Speech Generating Devices

MEDICAL POLICY NUMBER: 86

Effective Date: 8/1/2022

Last Review Date: 7/2022

Next Annual Review: 2/2023

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. 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.

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

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Note: Reimbursement for a Speech Generating Device (SGD) must be consistent with what is reasonable and medically necessary to serve the intended purpose. Therefore, payment for an SGD does not include "deluxe" or additional features beyond the function of speech generation and are the least costly alternative.

Devices

I. A non-tablet speech generating device (SGD) (E2500 - E2511) may be considered **medically necessary** when all of the following criteria are met (for the definition of SGD, see Policy Guidelines):

A. Prior to the delivery of the SGD, the member 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, 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;
3. A description of the functional communication goals expected to be achieved and treatment options;
4. Rationale for selection of a specific device and any accessories;
5. Demonstration that the patient possesses a treatment plan that includes a training schedule for the selected device;

6. The cognitive and physical abilities to effectively use the selected device and any accessories to communicate;
7. For a subsequent upgrade to a previously issued SGD, information regarding the functional benefit to the patient of the upgrade compared to the initially provided SGD; **and**

B. The member's medical condition is one resulting in a severe expressive speech impairment; **and**
C. The member's speaking needs cannot be met using natural communication methods; **and**
D. Other forms of treatment have been considered and ruled out; **and**
E. The member's speech impairment will benefit from the device ordered; **and**
F. A copy of the SLP's written evaluation and recommendation have been forwarded to the member's treating physician prior to ordering the device; **and**
G. The SLP performing the member evaluation may not be an employee of or have a financial relationship with the supplier of the SGD.

II. If criterion I is not met, the SGD is considered **not medically necessary and not covered.**

III. A tablet (e.g., iPad) with associated software (E2510 and E2511) when limited to use by a member with a severe speech impairment and is primarily used for the purpose of generating speech, may be considered **medically necessary** when general SGD coverage criteria (see Criterion I) are met.

IV. The capability to download updates to the covered features of the device from the manufacturer or supplier of the device may be considered **medically necessary**.

Accessories

V. Accessories to SGDs that do not meet the general requirements for the base SGD in criteria I-IV are considered **not medically necessary and not covered.**

VI. Alternative input devices may be considered **medically necessary** when a member is unable to use standard input devices.

VII. Alternative input devices for members who are able to use standard input devices is considered **not medically necessary and not covered**.

VIII. Eye tracking and gaze interaction accessories for speech generating devices may be considered **medically necessary** when furnished to individuals with a demonstrated medical need for such accessories.

IX. A carrying case (any type, with or without a shoulder strap or carrying handle; HCPCS code E2599) is considered **not medically necessary and not covered**.

Non-Covered Indications

X. Internet or phone services or any modification to a member's home to allow use of the speech generating device is considered **not medically necessary and not covered**.

XI. Specific features of a speech generating device that are not used by the member who has a severe speech impairment to meet his or her functional speaking needs considered **not medically necessary and not covered**. (See Policy Guidelines for examples)

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

This policy may be primarily based on the following Center for Medicare and Medicaid Services (CMS) guidance resources:

- Centers for Medicare and Medicaid Services LCD L33739. LCD Title: Speech Generating Devices[1]
- Centers for Medicare and Medicaid Services LCA A52469. LCA Title: Speech Generating Devices[2]
- National Coverage Decision NCD 50.1. Manual Section Title: Speech Generating Devices;[3] **and**
- Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Section 90 - Payment for Additional Expenses for Deluxe Features (Rev. 1, 10-01-03) B3-5107, PM AB-02-114.[4]

DEFINITIONS

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.

Speech generating devices are defined by Medicare as durable medical equipment that provides an individual who has severe speech impairment with the ability to meet his or her functional, speaking needs. Speech generating devices are speech aids consisting of devices or software that generate speech (as defined above) and are used solely by the individual who has severe speech impairment. The 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; **or**
- Software that allows a computer or other electronic device to generate speech.

- Other covered features of the device include the capability to generate email, text, or phone messages to allow the patient to "speak" or communicate remotely, as well as the capability to download updates to the covered features of the device from the manufacturer or supplier of the device.

- If a speech generating device is limited to use by a patient with a severe speech impairment and is primarily used for the purpose of generating speech, it is not necessary for the device to be dedicated only to audible/verbal speech output to be considered DME. Computers are generally not considered DME because they are useful in the absence of an illness or injury.

Examples of Non-Covered Specific Features

Examples of specific features of a SPG that are not used by the member include 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. These features of a speech generating device do not fall within the scope of § 1861(n) of the Social Security Act and the cost of these features are the responsibility of the patient.

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

Speech generating devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a member's equipment to be eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the Policy Criteria above must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

To meet the DME benefit category requirements, the speech generating device must meet all of the following requirements:

I. Can withstand repeated use; and,
II. Has an expected life of at least 3 years; and,
III. Is appropriate for use in the home; and,
IV. Be limited to use by a patient with a severe speech impairment; and,
V. Be primarily used for the purpose of generating speech, as defined above.

Desktops, laptops and smartphones are not considered DME, even though they may serve a medical purpose. Medicare will reimburse for speech generating **software only** (HCPCS code E2511) when installed on one of these general computing devices. While Medicare does not recognize tablets (e.g., iPads) as DME, the Company may choose to allow a **tablet** as a speech generating device (SGD) when all relevant criteria are met.

Nationally Non-Covered Indications

The following features of a speech generating device are non-covered because they do not fall within the scope of the durable medical equipment benefit:

- Specific features of a speech generating device that are not used by the individual who has a severe speech impairment to meet his or her functional speaking needs.
- Video communications or conferencing.
- Any computing hardware or software not necessary to allow for generation of speech, email, text or phone messages. Examples include, but are not limited to:
    - Hardware or software used to create documents and spreadsheets; or,
    - Hardware or software used to play games or music.

Internet service provider (ISP), phone service subscriptions or any modification to a patient's home to allow use of the speech generating device are non-covered.

A carrying case (including shoulder strap or carrying handle, any type) (E2599) is a convenience item and is denied as non-covered.

Accessories used with non-covered devices will be denied as non-covered.

Upgrades to speech generating devices and/or software programs that are provided within the 5 year useful lifetime of the device will be denied as statutorily non-covered.

Payment for Additional Expenses for Deluxe Features[4]

The payment amount for a given service or item, whether rented or purchased, must be consistent with what is reasonable and medically necessary to serve the intended purpose. Additional expenses for "deluxe" features, or items that are rented or purchased for aesthetic reasons or added convenience, do not meet the reasonableness test. Thus, where a service or item is medically necessary and covered under the Medicare program, and the patient wishes to obtain such deluxe features, the payment is based upon the payment amount for the kind of service or item normally used to meet the intended purpose (i.e., the standard item.) Usually this is the least costly item.

BACKGROUND

Augmentative and Alternative Communication (AAC) devices or communicators which are referred to as "Speech Generating Devices" (SGD) are defined as speech aids that provide an individual who has severe speech impairment with the ability to meet his functional speaking needs.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

BILLING GUIDELINES AND CODING

Codes E2500 - E2511 perform the same essential function - speech generation. Therefore, claims for more than one SGD (tablet or non-tablet) is considered **not reasonable and necessary**.

Codes E2500, E2502, 22504, E2506, E2508, E2510-E2512 are limited to one every five years.

CODING GUIDELINES

Code A4601 describes any lithium-ion rechargeable battery used with an SGD or related accessory.

Digitized speech (E2500, E2502 - E2506), sometimes referred to as devices with "whole message" speech output, utilize 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 (E2508, E2510), 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 pre-recorded messages but rather can independently create messages as their communication needs dictate.

E2508 devices require that the user make physical contact with a keyboard, touch screen or other display containing letters.

E2510 devices permit the user multiple methods of message formulation and multiple methods of device access. Multiple methods of message formulation must include the capability for message selection by two or more of the following methods: letters, words, pictures or symbols. Multiple methods of access must include the capability to access the device by two or more of the following: direct physical contact with a keyboard or touch screen, indirect selection techniques with a specialized access device such as a joystick, head mouse, optical head pointer, switch, light pointer, infrared pointer, scanning device, or Morse Code.

Devices that have the capability to generate both digitized and synthesized speech are coded as E2508 or E2510, depending on the method of synthesized speech formulation and device access.

Non-tablet SGDs only: Codes E2500, E2502-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. There is also no separate payment if a nonintegrated keyboard is provided with an SGD.

To be coded as E2510, a desktop, smartphone or laptop computer must only be capable of speech generation, as defined above. A desktop, smartphone or laptop computers with additional non-covered features (see Non-Medical Necessity Coverage and Payment Rules above) included at the time of initial issue must be coded A9270. For tablets used as SGDs, see below.

Tablet SGDs (e.g. iPads): These devices may be billed with E2510. If the tablet SGD does not include all applicable speech generating software programs, then E2511 may be billed. Batteries, battery chargers

and AC adapters may not be billed separately. There is also no separate payment if a nonintegrated keyboard is provided with a tablet SGD.

Software Programs

Code E2511 is used to code for speech generating software programs that enable a laptop computer, desktop computer, tablet, smartphone or other hand-held general computing device to generate speech. The allowance for code E2511 includes the speech generating software program only. Installation of the program or technical support must not be billed separately. Code E2511 must not be used to code for software programs that are installed at the time of delivery of an SGD (codes E2500, E2502-E2506, E2508 or E2510).

Code E2511 must **not** be used to code for software programs installed at the time of the initial provision of an SGD accessory or alternative access device. Software for the accessory or alternative access device is included in the reimbursement for the accessory or alternative access device. Claims for code E2511 billed with an accessory or alternative access device will be denied as unbundling.

Code E2511 may also be used for upgrade programs for SGDs (codes E2500, E2502-E2506, E2508 or E2510) or when code E2511 is used to bill for software only when installed on a general computing device. Replacement or upgrade of speech generating software loaded onto a covered speech generating device is not covered unless the replacement software is necessary due to a change in the patient's condition, or in cases where the software has been lost, stolen, irreparably damaged, or has been in continuous use for the reasonable useful lifetime of 5 years.

Mounting systems and stands (E2512) are accessories that are needed to place the SGD, switches or other access devices within the reach of the patient. For systems with multiple components, bill system on a single claim line with one (1) unit of service. There is no separate billing for any software, interfaces, cables, adapters, interconnects or switches necessary for the access device to interface with the SGD. Those components are included in the reimbursement for the access device itself.
A protective case or cover, any type (E2599) is not separately payable as they are required to make the SGD durable under the definition of DME. Claims for protective cases or covers **when billed with a covered SGD** will be denied as unbundled. However, if a protective case or cover is provided **separately**, such as when a replacement is required, then it may be reported and reimbursed separately.

Code E2599 is used for other separately payable accessories for speech generating devices. Examples include:

- Ocular tracking device, any type, describes an SGD accessory used with an SGD or SGD software to allow a speech-impaired person to use his or her eyes to communicate. Ocular tracking devices track the user's eye movement and determine where on screen their gaze is targeted.
- Head control mouse, any type, describes an SGD accessory that monitors head movement and translates those movements into actions by the pointer on the SGD screen.
- Alternative input device, any type, describes any accessory other than an ocular tracking device or head control mouse, not integrated into the SGD hardware, used to control the actions of an SGD. Examples of alternative input devices include (not all-inclusive): specialty keyboards,

joysticks, trackballs, trackpads, buddy buttons, jelly beans, beamers, roller balls, round pads, pal pads.
- Protective key guard, any type describes an overlay for a keyboard, alternative input device or SGD screen that assists the patient in preventing inadvertent selection of a button, icon or other input.
- Electronic components that allow the SGD to be operated by the drive control interface of a power wheelchair.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

The medical necessity requirements for each accessory (E2599) for E2500 - E2510 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.

When codes E2511 - E2599 are billed, the claim must include all of the following information:
- Description of the item or service
- Manufacturer name
- Product name and number

If billing a multicomponent mounting system, list each component's manufacturer and product name and number.

CODES*		
HCPCS	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
	E2599	Accessory for speech generating device, not otherwise classified

***Coding Notes:**

- The above code list 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.
- 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. Accessed 6/20/2022.
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. Accessed 6/20/2022.
3. Centers for Medicare & Medicaid Services. Medicare National Coverage Determinations Manual Chapter 1, Part 1 (Sections 10 – 80.12) Coverage Determinations. . https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part1.pdf. Accessed 6/20/2022.
4. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). . https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf. Accessed 6/20/2022.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.