Molina Clinical Policy
Speech Generating Devices: Policy No. 445

Last Approval: 12/11/2024
Next Review Due By: December 2025

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), also known as augmentative or alternative communication devices (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.

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.

Speech is generated 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
- 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, headpointers, lightpointers, switches, wheelchair integration devices, eye gaze technology, and scanning devices.

Speech generating software programs enable devices such as laptop computers, desktop computer, personal digital assistant, tablet devices, or smart phones to function as an SGD.

Speech generating devices are classified as Class II devices by the U.S. Food and Drug Administration with product code ILQ and are exempt from premarket notification procedures. The FDA identifies them as, "A powered communication system is an AC- or battery-powered device intended for medical purposes that is used to transmit or receive information" (FDA 2024). It is used by persons with communication deficits with or without a physical impairment.

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.

Speech Generating Devices

Speech Generating Devices may be covered and are **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 individual 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 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 individual and caregiver(s), programming needs and planned evaluations

2. The individual 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 method

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

5. A speech generative device is available in the individual's primary language and is being requested for the sole purpose of speech generation

6. The speech generating device is used primarily for speech, but may also include the following:
    a. The capability to generate email, text, or phone messages which allows the individual to communicate remotely
    b. The capability to download updates to the covered features of the device form the manufacturer or supplier of the device

Speech Generating Device Accessories

A speech generating device accessory is considered **medically necessary** for a speech generative device if the medical necessity for each accessory is documented through formal evaluation by a 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 not medically necessary or experimental, investigational, and/or unproven**, including **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. Devices that use pre-recorded messages
5. Features of a speech generating device 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

Gilroy et al. (2018) conducted a randomized control trial to evaluate the social and communication effects observed from high- and low-tech forms of AAC interventions. 35 school-aged children with a diagnosis of autism spectrum disorder who experienced deficits in communication, functional communicate 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 (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 improvement 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 PECS significantly improve communication in school-aged children with 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.

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.

Couper et al. (2014) analyzed the time it took for children with autism spectrum disorder and limited communication skills to learn to make requests for preferred stimuli using manual signs, picture exchange, and speech-generating devices. Nine children were taught to make requests for more toy play by selecting the MORE icon from the screen, exchanging a picture card representing MORE, and producing a manual sign for MORE. In addition to teaching the requesting responses, AAC modality preference assessment probes were conducted during and after intervention. These probes were used to determine if the children would show a preference for using one modality over others. Seven children showed increases in their use of the AAC modalities to make requests. Four children required fewer sessions to learn the SGD option compared with picture exchange and manual signing. When given a choice as to which modality to use, eight children showed a preference for using the SGD. All six children who received follow-up sessions maintained accurate use of the SGD.

National and Specialty Organizations

The **American Speech Language Hearing Association (ASHA)** published clinical guidelines, *Augmentative and Alternative Communication.* These guidelines provide an overview on augmentative and alternative communication including methods, devices, and key issues related to this topic.

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

12/11/2024 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.

REFERENCES

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3. Couper L, van der Meer L, Schäfer MC, et al. Comparing acquisition of and preference for manual signs, picture exchange, and speech-generating devices in nine children with autism spectrum disorder. Dev Neurorehabil. 2014 Apr;17(2):99-109. doi: 10.3109/17518423.2013.870244. Epub 2014 Jan 6. PMID: 24392652.
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communication system for children diagnosed with autism spectrum disorder. Autism Res. 2018 Dec;11(12):1701-1711. doi: 10.1002/aur.2025. Epub 2018 Nov 26. PMID: 30475454.
5. Waddington H. Meta-analysis provides support for the use of high tech speech-generating devices for teaching a range of communication skills to children with autism spectrum disorders, Evidence-Based Communication Assessment and Intervention, 2018 Dec;1-2, 7-11. DOI: 10.1080/17489539.2018.1472903.
6. United States Food and Drug Administration (FDA). Code of federal regulations. Powered communication system. Updated August 30, 2024. Accessed November 6, 2024. https://www.accessdata.fda.gov