

Medicare Medical Policy

Speech Generating Devices (SGDs)

MEDICARE MEDICAL POLICY NUMBER: 519

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
<i>Speech Generating Devices (SGD) – Initial Provision (E2500, E2502, E2504, E2506, E2508, E2510)</i>	<ul style="list-style-type: none"> Local Coverage Determination (LCD) for Speech Generating Devices (L33739) Local Coverage Article (LCA) for Speech Generating Devices – Policy Article (A52469) <p>NOTE: While there is a national coverage determination (NCD) for Speech Generating Devices (50.1) available, it does not provide <i>coverage</i> criteria. Instead, it states coverage is left to Medicare Contractor (MAC) discretion. Therefore, the above LCD is the primary coverage reference.</p>
<i>Accessories and Software (E2511, E2512, E2599)</i>	<p>For general coverage criteria:</p> <ul style="list-style-type: none"> LCD for Speech Generating Devices (L33739) <p>For non-covered features/accessories/services:</p> <ul style="list-style-type: none"> LCA for Speech Generating Devices – Policy Article (A52469)
<i>Replacement or Upgrades</i>	LCA for Speech Generating Devices – Policy Article (A52469)
<i>Duplicate Requests (Request for more than one SGD)</i>	LCD for Speech Generating Devices (L33739)

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member’s benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (*Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021*)

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

While most of the codes in this medical policy are not subject to routine review for medical necessity, the following documentation must be in the medical record to support medically necessity has been established:

- For speech generating devices (SGDs), the following must be available:
 - Description of the item or service
 - Manufacturer name
 - Product name and number
- For accessories, medical necessity for each item must be clearly documented in the formal evaluation by the speech-language pathologist (SLP).
- For alternative input devices, there must be information in the SLP evaluation about why standard input access devices are unable to be used.
- For a multicomponent mounting system, list each component's manufacturer and product name and number.

BACKGROUND

Speech generation is defined as audible generation of words or phrases and in addition, may include:

1. Communication via written text (i.e., email or text (SMS) messaging); or,
2. Communication via phone messaging.

In order to satisfy the Medicare durable medical equipment (DME) benefit requirements, the speech generating device (SGD) must meet **all** of the following requirements:

1. Can withstand repeated use; and,
2. Has an expected life of at least 3 years; and,
3. Is primarily and customarily used to serve a medical purpose; and,
4. Generally is not useful to an individual in the absence of an illness or injury; and,
5. Is appropriate for use in the home; and,
6. Be limited to use by a patient with a severe speech impairment; and,
7. Be primarily used for the purpose of generating speech.
 - a. A device utilizing tablet, smartphone or computer hardware must be designed by the manufacturer to function solely as a SGD, as defined above, at the time of initial issue.

The Medicare life expectancy requirement of at least three years is known as the minimum life requirement, or MLR. This is necessary in order for a device to meet the definition of the term “durable.” However, the MLR is not the same thing as “reasonable useful lifetime” (RUL). The RUL is used to determine how often a piece of equipment or a device is eligible for coverage of a replacement.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

Effective June 1, 2016, the only products which may be billed using HCPCS code E2510 are those which have received a written coding verification by the Medicare Pricing, Data Analysis and Coding (PDAC) contractor and are listed on the [Product Classification List \(PCL\)](#) maintained on the PDAC website. If a product is billed using a HCPCS code that requires written coding verification review, but the product is not on the PCL for that particular HCPCS code, that claim line will be denied as incorrect coding. (LCA A52469)

Desktop, laptop, tablet, smartphone and other hand-held computers (i.e., general computing devices) are not considered DME because they do not meet criteria 3, 4, 6 and 7 above (see *Policy Guidelines*), even though they may serve a medical purpose. Only the speech generating software (HCPCS code E2511) may be eligible for coverage when installed on a general computing device, but the device itself must be coded A9270.

HCPCS code A4601 describes any lithium ion rechargeable battery used with an SGD or related accessory.

Codes E2500, E2502, E2504, E2506, E2508 and E2510 include all applicable speech generating software programs (whether they are on the device when shipped by the manufacturer or added by the supplier prior to delivery), batteries, battery chargers and AC adapters. These items may not be billed separately.

NeuroNode®

Prior to October 1, 2024, the PDAC says to report NeuroNode Speech Generator with HCPCS code E2510, while the NeuroNode system would use E2599.

However, as of October 1, 2024, CMS developed a new code for the NeuroNode® system – E2513.⁴ The policy will be updated as needed if Medicare or Noridian publish coverage information regarding this specific device.

CODES*	
CPT	None

HCPCS	A4601	Lithium ion battery, rechargeable, for non-prosthetic use, replacement
	A9720	Non-covered item or service
	E2500	Speech generating device, digitized speech, using pre-recorded messages, less than or equal to 8 minutes recording time
	E2502	Speech generating device, digitized speech, using pre-recorded messages, greater than 8 minutes but less than or equal to 20 minutes recording time
	E2504	Speech generating device, digitized speech, using pre-recorded messages, greater than 20 minutes but less than or equal to 40 minutes recording time
	E2506	Speech generating device, digitized speech, using pre-recorded 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 Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, “presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare.” The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. (*Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician’s Fee Schedule, A. Physician’s Services*)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Speech Generating Devices (SGD) (L33739). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33739>. Published 2020. Accessed 12/10/2020.
2. Centers for Medicare & Medicaid Services. Local Coverage Article: Speech Generating Devices (SGD) - Policy Article (A52469). <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52469>. Published 2015. Accessed 12/10/2020.
3. Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §90 - Payment for Additional Expenses for Deluxe Features; Available at: <https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/Downloads/clm104c20.pdf>

4. Centers for Medicare & Medicaid Services' (CMS') Healthcare Common Procedure Coding System (HCPCS) Level II Final Coding, Benefit Category and Payment Determinations. First Biannual (B1), 2024 HCPCS Coding Cycle. Available at: <https://www.cms.gov/files/document/2024-hcpcs-application-summary-biannual-1-2024-non-drug-and-non-biological-items-and-services.pdf>. Accessed 8/27/2024.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
3/2022	New Medicare Advantage medical policy (converted to new format 2/2023)
3/2023	Annual review; no changes
3/2024	Annual review; no changes
10/2024	Q4 2024 code updates