Medical Coverage Policy

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Speech Generating Devices

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses speech generating devices, which assist individuals with severe speech impairments in meeting functional speaking needs.

Coverage Policy

Coverage for Durable Medical Equipment (DME), including speech generating devices, varies across plans. Refer to the customer's benefit plan document for coverage details.

If coverage for speech generating devices is available, the following conditions of coverage apply.

Synthesized Speech Generating Devices
A speech generating device that utilizes synthesized speech is considered medically necessary when ALL of the following criteria are met:

- The individual has a permanent and severe expressive speech impairment such as dysarthria, anarthria, aphasia, or aphonia, including a severe speech impairment associated with an autism spectrum disorder or pervasive developmental disorders.
- A speech evaluation, conducted by a speech-language pathologist, has documented the severity of the individual's disability, specific to their primary language.
- Speaking needs cannot be met using natural communication methods.
- Other forms of treatment have failed, are contraindicated, or are otherwise not appropriate.
- A speech generating device is available in the individual's primary language and is being requested for the sole purpose of speech generation.
- The speech generating device is used primarily for speech, but may also include the following:
    - the capability to generate email, text, or phone messages which allows the individual to communicate remotely
    - the capability to download updates to the covered features of the device from the manufacturer or supplier of the device

Not Medically Necessary
The following devices are considered not medically necessary:

- Tablet devices (e.g., iPads) that are not dedicated to the sole purpose of communication
- Multi-purpose, general consumer electronic devices such as computers, smartphones, smartwatches, personal digital assistants (PDAs), and pagers.
- Implantable brain-computer interface (BCI) (e.g., imagined speech) used in a synthesized speech-generating device for ANY indication

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Synthesized Speech Generating Devices

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
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

Not Medically Necessary

Considered Not Medically Necessary:

HCPCS Codes	Description
C1889†	Implantable/insertable device, not otherwise classified
E1399††	Durable medical equipment, miscellaneous

†**Note: Considered Not Medically Necessary when used to report implantable brain-computer interface**

††**Note: Considered Not Medically Necessary when used to report multi-purpose, general consumer electronic devices**

General Background

Effective communication relies on receptive and expressive language abilities, as well as the physical capability to consistently produce intelligible speech sounds. Vocal communication enables individuals to interact, form relationships, and exercise autonomy through choice and participation. Communication impairments may result from congenital conditions such as intellectual and developmental disabilities, cerebral palsy, developmental verbal apraxia, and developmental language disorders. They may also be acquired due to traumatic brain injury, stroke, multiple sclerosis, amyotrophic lateral sclerosis (ALS), tetraplegia, ventilator dependence, or laryngectomy resulting from cancer. Assistive technologies that support or replace expressive language are commonly referred to as augmentative and alternative communication (AAC) devices. The term speech generating device (SGD) is used to distinguish medical devices from standard consumer electronics. AAC systems are categorized as either low-tech (e.g., picture books, communication boards), or high-tech electronic devices with voice output capabilities using digitized or synthesized speech (Chen, et al., 2021).

Digitized AAC devices store prerecorded messages that are activated by the user enabling quick, simple communication. These are typically used by individuals who are preliterate, have

intellectual and developmental disabilities, or require basic communication tools for daily activities. However, they are not suitable for users who need to express complex thoughts or emotions. In contrast, synthesized speech devices, also known as text-to-speech (TTS) devices, use software that applies phonics and pronunciation rules to translate alphanumeric text into spoken output through speech synthesizer hardware. These devices feature built-in speech synthesis capabilities that vocalize words and phrases that have been typed and/or previously stored in the device. They enable open-ended communication on any topic by allowing users to express themselves freely using any words they choose (Chen, et al., 2021).

According to the **American Speech-Language-Hearing Association (ASHA)**, licensed speech-language pathologists (SLPs) are integral to the screening, assessment, diagnosis, and treatment of individuals requiring augmentative and alternative communication (AAC). The primary objective of assessment is to identify system components that optimize functional communication. Evaluation addresses individual needs, including augmentative strategies to support natural speech, alternative methods to replace verbal or written expression, and temporary versus permanent AAC requirements. Assessment also considers AAC system components including primary components that perform core language functions and most directly impact communication (e.g., symbols, vocabulary, methods of utterance generation); secondary components which influence system interaction (e.g., user interface, selection techniques, output modalities); and tertiary components external to the system but impacting long-term success (e.g., switches, portability, mounting, training and support). A comprehensive AAC evaluation by an SLP should include:

- current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment
- an assessment of whether the individual's daily communication needs could be met using other natural modes of communication
- a description of the expected functional communication goals and treatment options
- rationale for device selection
- demonstration that the individual possesses a treatment plan that includes a training schedule for the selected device
- documentation of the individual’s cognitive and physical abilities to effectively use the selected device
- for an upgrade to a previously issued SGD, information regarding the functional benefit of the upgrade to the individual is documented

Individuals with severe disabilities often present with complex physical, cognitive, linguistic, sensory and motor needs. Upon completion of the evaluation, a speech generating device may be recommended according to the permanence and severity of expressive speech impairment, and alignment with short and long-term communication goals.

U.S. Food and Drug Administration (FDA)
Speech Generating Devices (SGDs) are considered Class II medical devices and are categorized as powered communication systems with product code ILQ. These devices are designed to transmit or receive information for medical purposes and are intended for use by individuals who are unable to communicate through typical means due to physical impairments. Under regulation number 890.3710, SGDs are exempt from the FDAs 510(k) premarket notification process as outlined in the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the 21st Century Cures Act of 2016 (FDA, 2025a).

Synthesized Speech Generating Devices

Synthesized speech generating devices (SGDs), also referred to as voice output communication aids (VOCAs), provide computer generated speech and may integrate with email, word processing, and environmental control systems. These high-tech devices often support multiple access methods including direct touch-screen selection, scanning techniques, joystick or mouse controls, and encoding systems that utilize simplified movements such as eye blinks to facilitate communication (Desch et al., 2025).

Synthesized speech devices include, but are not limited to the following:

- Allora (ZYGO Industries, Inc., Fremont, CA)
- ECO2 (Prentke Romich Company, Wooster, OH)
- Lightwriter (Forbes AAC, Mansfield, OH)
- Nova Chat 8, Nova Chat 10 (Saltillo Corp., Millersburg, OH)
- Tobii Dynavox TD I-Series, TD Pilot, TD Navio, TD I-110 (Tobii Dynavox USA, Pittsburgh, PA)
- Accent™ 800-M (Prentke Romich Company, Wooster, OH)
- Accent™ 1000-M (Prentke Romich Company, Wooster, OH)
- QuickTalker™ Freestyle (AbleNet, Inc., Roseville, MN)
- QuickTalker™ Freestyle mini (AbleNet, Inc., Roseville, MN)

Literature Review
Systematic reviews, descriptive studies, retrospective analyses, observational research, and a limited number of randomized controlled trials suggest that augmentative and alternative communication (AAC) devices, including synthesized speech-generating devices (SGDs), may be effective in supporting communication for children and adults with various developmental disabilities such as autism spectrum disorder (ASD), Down syndrome (DS), and cerebral palsy (CP). Evidence indicates that SGD use can positively influence communicative, educational, social, and emotional outcomes. However, consistent recommendations remain challenging due to significant heterogeneity in participant age, diagnoses, skill levels, AAC modalities, and variabilities in long-term benefits (Kent-Walsh, et al., 2025; Leonet, et al., 2022; Avagyan, et al., 2021; Crowe, et al., 2021; Barker, et al., 2019; Barbosa, et al., 2018; Muharib and Alzrayer, 2018; Kasari, et al., 2014; Kagohara, et al., 2012; Millar, et al., 2006).

Although evidence remains limited, the use of augmentative and alternative communication (AAC) devices, including synthesized speech-generating devices (SGDs), is an accepted intervention for select patients with acquired neurologic conditions such as amyotrophic lateral sclerosis (ALS), traumatic brain injury (TBI), brainstem impairment (e.g., stroke, tumor), and locked-in syndrome (LIS). Current research primarily consists of observational and descriptive studies that report improvements in communication abilities and quality of life scores when high-technology AAC interventions are implemented. However, additional well-designed studies are needed to validate these findings and establish standardized treatment parameters (Formica, et al., 2024; Russo, et al., 2017; Fried-Oken, et al., 2011; Beukelman, et al., 2007).

Corallo et al. (2017) conducted an observational study to evaluate the impact of augmentative and alternative communication (AAC) systems on anxiety, depression, and quality of life (QoL) in individuals with locked-in syndrome (LIS) and their caregivers. The study included 15 participants (mean age 48.7 years; 9 males, 6 females) diagnosed with LIS per Plum and Posner criteria, characterized by preserved eye movements, anarthria, dysphagia, tetraplegia, and intact consciousness and cognition. LIS onset followed hemorrhagic brain injury, with diagnosis confirmed one-month post-injury. Cognitive status was evaluated using adapted standardized tools, including the Level of Cognitive Functioning Scale, Rey Auditory Verbal Learning Test, Raven's Progressive Matrices, Token Test, and Wisconsin Card Sorting Test. Exclusion criteria

included aphasia comprehension deficits and non-cooperation. Participants utilized AAC devices operated via head movements with software enabling selection from 100 characters. Primary outcomes were measured using the Short Form-36 (SF-36), Hamilton Anxiety Rating Scale (HAM-A), and Beck Depression Inventory-II (BDI-II) over a 3-month follow-up. Results demonstrated significant improvements in depression, anxiety, and QoL among participants ($p<0.001$). Caregivers showed significant improvements in HAM-A ($p=0.003$), vitality ($p<0.001$), social role functioning ($p<0.001$), and emotional role functioning ($p<0.001$). Correlation analysis revealed positive associations between BDI-II scores and SF-36 subscales, including participant's vitality and mental health, as well as anxiety symptoms and bodily pain ($p<0.05$). Limitations include study design, small sample size, and short follow-up duration.

Professional Societies/Organizations
The **American Heart Association (AHA)** and **American Stroke Association (ASA)** clinical practice guideline, endorsed by the **American Speech-Language-Hearing Association (ASHA)**, emphasizes that communication is essential for daily functioning and is frequently impaired following stroke. Such impairments can significantly affect activities of daily living, limit participation in various activities, and lead to long-term deficits. Communication disorders are common after stroke and may include dysarthria (i.e. a group of speech disorders that result from paralysis, weakness, or incoordination of speech musculature after neurological damage) and apraxia of speech (i.e. a disorder of motor planning resulting in difficulty in volitionally producing the correct sounds of speech including rate, pitch, and volume). Following evaluation by a certified speech language pathologist (SLP), the guideline recommends the use of augmentative and alternative communication (AAC) devices, including high-tech speech-generating devices, to supplement speech in individuals with dysarthria or apraxia of speech (Winstein, et al., 2016).

American Academy of Neurology (AAN) endorsed by the **American Association of Neuromuscular and Electrodiagnostic Medicine:** In their practice parameters on the care of patients with amyotrophic lateral sclerosis (2009; reaffirmed 2023), the AAN accentuates that communication is essential for meaningful participation in life, particularly in fostering social connection. For individuals with amyotrophic lateral sclerosis (ALS), communication strategies may include the use of alphabet boards, computerized communication systems, Morse code, and infrared eye-tracking technologies. However, the guideline notes that no controlled studies have specifically evaluated communication interventions in ALS. As a result, there is currently insufficient evidence to support or refute the effectiveness of any particular treatment approach aimed at optimizing communication in this population.

A 2025 clinical report from the **American Academy of Pediatrics** provides guidance on prescribing assistive technology for children with complex communication needs (CCN). The report supports the use of augmentative and alternative communication (AAC) systems, citing evidence that AAC promotes language development. Children with severe communication impairments and CCN may achieve a degree of independence in adulthood, including employment in fields such as editing, writing, and computer-based work, which rely on judgment and reasoning rather than speed of output. Successful outcomes depend on early access to high-quality AAC tools and comprehensive training during childhood. High-tech speech-generating devices (SGDs) offer important advantages, including expandability and flexibility as vocabulary can be modified over time to align with evolving communication skills, enabling the device and child to work in tandem to support proficiency across the continuum of care. Evaluation for high-tech SGDs should include a comprehensive assessment of functional abilities, environment, and personal preferences, and be led by a speech-language pathologist (SLP) in collaboration with an interdisciplinary team that may include occupational therapists (OTs), physical therapists (PTs), and assistive technology professionals (ATPs). Device selection should be based on individual needs and SGD feature requirements. Although successful use of complex SGDs has been documented in children younger

than three years, there is no consensus on the earliest age for implementation, and further research is needed to determine the benefits of earlier exposure (Desch et al., 2025).

The **National Institute on Deafness and Other Communication Disorders (NIDCD)** fact sheet discussing assistive devices for people with hearing, voice, speech, or language disorders (2011; updated 2019) reports that augmentative and alternative communication (AAC) devices, including speech-generating devices that translate words or pictures into speech, support individuals with voice, speech, and language disorders by enhancing meaningful communication and promoting participation in daily activities. The NIDCD does not outline specific patient populations or clinical indications for the use of this technology.

Brain-Computer Interfaces

Brain-computer interfaces (BCIs), also referred to as brain-machine interfaces, translate neuronal signals into actionable outputs such as cursor control or text entry for external devices like speech generating devices. These signals are captured via non-invasive scalp electrodes or surgically implanted intracranial electrodes. Originally developed to support individuals with severe neurological impairments (e.g., advanced amyotrophic lateral sclerosis or brainstem stroke), BCIs aim to facilitate communication and daily functioning. A limited number of long-term human implants have been conducted exclusively for research purposes, and significant challenges remain. Key concerns include the practicality and long-term viability of BCI systems, particularly in relation to surgical risks and durability of implanted components (Puthuveetil and Krusienski, 2025).

U.S. Food and Drug Administration (FDA)

Brain-computer interfaces for speech generating device access are not FDA-approved.

Literature Review

Emerging research suggests that implantable brain-computer interfaces (iBCIs) may improve speech generating device (SGD) communication through cursor-controlled typing or speech phoneme decoding for individuals with neurological conditions such as stroke, amyotrophic lateral sclerosis (ALS), and spinal cord injury (SCI). Current evidence is limited to case reports, case series, and retrospective reviews involving small, heterogenous patient populations. Substantial variability exists in device types, participant selection, iBCI applications, and outcome measures (Dohle, et al., 2025; Rubin, et al., 2023).

ECRI (2023) conducted a clinical evidence assessment of implantable brain-computer interfaces (iBCIs) for restoring communication in individuals with severe speech and motor impairments. The review included one systematic review (8 studies; n=48) and four clinical trial case series (n=1–14), totaling 55 participants. Eligible studies reported patient-oriented outcomes such as adverse events (AEs), quality of life, functional improvement, achievement of communication goals, and participation in desired activities among individuals with conditions like locked-in syndrome, amyotrophic lateral sclerosis (ALS), or post-stroke paralysis. Studies assessing BCI system accuracy for communication tasks (e.g., spelling, answering questions, following commands) were also included. Safety data were considered from studies with >10 participants receiving iBCIs for non-communication purposes, such as epilepsy monitoring. Exclusion criteria included conference abstracts and studies reporting only technical outcomes (e.g., signal quality, algorithm development). Follow-up ranged from 10 months to 5 years. Reported outcomes included: a single-center case series where all four participants achieved wireless control of a personal computer; a case study using a microelectrode array in an individual with quadriparesis and anarthria demonstrated decoding of 6.87 words/min (silent speech; error rate 10.53%) and 15.2 words/min (overt speech; error rate 25.6%); and in another case study in an individual with spinal cord injury and tetraplegia achieved decoding of 90 handwritten characters/min with 94.1% raw accuracy and >99% accuracy using autocorrect. In a study of 14 participants with

quadriparesis, 68 device-related AEs occurred, including 35 cases of skin irritation at the implant site; no deep tissue infections were reported. Perioperative AEs included low-grade fever, headache, and nausea. Postoperative complications included hypertension (n=1), pulmonary embolus (n=1), and seizures (n=2), with one case of new-onset refractory status epilepticus. All five patients with electively removed implants exhibited arachnoid tissue growth over the array; in two cases, the array adhered to brain tissue. ECRI identified limitations including small sample sizes, incomplete reporting, and high risk of bias. Comparative studies of invasive versus noninvasive BCIs (e.g., P300 headsets, ocular tracking) were recommended.

The current available evidence is insufficient to permit conclusions regarding the safety and efficacy of speech generating devices using implantable brain-computer interfaces.

General Consumer Electronic Devices

Touchscreen devices (e.g., iPads, computers, smartphones, smartwatches) have become increasingly popular platforms for AAC through downloadable applications. However, these devices are not considered medical in nature unless computing functions are disabled. The commercial apps that are available for these devices do not always incorporate robust, research-based language programs, and for younger users multifunctionality can be distracting, often leading to preference for entertainment over communication (Chen, et al., 2021).

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Approximately 10% of the U.S. adult population has a speech, language, and/or voice disability, collectively referred to as communication disabilities. An increasing number of studies demonstrate that persons with communication disabilities have worse health and health care outcomes as compared to those without communication disabilities (Morris, 2022). People with communication disabilities have significantly higher rates of multiple chronic conditions. These results differ by type of communication disability, with 40.4% of those with voice only and 62.7% of those with speech, language, and voice disability having two or more chronic conditions. In comparison, 24.5% of those without a communication disability have multiple chronic conditions, controlling for other demographic characteristics, such as race, ethnicity, age, and gender (Stransky et al., 2018). In addition, individuals with communication disabilities are more likely to experience a preventable adverse medical event in the hospital compared to those without communication disabilities (Bartlett et al., 2008).

A 2025 clinical report from the American Academy of Pediatrics highlights societal barriers impacting access to augmentative and alternative communication (AAC) for children with communication impairments. Structural inequities, including racism and poverty, exacerbate these challenges. Data indicate that 24.5% of caregivers report unmet needs for communication support, rising to 29.1% among Black children. Families of children with communication difficulties are less likely to have adequate health insurance and less likely to receive care in a medical residence. Even among middle-income families (200–299% of the federal poverty level), 31.3%

report unmet needs for communication devices. Additional disparities affect children from non-English-speaking households, where limited culturally responsive interventions may hinder AAC access and training. Geographic barriers also contribute with children in rural areas experiencing reduced access to AAC and related therapy services (Desch et al., 2025).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Speech Generating Devices (50.1)	7/29/2015
LCD	CGS & Noridian	Speech Generating Devices (SGD) (L33739)	10/01/2024

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Revised policy statements on referring to benefit plan documents. • Revised policy statement on synthesized speech generating devices. • Revised policy statement on not medically necessary devices. • Updated to new formatting standards.	1/15/2026
Annual Review	• No clinical policy statement changes.	1/15/2025
Annual Review	• Removed policy statements on speech generating device accessories. • Removed policy statements on speech generating devices, digitized speech, using pre-recorded messages.	4/15/2024