded messages, greater than 20 minutes but less than or equal to 40 minutes recording time
E2506	Speech generating device, digitized speech, using prerecorded messages, greater than 40 minutes recording time
E2508	Speech generating device, synthesized speech, requiring message formulation by spelling and access by physical contact with the device
E2510	Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access
E2511	Speech generating software program, for personal computer or personal digital assistant **(not separately reimbursable) NO FEE**
E2512	Accessory for speech generating device, mounting system **(not separately reimbursable) NO FEE**

Diagnosis Codes

ICD-10 Code	Description
F80.0	Phonological disorder
F80.1	Expressive language disorder
F80.2	Mixed receptive-expressive language disorder
F80.4	Speech and language development delay due to hearing loss
F80.81	Childhood onset fluency disorder
F80.82	Social pragmatic communication disorder
F80.89	Other developmental disorders of speech and language
F80.9	Developmental disorder of speech and language, unspecified

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

Reference Sources

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