# Medical Policy


# Speech Generating Devices

## Description

Speech generating devices (SGDs) are speech aids that provide individuals with severe speech impairment the ability to meet their functional speaking needs.

## Policy

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.

**Refer to Coverage Criteria for Massachusetts Medicaid Managed Care Members for members covered under Northwood managed Massachusetts Medicaid programs.**

## Policy Guidelines

Coverage Criteria:

Speech generating devices are defined as durable medical equipment that provides an individual who has a 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), are used solely by the individual who has a severe speech impairment and be primarily used for the purpose of generating speech (any device must be designed by the manufacturer to function solely as a speech generation device at the time of initial issue). The speech is generated using one of the following methods:

1. Digitized audible/verbal speech output, using prerecorded messages;
2. Synthesized audible/verbal speech output which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
3. Synthesized audible/verbal speech output which permits multiple methods of message formulation and multiple methods of device access; or
4. Software that allows a computer or other electronic device to generate speech.

A speech generating device (SGD) (E2500 - E2511) is covered when all of the following criteria (1-7) are met:


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1. 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:

    a. Current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment;

    b. An assessment of whether the individual's daily communication needs could be met using other natural modes of communication;

    c. A description of the functional communication goals expected to be achieved and treatment options;

    d. Rationale for selection of a specific device and any accessories;

    e. Demonstration that the member possesses a treatment plan that includes a training schedule for the selected device;

    f. The cognitive and physical abilities to effectively use the selected device and any accessories to communicate;

    g. For a subsequent upgrade to a previously issued SGD, information regarding the functional benefit to the member of the upgrade compared to the initially provided SGD; and

2. The member's medical condition is one resulting in a severe expressive speech impairment; and

3. The member's speaking needs cannot be met using natural communication methods; and

4. Other forms of treatment have been considered and ruled out; and

5. The member's speech impairment will benefit from the device ordered; and

6. A copy of the SLP's written evaluation and recommendation have been forwarded to the member's treating practitioner prior to ordering the device; and

7. The SLP performing the member evaluation may not be an employee of or have a financial relationship with the supplier of the SGD.

If one or more of the SGD coverage criteria 1-7 is not met, the SGD will be denied as not reasonable and necessary.


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Codes E2500 - E2511 perform the same essential function - speech generation. Therefore, claims for more than one SGD will be denied as not reasonable and necessary.

The capability to download updates to the covered features of the device from the manufacturer or supplier of the device is covered. See related Policy Article for additional Non-Medical Necessity Coverage and Payment Rules.

**ACCESSORIES:**

Claims for accessories to SGDs must meet the general coverage requirements for the base SGD described in criteria 1-7 above. Claims for SGD accessories for beneficiaries who do not meet criteria 1-7 above will be denied as not reasonable and necessary.

Alternative input devices are covered when a member is unable to use standard input devices. Claims for alternative input devices for beneficiaries who are able to use standard input devices will be denied as not reasonable and necessary.

Eye tracking, gaze interaction and electromyographic sensor accessories for speech generating devices are covered when furnished to individuals with a demonstrated medical need for such accessories.

If the SGD is denied as not reasonable and necessary, any related accessories will be denied as not reasonable and necessary.

## Policy Limitations

1. If one or more of the SGD coverage criteria 2a-g is not met, the SGD will be denied as not medically necessary.
2. Codes E2500- E2511 perform the same essential function - speech generation. Therefore, claims for more than one SGD will be denied as not medically necessary.
3. Accessories (E2599) for E2500- E2510 are covered if the basic coverage criteria (a-g) for the base device are met and the medical necessity for each accessory is clearly documented in the formal evaluation by the SLP.
4. Repair of a SGD is limited to restoration of a serviceable condition which is not the result from misuse, non-intentional or intentional.
5. Prior to the purchase of a SGD, the Member should undergo a 3-month trial rental of the device, with an evaluation by a SLP to determine the appropriateness of continued use of the device.
6. Desktop, laptop, tablet, smartphone and other hand-held computers (i.e. general computing devices) are not considered DME because they do not meet the definition of DME even though they may serve a medical purpose.
7. 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:

   a. 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.
   b. Video communications or conferencing.
   c. 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 1) hardware or software used to create documents and spreadsheets; or; 2) hardware or software used to play games or music.
8. 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 because such services or modifications could be used for non-medical equipment such as standard phones or general computing devices.
9. A carrying case (including shoulder strap or carrying handle, any type) (E2599) is a convenience item and is denied as non-covered.
10. 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 noncovered.

**Policy Exclusions**

1. Laptop computers, desktop computers, PDAs or other devices that are not dedicated SGDs are not reasonable and necessary as they are not used primarily for medical purposes.
2. Installation and/or technical support of the software that enables a laptop computer, desktop computer, or PDA to function as an SGD is not reasonable and necessary when billed separately.

**Coverage Criteria for Massachusetts Medicaid Managed Care Members**

Clinical Coverage:

Mass Health bases its determination of medical necessity for AAC (Alternative and Augmentative communication devices) or software for devices that produce speech on clinical data including, but not limited to, indicators that would affect the relative risks and medical benefits related to the use of the equipment. These criteria include, but are not limited to, all of the following:

1. The member has a severe expressive communication impairment related to a medical condition or developmental disability that severely limits daily functional communication; AND

2. The member cannot meet daily functional communication needs by using unaided strategies; AND

3. The member has the cognitive, visual, language, and physical abilities to effectively use an AAC device; AND

4. A multidisciplinary team must recommend the device or software. The team must include a licensed, certified speech-language pathologist meeting nationally accepted knowledge and skill qualifications for augmentative and alternative communication service delivery. A licensed physician, nurse practitioner, or physician's assistant must prescribe the device or software. Other professionals may be included as needed for determining motor or other needs, such as physical access to the device; AND

5. The recommended device, system, or software is the least costly, medically appropriate alternative; AND

6. For members under age 21, MassHealth covers non-dedicated devices under certain circumstances if the total net cost to MassHealth for the non-dedicated device is equal to or less than the total net cost of a comparable dedicated device. Specifically, MassHealth covers non-dedicated devices for:
    - Members under 21;
    - With a diagnosis of an autism spectrum disorder;
    - Who meet prior authorization (PA) requirements set forth in these guidelines;
    - Only if the total cost for a comparable non-covered, non-dedicated device is equal to or less than the net cost of the approved, covered (dedicated) AAC device. For purposes of this cost comparison, MassHealth will compare its net cost for a dedicated device after applying any costs covered by a member's insurance other than MassHealth (third party liability or TPL) to the cost of a non-dedicated device.

   Note that all other requirements apply and must be met, including but not limited to, member eligibility requirements and third party liability requirements, such as those related to Medicaid's role as payor of last resort. AND

7. The recommended device or software matches the cognitive and physical capabilities of the member; AND

8. Device recommendations include the consideration of the impact of the presence of significant behaviors, if applicable, such as physical aggression and property destruction; AND

9. The member has demonstrated the ability to learn to effectively use the recommended device and accessories or software for functional communication as evidenced by a data-driven device trial supporting the ability to use the device and any necessary accessories functionally for communication.

10. For subsequent upgrade of a previously provided AAC device or software, the determination of medical necessity will also be based on additional clinical data including, but not limited to clinical data-driven information supporting the functional medical benefit of the upgrade to the member in comparison to the initially provided AAC device or software.

**Noncoverage for Massachusetts Medicaid Managed Care Members**

Under certain circumstances, MassHealth does not cover AAC devices or software for devices that produce speech. Examples of such circumstances include, but are not limited to, the following.

1. Devices or software used primarily for school or educational purposes.

2. Devices or software not limited to or configured to limit use to the purpose of communication (i.e., "dedicated" devices) except for non-dedicated devices that meet the net cost comparison described above for children under 21 years of age with autism spectrum disorder. Multiuse and general use devices not configured to limit the primary use to a medical purpose, such as for use as a speech-generating device, and not configured to prevent uses unrelated to communication.

3. Devices without accessories to protect them from damage.

4. Duplicate devices or software, including accessories for mounting and protection.

5. Web, cellular, or other device connectivity charges, and home modifications.
6. Failure to demonstrate during the trial period or at any subsequent time the ability to learn to use the device or software functionally for communication.

**HCPCS Level II Codes and Description**

E2500 SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, LESS THAN OR EQUAL TO 8 MINUTES RECORDING TIME

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| 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 |

**Documentation Requirements**

Items in this policy may be subject to the Affordable Care Act (ACA) 6407.

The Affordable Care Act (ACA) 6407 requires that the treating practitioner conduct a face-to-face examination during the six month period preceding the written order. The documentation must be received by the provider prior to delivery for certain DME items. The documentation must describe a medical condition for which the DME is being prescribed.

1. When codes E2511- E2599 are billed, the claim must include a narrative description of the item, the manufacturer, and the product name/number. If billing

a multi-component mounting system (E2512), list each manufacturer and product name/number.

**Coding Guidelines**

1. 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.
2. 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.
3. E2508 devices require that the user make physical contact with a keyboard, touch screen or other display containing letters.
4. 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, electromyographic sensor or Morse Code.
5. 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.
6. Codes E2500, E2502-E2506, E2508 and E2510 include all applicable 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.
7. Code 2511 is used to code for a speech generating software program that enables a laptop computer, desktop computer or PDA to function as an SGD. (Within this policy, the term SGD also describes these speech generating software programs.) 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 that is billed with 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 access device (E2599). E2511 is used for upgrade programs for a computer or PDA that are provided after the initial provision of the software.

8. Mounting systems (E2512) are accessories that are needed to place the SGD, switches or other access devices within the reach of the member. For systems with multiple components, bill system on a single claim line with one (1) unit of service.
9. Code E2513 describes an electromyographic sensor accessory that utilizes bioelectric signals to generate synthesized speech. E2513 is only for use with Code E2510.
10. Code E2599 is used for other separately payable accessories for speech generating devices. Examples include:
    - An access device that enables the selection of letters, words or symbols via direct or indirect selection techniques. Access devices include, but are not limited to, optical head pointers, joysticks, switches and scanning devices. However, 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 should be included in the charge for the access device itself.
    - Replacement accessories such as batteries, battery chargers and AC adapters.
    - Upgrade software programs for E2500, E2502-E2506, E2508 or E2510 devices that are provided after the initial provision of the SGD.
    - Electronic components that allow the SGD to be operated by the drive control interface of a power wheelchair.
11. Code E2511 is used to code for a speech generating software program that enables a laptop computer, desktop computer or personal digital assistant (PDA) to function as an SGD. 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 software included with the initial provision of the SGD (E2500, E2508, E2510, E2502 - E2506) since the software cost is included in the reimbursement for those SGD codes. In addition, code E2511 must not be used to code software included with the initial provision of the access device (E2599) since the software cost is included in the reimbursement for the access device.
12. Upgrades to E2511 are subsequent versions of a speech generating software program that may include enhanced features or other improvements. Upgrades to E2511 must be coded E2511.
13. Mounting systems necessary to place the SGD device, switches and other access devices within the reach of the Member must be coded E2512.

14. Accessories to SGDs such as access devices should be coded E2599. There should be no separate billing of any software, interfaces, cables, adapters, interconnects, or switches necessary for the accessory to interface with the SGD (E2500, E2508 - E2511, E2502 - E2506).
15. Upgrades to E2500, E2508, E2510, and E2502 - E2506 are subsequent versions of the device's software program or memory modules that may include enhanced features or other improvements. Upgrades to E2500, E2508, E2510, and E2502 - E2506 must be coded E2599.

**Important Note:**

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating practitioner in connection with diagnosis and treatment decisions.

Northwood follows all CMS National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), as applicable.

Northwood

# Speech Generating Devices

## References

Centers for Medicare and Medicaid Services, Medicare Coverage Database, National Coverage Documents; October 2015. Accessed and reviewed December 5, 2022.

CGS Administrators, LLC. Speech Generating Devices. Local Coverage Determination No. L33739. Durable Medical Equipment Medicare Administrative Carrier Jurisdiction B; Last accessed and reviewed December 2, 2024.

Noridian Healthcare Solutions, Speech Generating Devices. Local Coverage Determination No. L33739. Durable Medical Equipment Medicare Administrative Carrier Jurisdiction A. Chico, CA: NHIC; revised January 1, 2020; Last accessed and reviewed December 5, 2022.

MassHealth. Guidelines for Medical Necessity Determination for Augmentative and Alternative Communication Devices and Speech Generation Devices. Last accessed December 2022.

Hayes, Inc. Health Technology Brief. Speech-Generating devices for treatment of Dysarthria. Lansdale, PA: Hayes, Inc. October 3, 2008.

**Change/Authorization History**

| Revision Number | Date | Description of Change | Prepared / Reviewed by | Approved by | Review Date: | Effective Date: |
|---|---|---|---|---|---|---|
| A | 11-20-06 | Initial Release | Rosanne Brugnoni | Ken Fasse | n/a | |
| 01 | | Annual Review – no changes | Susan Glomb | Ken Fasse | Dec.2008 | |
| 02 | 12-09-10 | Instructions for mounting systems (E2512) | Susan Glomb | Ken Fasse | | |
| 03 | 12-22-09 | Annual Review/ no changes | Susan Glomb | Ken Fasse | Dec.2009 | |
| 04 | 12-03-10 | Annual Review/No changes | Susan Glomb | Ken Fasse | Dec.2010 | |
| 05 | 07-20-11 | Added Important Note to all Medical Policies | Susan Glomb | Dr. B. Almasri | | |

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| 06 | 11-10-11 | Annual Review. Added References to Policy | Susan Glomb | Dr. B. Almasri | Nov. 2011 | |
| 07 | 12-03-12 | Annual review – no changes. | Susan Glomb | Dr. B. Almasri | Dec. 2012 | |
| 08 | 12-18-13 | Annual review. No changes. | Susan Glomb | Dr. B. Almasri | | |
| 09 | 12-3-14 | Annual Review. Added: Items in this policy may be subject to the Affordable Care Act 6407 (ACA) requirements. | Susan Glomb | Dr. B. Almasri | | |
| 10 | 12-11-15 | Annual Review. References updated | Susan Glomb | Dr. B. Almasri | | |
| 11 | 10-11-16 | Policy updated to include BMCHP coverage. Highlighted area. | Susan Glomb | Dr. B. Almasri | | |
| 12 | 12-7-16 | Annual Review. No changes | Lisa Wojno | Dr. B. Almasri | Dec 2016 | |
| 13 | 12-13-17 | Annual review. No changes. | Carol Dimech | Dr. C. Lerchin | December 2017 | |
| 14 | 12-03-18 | Annual Review. Updated policy to clarify coverage criteria for Massachusetts Medicaid Managed Care member plans managed by Northwood. Updated policy limitations and exclusions per Medicare Policy Article for Speech Generating Devices for other members. Updated Medicare references. Added MassHealth reference. | Lisa Wojno | Dr. C. Lerchin | December 2018 | |
| 15 | 12-04-19 | Annual review. No changes. | Carol Dimech | Dr. C. Lerchin | December 2019 | December 2019 |
| 16 | 12-03-20 | Annual Review. Added language to the Massachusetts Medicaid Managed Care section regarding non-dedicated | Lisa Wojno | Dr. C. Lerchin | December 2020 | December 2020 |

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| | | device coverage for members under 21 with autism spectrum disorders meeting all other requirements consistent with MassHealth guidelines reference. Updated 'physician' to 'practitioner'. | | | | |
| 17 | 12-7-21 | Annual review. Added NCD, LCD verbiage to "Important Note". | Carol Dimech | Dr. C. Lerchin | December 7, 2021 | December 7, 2021 |
| 18 | 12-5-22 | Annual review. No changes. | Lisa Wojno | Dr. C. Lerchin | December 5, 2022 | December 2022 |
| 19 | 12-5-23 | Annual review. No changes. | Carol Dimech | Dr. C. Lerchin | December 5, 2023 | December 2023 |
| 20 | 12-2-24 | Annual review. Added HCPCS Code E2513 Electromyographic Sensor Accessory is covered when there is a demonstrated need. Coding information included. | Susan Glomb/Carol Dimech | Dr. C. Lerchin | December 2, 2024 | December 2, 2024 |