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## Speech Generating Devices (SGD)

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Related Policies (if applicable)
None

### Disclaimer

**Carefully check state regulations and/or the member contract.**

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

### Legislative Mandates

**EXCEPTION: For Illinois only:** Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

**EXCEPTION:** For HCSC members residing in the state of Arkansas, § 23-79-130 relating to speech or hearing impairment, requires coverage for the necessary care and treatment of loss or impairment of speech or hearing. The phrase "loss or impairment of speech or hearing" shall include those communicative disorders generally treated by a speech pathologist or audiologist licensed by the Board of Examiners in Speech-Language Pathology and Audiology and which fall within the scope of his or her area of certification. Coverage shall not apply to hearing instruments or devices. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

## Coverage

A speech generating device (SGD) **may be considered medically necessary** when **ALL** the following criteria are met:

- Prior to delivery of the SGD, the individual has had a formal evaluation of their cognitive and communication abilities by a speech-language pathologist (SLP). The formal written evaluation must include, at a minimum, **ALL** of the following elements:
  1. Current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment;
  2. An assessment of whether the individual's daily communication needs could be met using other natural modes of communication (gestural, speech, and/or written communication);
  3. A description of the functional communication goals expected to be achieved and the treatment options;
  4. Rationale for selection of a specific device and any accessories;
  5. Demonstration that the individual possesses a treatment plan that includes a training schedule for the selected device;
  6. Individual has the cognitive and physical abilities to effectively use the selected device and any accessories to communicate;
  7. Any request for upgrading from a previously issued SGD must provide information regarding the functional benefit to the individual of the upgrade compared to the original device; AND
- The individual's medical condition is one resulting in a permanent severe expressive speech impairment; AND
- The individual's speaking needs cannot be met using gestural, speech, and/or written communication; AND
- Other forms of treatment have been considered and ruled out; AND
- The individual's ability to communicate will benefit from the device ordered; AND
- A copy of the SLP's written evaluation and recommendation must be forwarded to the individual's treating physician prior to ordering the device; AND
- The SLP performing the individual's evaluation may not be an employee of or have a financial relationship with the supplier of the SGD.

Software that enables a laptop computer, desktop computer or personal digital assistant (PDA) to function as an SGD **may be considered medically necessary** as an SGD.

Accessories and upgrades **may be considered medically necessary** if the Coverage criteria are met and documentation supporting the medical necessity is clearly documented in the evaluation by the SLP.

An SGD **is considered not medically necessary** for **ANY** of the following:

- Situations in which any one or more of the SGD coverage criteria listed above is not met; OR

- Laptop computers, desktop computer, PDAs, or other devices that are not dedicated SGDs;  
OR
- More than one SGD.

Communication aids that are not SGDs **are considered not medically necessary** as they:

- Are not prosthetics for speech,
- Do not replace all or part of a body organ,
- Do not replace all or part of the function of a permanently inoperative, absent, or malfunctioning body part.

Examples of non-covered communication aids include, but are not limited to, the following:

- Picture books,
- Flash cards,
- Braille typewriters,
- Text telephone or telecommunication device for the deaf (TDD),
- Devices that allow the individual to communicate messages to others with writing (e.g., a display screen or printout) rather than synthesized speech, or
- Devices that allow the user to communicate with a computer rather than with another person.

## Policy Guidelines

None.

## Description

### Speech Generating Devices (SGD)

SGDs provide individuals with severe speech impairment the ability to meet their functional speaking needs. SGDs are speech aids consisting of devices or software that generate speech and are used solely by the individual who has a severe speech impairment. These devices generate speech using one of the following methods:

- Digitized audible/verbal speech output, using prerecorded messages;
- Synthesized audible/verbal speech output which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
- Synthesized audible/verbal speech output which permits multiple methods of message formulation and multiple methods of device access; or
- Software that allows a computer or other electronic device to generate audible/verbal speech.

The following do not meet the definition of SGD:

- Internet or phone services or any modification to a patient's home to allow use of the speech generating device because such services or modifications could be used for non-medical equipment;
- Standard phones or personal computers;
- Specific features of an SGD that are not used by the individual who has a severe speech impairment to meet their functional speaking needs;
- Any computing hardware or software not necessary to allow for generation of audible/verbal speech, email, text, or phone messages, such as hardware or software used to create documents and spreadsheets or play games or music, and any other function a computer can perform that is not directly related to meeting the functional speaking communication needs of the patient, including video communications or conferencing. (1)

Speech-Language Pathologists (SLPs) are licensed health professionals educated at the graduate level in the study of human communication and swallowing disorders in individuals of all ages. An SLP holds a Certificate of Clinical Competence (CCC) in speech-language pathology from the American Speech-Language-Hearing Association (ASHA). (2)

Digitized speech, sometimes referred to as a device with whole message speech output, utilizes words or phrases that have been recorded by an individual other than the SGD user for playback upon command of the SGD user.

Synthesized speech, unlike the pre-recorded messages of digitized speech, is a technology that translates a user's input into device-generated speech. Users of synthesized speech SGDs are not limited to re-recorded messages but rather can independently create messages as their communication needs dictate.

Personal Digital Assistants (PDA) are handheld devices that integrate the functions of a small computer with features such as a cell phone, personal organizer, electronic mail, or pager. Information may be input via a pen-based system using a stylus and handwriting recognition software, keyboard or downloaded from a personal computer using special cables and software.

Speech generating software programs enable a laptop computer, desktop computer, or PDA to function as an SGD. Within this policy, the term SGD also describes these speech generating software programs.

Accessories for SGDs include, but are not limited to, 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.

Mounting systems are devices necessary to place the SGD device, switches, and other access devices within reach of the patient.

Accessories for SGDs (3) include, but are not limited to, access devices that enable selection of letters, words, or symbols via direct or indirect selection techniques. Examples of access devices include, but are not limited to:

- Optical head pointers,
- Joysticks,
- SGD scanning devices,
- Switches,
- Wheelchair integration devices, and
- Replacement accessories, such as batteries, battery chargers, AC adapters, etc.

### **Regulatory**

The U. S. Food and Drug Administration (FDA) classifies SGD's as a class II device. 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. (7)

## **Rationale**

This medical policy was originally developed in 2004 and has been reviewed regularly, with the most recent review as of January 2024. It follows closely with the Medicare National and Local Coverage Determinations regarding Speech Generating Devices.

Speech generating devices (SGDs) have been proven to be a valuable tool to aid individuals with severe speech impairment. Typically, speech impairment caused by certain medical conditions (e.g., head trauma or stroke) gradually improves. Therefore, for such conditions an SGD should only be used as a last option and not initiated until the patient has ceased to improve and the condition is determined to be permanent.

In 2010, Rispoli et al. (3) reviewed synthesized communication interventions for individuals with developmental disabilities. Systematic searches of electronic databases, journals and reference lists identified 35 studies meeting the inclusion criteria. Studies were evaluated in terms of (a) participants, (b) SGD function, (c) SGD characteristics, (d) intervention procedures, (e) intervention results and (f) certainty of evidence. Intervention was provided to a total of 86 participants from 1-42 years of age. Target communication skills included requesting, social or conversational skills, labelling items and receptive language. Intervention approaches were categorized using Discrete Trial Training, Milieu teaching, or a combined instructional approach. Positive outcomes were reported in 86% of the studies with 54% of studies categorized as providing conclusive evidence. The study concluded that the literature base is considered promising due to the large number of conclusive studies and the replication of intervention approaches.

In 2010, van der Meer and Rispoli (4) evaluated communication interventions involving SGD's for children with autism. Twenty-three studies were identified that met the inclusion criteria following systematic searches of electronic databases, journals and reference lists. Studies were evaluated in terms of: (a) participants, (b) setting, (c) mode of communication, (d) communication skill(s) taught to the participant, (e) intervention procedures, (f) outcomes, (g) follow-up and generalization, (h) reliability and treatment integrity and (i) design and certainty of evidence. Intervention, most commonly targeting requesting skills, was provided to a total of 51 children aged 3-16 years. Intervention strategies followed 2 main approaches: operant/behavioral techniques and naturalistic teaching procedures. Positive outcomes were reported for 86% of the studies and 78% of the studies were categorized as providing conclusive evidence. In conclusion, the literature base suggests that SGDs may be a viable communication options for children with autism. However, several areas warrant future research.

In 2016, Almirall et al. (5) stated that there are limited data on the effects of adaptive social communication interventions with a SGD in autism. A sequential, multiple assignment randomized trial (SMART) was conducted to compare growth in communications outcomes among 3 adaptive interventions in children aged 5-8 years old minimally verbal with autism spectrum disorder (ASD). Sixty-one children participated and received a developmental behavioral communication intervention: joint attention, symbolic play, engagement, and regulation (JASP) with enhanced milieu teaching (EMT). The SMART included three 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. It was 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. The authors 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.

In 2016, Chen et al. (6) analyzed the efficacy of the interface design of SGDs on three non-verbal adolescents with 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: (i) the Hierarchical Relating Menu, and (ii) the Pie Abbreviation-Expansion Menu. The experiment used the ABCACB multiple treatment reversal design. The test items included: (i) accuracy of

operating identification; (ii) interface operation in response to questions; and (iii) degree of independent completion. Each of these 3 items improved with both intervention interfaces. 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. The study did have limitations. The first because of the 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 3 participants; thus, those IQs might have affected the results.

In 2018, Thiemann-Bourque et al. (8) examined the effects of incorporating a peer-mediated approach into a speech-generating device (SGD) intervention on communication of 45 nonverbal and minimally verbal preschoolers with autism spectrum disorder (ASD) and 95 peers without disabilities. The effects were evaluated using a multivariate randomized control trial design with repeated measures for 4 cohorts across baseline, intervention, generalization, and maintenance phases. Children were randomly assigned to an experimental treatment that trained peers on use of the SGD or a business-as-usual comparison condition with untrained peers. Children receiving the treatment demonstrated significant increases in rates of communication and more balanced responses and initiations (a measure of reciprocity) than children in the comparison group. They were able to generalize improvements and maintain communication gains. Results support positive effects on communication of teaching young children with ASD and peers without disabilities to use the same SGD system in typical preschool activities. SGD interventions that utilize peer-mediated approaches may improve core deficits in communication and reciprocity and allow for greater classroom social participation and interactions with peers. The RCT identified several limitations. First, the participants with ASD varied in skill level for symbol selection at the start of each year. Some children could select between two enlarged pictures, whereas some children were selecting from 15 to 20 symbols per page and scrolling pages. These differences were attributed to varied experiences with the SGDs. A second limitation was sample size. Finally, the researchers who administered the post intervention standardized language measures were not blind to group assignment at the end of the year. They stated that much more research is needed that focuses on support and training for early education service providers working with this population in inclusive settings; and 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 is already known as effective SGD and peer-mediated instructional strategies to support staff using this technology.

## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member’s benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

<b>CPT Codes</b>	92609
<b>HCPCS Codes</b>	E1399, E1902, E2500, E2502, E2504, E2506, E2508, E2510, E2511, E2512, E2513, E2599

\*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

## References

1. CMS-National Coverage Determination for Speech Generating Devices (50.1) (July 29, 2015). Centers for Medicare and Medicaid Services. Available at <<https://www.cms.hhs.gov>> (accessed January 2, 2024).
2. American Speech-Language-Hearing Association. Speech-Language Pathologists. Available at <<https://asha.org>> (accessed January 19, 2024).
3. Rispoli MJ, Franco JH, van der Meer L, et al. The use of speech generating devices in communication interventions for individuals with developmental disabilities: A review of the literature. *Dev Neurorehabil.* 2010; 13(4):276-293. PMID 20629594
4. van der Meer LA, Rispoli M. Communication interventions involving speech-generating devices for children with autism: a review of the literature. *Dev Neurorehabil.* 2010; 13(4):294-306. PMID 20629595
5. 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.* Jul-Aug 2016; 45(4):442-456. PMID 26954267
6. Chen CH, Wang CP, Lee IJ, et al. Speech-generating devices: effectiveness of interface design-a comparative study of autism spectrum disorders. *Springerplus.* Sep 29 2016; 5(1):1682. PMID 27733984
7. FDA – Physical Medicine Prosthetic Devices. U.S. Food and Drug Administration – Medical Devices (October 17, 2023). Available at <<https://www.accessdata.fda.gov>> (accessed January 2, 2024).
8. Thiemann-Bourque K, Feldmiller S, Hoffman L, et al. Incorporating a Peer-Minded Approach Into Speech-Generating Device Intervention: Effects on Communication of Preschoolers With Autism Spectrum Disorder. *J Speech Lang Hear Res.* Aug 8 2018; 61(8):2045-2061. PMID 30054629
9. CMS-Local Coverage Determination Speech Generating Devices (L33739) (January 1, 2020). Centers for Medicare and Medicaid Services. Available at <<http://www.cms.hhs.gov>> (accessed January 2, 2024).

## Centers for Medicare and Medicaid Services (CMS)



The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <<http://www.cms.hhs.gov>>.

<b>Ag</b>	
<b>Date</b>	<b>Description of Change</b>
03/15/2024	Document updated with literature review. Coverage unchanged. Reference 2 and 8 added.
03/15/2023	Reviewed. No changes.
05/15/2022	Document updated with literature review. Coverage unchanged. References updated.
03/01/2021	Reviewed. No changes.
07/01/2020	Document updated with literature review. Coverage revised; removed statement "The patient will gain intelligible speech with the device despite the patient's severe communication impairment demonstrated by a one-month trial therapy utilizing the device prior to purchase" and replaced with "The patient's speech impairment will benefit from the device ordered." Added reference 8.
07/15/2018	Reviewed. No changes.
10/15/2017	Document updated with literature review. Coverage unchanged.
04/01/2016	Reviewed. No changes.
08/01/2015	Document updated with literature review. The following was added to coverage: added "permanent" to the following criteria "The patient's medical condition is one resulting in a permanent severe expressive speech".
07/01/2014	Reviewed. No changes.
12/15/2013	Document updated with literature review. Coverage unchanged.
12/01/2007	Revised/updated entire document.
12/01/2005	Codes revised/added/deleted.
09/20/2004	New medical document.