



CLINICAL MEDICAL POLICY	
<b>Policy Name:</b>	Speech Generating Devices
<b>Policy Number:</b>	MP-110-MD-PA
<b>Responsible Department(s):</b>	Medical Management
<b>Provider Notice/Issue Date:</b>	04/01/2024; 02/01/2023; 05/01/2022; 03/19/2021; 02/17/2020
<b>Effective Date:</b>	05/01/2024; 03/01/2023; 06/01/2022; 04/19/2021; 03/16/2020
<b>Next Annual Review:</b>	11/2024
<b>Revision Date:</b>	11/15/2023; 11/16/2022; 11/17/2021; 11/18/2020
<b>Products:</b>	Highmark Wholecare <sup>SM</sup> Medicaid
<b>Application:</b>	All participating hospitals and providers
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### Policy History

Date	Activity
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<sup>SM</sup> 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<sup>SM</sup> 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.

## **Procedures**

1. Speech-Generating Devices (SGDs) may be considered medically necessary durable medical equipment (DME) when ALL of the following criteria are met:
  - A. Prior to delivery of the SGD, the individual has received a formal cognitive and language abilities evaluation by a licensed speech-language pathologist (SLP). The SLP must complete a written augmentative communication evaluation that must include the ALL of the following information:
    - 1) Documentation that the individual's natural modes of communication are inadequate; AND
    - 2) Evaluation of the individual's current communication, speech and language issues, including type, severity, language skills, cognitive abilities; AND
    - 3) Anticipated course of impairment, with a therapeutic history including speech, occupational, or physical therapies, as appropriate; AND
    - 4) A description of the functional communication goals expected to be achieved and treatment options; 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) Rationale for the selected device and accessories; AND
    - 7) A treatment plan that includes a training schedule for the selected devices; AND
    - 8) 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 diagnosis and physiological description includes, at least ONE of the following underlying disorders:
    - 1) Aphasia; OR
    - 2) Aphonia; OR
    - 3) Apraxia; OR
    - 4) Anarthria; OR
    - 5) Dysarthria; AND

- C. A copy of the SLP's written evaluation and recommendation have been forwarded to the individual's treating physician prior to ordering the device; AND
- D. Other forms of treatment have been considered and ruled out; AND
- E. The individual's speaking needs cannot be met using natural communication methods; AND
- F. The individual's speech disability will benefit from the device ordered; AND
- G. The SLP performing the evaluation of the individual may not be an employee or have a financial relationship with the supplier of the SGD.

2. Limitations

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

3. 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, 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

4. 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.

5. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare<sup>SM</sup> at any time pursuant to the terms of your provider agreement.

6. 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 (Ronski 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

<b>HCPCS Code</b>	<b>Description</b>
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 <b>(not separately reimbursable) NO FEE</b>
E2512	Accessory for speech generating device, mounting system <b>(not separately reimbursable) NO FEE</b>

### Diagnosis Codes

<b>ICD-10 Code</b>	<b>Description</b>
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<sup>SM</sup> contract.



## **Reference Sources**

American Speech-Language-Hearing Association (ASHA). Medicare Speech-Generating Devices Information. Accessed on September 27, 2021.

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Thiemann-Bourque K, Feldmiller S, Hoffman L, Johner S. Incorporating a Peer-Mediated Approach Into Speech-Generating Device Intervention: Effects on Communication of Preschoolers With Autism Spectrum Disorder. J Speech Lang Hear Res. 2018. Accessed on September 28, 2020.

Barton-Hulsey A, Wegner J, Brady NC, et al. Comparing the effects of speech-generating device display organization on symbol comprehension and use by three children with developmental delays. Am J Speech Lang Pathol. 2017. Accessed on September 28, 2020.

Almirall D, DiStefano C, Chang YC, et al. Longitudinal effects of adaptive interventions with a speech-generating device in minimally verbal children with ASD. J Clin Child Adolesc Psychol. 2016. Accessed on September 28, 2020.

American Speech-Language-Hearing Association (ASHA). Augmentative and Alternative Communication. 2023. Accessed on October 26, 2023.