Molina Clinical Policy
Speech Generating Devices
Policy No. 445

Last Approval: 12/10/2025
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Speech generating devices (SGDs), a type of augmentative and alternative communication device (AAC), are used to facilitate functional communication for individuals with speech or language impairments. Communication disorders may include dysarthria, apraxia, aphasia, or anarthria. Individuals with severe disabilities may also experience expressive speech impairment. Associated functional disabilities may limit an individual's ability to use other natural methods of communication (Hayes 2024).

SGDs use pictures, words, or other symbols that represent parts of speech including nouns, verbs, adjectives, and adverbs. When symbols are selected on the screen of the device an audible output is produced and used to communicate the message.

SGDs generate speech using one of the following methods (Hayes 2024):

- 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
- Software that allows a computer or other electronic device to generate audible/verbal speech

SGDs are accessed by direct or indirect selection. Direct selection requires the individual to make physical contact with the device to produce communication and is only appropriate for those who have reliable fine motor skills. Indirect selection allows for communication through access devices such as a head mouse, joystick, infrared pointers, head pointers, light pointers, switches, wheelchair integration devices, eye gaze technology, and scanning devices (Hayes 2024). Speech generating software programs enable devices such as laptop computers, desktop computers, personal digital assistants, tablet devices, or smart phones to function as an SGD.

Regulatory Status

SGDs are regulated by the FDA as powered communication systems and are considered Class II devices under product code ILQ, and are exempt from the 510(k) premarket notification process. While there are many SGDs on the market, notable devices include the noddle System (Voxello), Wego 5A, Wego 13A (Talk To Me Technologies), TD I-13, TD-16, TD Pilot, TD Navio, TD I-110 (Tobii Dynavox), Vibe 10, Vibe 12+, Allora 3, Tellus 6, and Tellus i6 (Jabbla).

COVERAGE POLICY

Please review all applicable State and Federal mandates and health plan regulations before applying the criteria below. Refer to requirements, criteria, and guidance provided by the State in which the Member is receiving treatment, as the State's documents will supersede this Molina Clinical Policy

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Speech Generating Devices

Speech generating devices (SGDs) may be **considered medically necessary** when ALL the following criteria are met:

1. A speech evaluation is conducted by a speech language pathologist who is licensed in the state where the services are being performed and who is certified by the American Speech-Language-Hearing Association. The evaluation must include ALL the following elements:
   a. An evaluation of current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of impairment
   b. Demonstration that the Member possesses the cognitive and physical abilities to effectively use the selected device and any accessories to communicate
   c. Description of the functional communication goals expected to be achieved and treatment plan that includes a training schedule for the selected device
   d. Documentation of a trial with the requested device, including six (6) thirty-minute training sessions, showing specific words, sounds, and/or messages being communicated using the device that cannot be communicated at baseline
   e. Rationale for selection of a specific device and accessories
   f. Plan of care for the device including training needs for the Member and caregiver(s), programming needs, and planned evaluations

2. The Member has a permanent and severe expressive speech impairment such as dysarthria, anarthria, aphasia, or aphonia, including communication impairments associated with an autism spectrum disorder or developmental disorder

3. Speaking needs cannot be met using natural communication methods

4. Other forms of treatment have failed, are contraindicated, or are otherwise not appropriate

5. A SGD is available in the Member's primary language and is being requested as a dedicated device for the sole purpose of speech generation and communication, and may include:
   a. The capability to generate email, text, or phone messages which allows the Member to communicate remotely
   b. The capability to download updates to the covered features of the device from the manufacturer or supplier of the device

Speech Generating Device Accessories

A SGD accessory may be **considered medically necessary** for a SGD if the medical necessity for each accessory is documented through formal evaluation by a licensed speech language pathologist. For any upgrades to equipment or accessories, documentation must be submitted to demonstrate medical necessity

Limitations and Exclusions

All other treatment requests that do not meet the above criteria are considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes, including but not limited to ALL the following:

1. Tablet devices (e.g., iPads) that are not dedicated to the sole purpose of communication

2. Multi-purpose, general consumer electronic devices such as computers, smart phones, electronic mail devices, pages, personal digital assistants

3. Internet providers, phone service subscriptions, or modifications to an individual's home

4. Simple communication devices that do not meet the definition of a SGD, such as those that only use pre-recorded messages

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5. Features of a SGD that are not used to meet functional speaking or communication needs, including but not limited to:
    a. Computing hardware or software not necessary for generation of audible/verbal speech, email, text, or phone messages
    b. Video communications or conferencing
    c. Hardware or software used to create documents and spreadsheets, play games or music, video communications or video conferencing

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Randomized Controlled Trials

Gilroy et al. (2018) conducted a randomized control trial to evaluate the social and communication effects observed from high- and low-tech forms of augmentative and alternative communication (AAC) interventions. 35 school-aged children with a diagnosis of autism spectrum disorder who experienced deficits in communication, functional communication at low or zero rates, social and communicative function one or more standard deviations below average, and did not have another diagnosis to account for impairment were included in the study. Participants either received intervention with a speech generating device (SGD) (high-tech AAC) or the picture exchange communication system (low-tech AAC). Participants received four months of communication training in which they were taught to either use a tablet or pictures cards to communicate. Primary outcome measurements in the study included rates of functional communication, rates of unprompted requesting, rates of queried requesting, and rates of queried social responding. In both groups there was a significant increase in the overall rates of functional communication and rates of unprompted requesting compared to baseline ($p < 0.001$), but there was not a significant difference between the two AAC interventions. Rates of queried requesting were also significantly improved from baseline ($p < 0.001$), but the difference between the AAC modalities were not significant. There was no significant difference from baseline in rates of queried social responding in either AAC group ($p = 0.162$). These results indicate that both SGD and picture exchange communication systems significantly improve communication in school-aged children with autism spectrum disorder (ASD), but results did not differ significantly between the two approaches. Limitations of the study included a small sample size and the length of the intervention. Further studies are needed to understand situations in which one method may be better suited than another. This study also did not allow for participants degree of preference which may have influenced outcomes.

Systematic Reviews and Meta-Analyses

Yuan et al. (2024) performed a systematic review to evaluate how SGD interventions affect natural speech production among children with ASD and severe communication impairment, of which approximately one-third remain nonverbal or minimally verbal throughout their lifespan. The review included 18 studies, which included 14 single-subject and 4 group design prospective studies, for a total population of 108 children ($n = 108$) aged 3 to 13 years (mean age 6.5 years old) who had ASD and participated in SGD-based interventions. The majority of participants were minimally verbal, typically producing fewer than 20 spontaneous words prior to intervention; prior expressive and receptive language abilities were very limited, with verbal age equivalents between 6 and 24 months old. All study interventions incorporated an SGD and were typically paired with established behavioral or naturalistic teaching strategies, such as time delay, prompting, differential reinforcement, Enhanced Milieu Teaching, and Joint Attention Symbolic Play Engagement and Regulation (JASPER). While intervention intensity varied, single-subject studies typically lasted between 1 and 17 weeks, with typically 5 to 10 device trials per session, and with sessions lasting between 15 and 25 minutes. Group design studies used a 24-week intervention followed by a 12-week follow-up period. Outcomes were measured using various speech-related metrics, such as vocal requesting, labeling, novel words, word approximations, and vocal initiations. In 9 of the 14 single-subject design studies, there was a clear and functional relationship demonstrated between the SGD intervention and increased speech, whereas the other studies showed mixed outcomes. Group design studies consistently showed significant gains in spontaneous communication utterances and other speech outcomes when SGDs were added to naturalistic interventions. Overall, 95 of 108 children (87%)

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demonstrated improvement in vocal utterances following SGD-based interventions and no study reported a decrease in spoken language as a result of SGD use. While the strongest predictor of positive response was prelinguistic abilities, some children, with no speech at baseline, acquired vocalizations during intervention, indication that prior speech is not necessary for benefit. Study limitations include inconsistent reporting of fidelity data, inadequate description of intervention procedures, incomplete or absent baseline information, and minimal reporting of intervention agent credentials. The authors concluded that SGS combined with evidence-based practices can increase children's verbal language and social communication utterances. The authors emphasize that this emerging topic needs further research, including the differences between SGD interventions and interventions using tablet-based devices (e.g., iPads).

Waddington (2018) conducted a systematic review and meta-analysis evaluating interventions involving high-tech speech generating devices. Studies were selected if they included participants under the age of 8 years with a diagnosis of ASD, involved intervention with a high-tech SGD, and targeted a functional/social communication skill. Eighteen studies were used in the analysis and included 54 participants, 44 males and 10 females. The improvement rate difference was used as the effect size indicator for each study. Thirteen studies had strong effects on the target verbal operant, 4 had moderate effects, and 1 had weak effects. It was concluded that high-tech SGDs are strongly effective for teaching single- and multi-step manding, multi-step tacting, and multi-step intraverbals. High-tech SGDS were moderately effective for teaching single-step tacting, and only weakly effective for increasing vocal production.

National and Specialty Organizations

The **American Speech-Language-Hearing Association (ASHA)** published information about *Augmentative and Alternative Communication,* which provides an overview on augmentative and alternative communication including methods, devices, and key issues related to this topic. ASHA states that speech-language pathologists play a central role in the screening, assessment, and treatment of individuals who require an AAC intervention, including diagnosis, assessment, planning, and treatment. Communication disorders can be a result of congenital disabilities (e.g., cerebral palsy, developmental apraxia, genetic disorders, intellectual disabilities), acquired disabilities (e.g., neurodegenerative diseases, traumatic brain injury), or neurological differences (e.g., autism). SGDs are considered a high-tech, aided type of AAC which uses synthesized and/or digitized speech. While many factors can serve as barriers to AAC use, they can be reduced through thorough training conducted with both the user and the family or caregiver, including theoretical and practical experience. Barriers can also be reduced when there is collaboration with the user, their family, and a multidisciplinary team to incorporate their needs and values during selection of the device ([1]ASHA date unknown).

Additionally, **ASHA** published information about *Telepractice*. ASHA states that telepractice is an appropriate model of service delivery for speech language pathologists and audiologists, and that it may be the primary mode of service delivery or supplement in-person services, including for screening, assessment, intervention, consultation, and education. "There are no inherent limits to where telepractice can be implemented, as long as the services comply with national, state, institutional, and professional regulations and policies" ([3]ASHA date unknown).

The **ASHA** Certificate of Clinical Competence (CCC), which is a nationally recognized credential, represents a level of excellence in audiology and speech-language pathology. Certified professionals have the knowledge, skills, and expertise to provide high quality clinical services, and are actively engaged in ongoing professional development. More than 228,000 professionals currently hold the ASHA certification, and certification is not contingent upon membership in any professional organization ([2]ASHA date unknown).

The **Royal College of Speech and Language Therapists (RCSLT)** published *guidance on augmentative and alternative communication*. The authors recommend that speech language therapists consider AAC told and techniques as potentially supportive to anyone presenting with aphasia, aphonia/dysphonia, cognitive communication impairment, developmental language disorder, dysarthria/anarthria, dysfluency, dyspraxia, learning disabilities, pre-intentional communication linked to cognition, speech sound disorders, selective mutism, and social communication disorder. SGDs, also referred to as voice output communication aids, whether digitized or synthesized, are a type of AAC. According to the RCSLT, Guideline 2, "an AAC system is often for life, regardless of the age at which it is introduced and may take time to learn. This should be factored into the ongoing management and support of the AAC." Additionally, according to Guideline 8, an "AAC assessment referrals and final recommendations should be based on consistent reporting of speech, language and communication characteristics. Reporting should include consideration of all forms of AAC, vocabulary selection and, in aided forms of AAC, vocabulary organisation, graphic representation options and trajectory plans" (RCSLT 2024).

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An appropriate AAC system is a long-term commitment, and choosing the right system is important to ensure there isn't a hiatus or loss for the AAC user. It's key to choose reliable and proven technologies, and "not be beguiled by mainstream technologies when a dedicated AAC system and/or device solution may better support the AAC user now and in the future." The introduction of an AAC requires sufficient communication partner training to ensure that a user's abilities and needs are recognized and supported appropriately (RCSLT 2024).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
92607	Evaluation for prescription for speech-generating augmentative and alternative communication device, face-to-face with the patient; first hour
92608	Evaluation for prescription for speech-generating augmentative and alternative communication device, face-to-face with the patient; each additional 30 minutes (List separately in addition to code for primary procedure)
92609	Therapeutic services for the use of speech-generating device, including programming and modification

HCPCS (Healthcare Common Procedure Coding System)

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
E2512	Accessory for speech generating device, mounting system
E2513	Accessory for speech generating device, electromyographic sensor
E2599	Accessory for speech generating device, not otherwise classified

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/10/2025 Policy reviewed. No changes to coverage criteria.
12/11/2024 Policy reviewed. No changes to coverage criteria.
12/13/2023 New Policy. IRO Peer Review on November 27, 2023, by a practicing physician board-certified in Speech Pathology.

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