## Coverage Summary

**Speech Generating Devices**

<table>
<thead>
<tr>
<th>Policy Number:</th>
<th>S-011</th>
<th>Products:</th>
<th>UnitedHealthcare Medicare Advantage Plans</th>
<th>Original Approval Date:</th>
<th>02/18/2009</th>
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</thead>
<tbody>
<tr>
<td>Approved by:</td>
<td></td>
<td></td>
<td>UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date:</td>
<td>02/19/2019</td>
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<tr>
<td>Related Medicare Advantage Policy Guideline:</td>
<td>Speech Generating Devices (NCD 50.1)</td>
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The benefit information in this Coverage Summary is based on existing national coverage policy, however, Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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### I. COVERAGE

**Coverage Statement:** Speech generating devices are covered when the treating physician determines that the patient suffers from severe speech impairment and that the medical condition warrants the use of a device based on the Medicare definitions outlined below.

**DME Face to Face Requirement:** Effective July 1, 2013, Section 6407 of the Affordable Care Act (ACA) established a face-to-face encounter requirement for certain items of DME (including speech generating devices). For DME Face to Face Requirement information, refer to the Coverage Summary of Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid.
**Guidelines/Notes**

1. Speech generating devices are considered to fall within the durable medical equipment benefit category established by § 1861(n) of the Social Security Act. They are covered for patients who suffer from a severe speech impairment and have a medical condition that warrants the use of a device based on the following definitions.

   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 and are used solely by the individual who has a severe speech impairment. The speech is generated using one of the following methods:

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

2. 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.

3. 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 a speech-generating device to be dedicated only to speech generation to be considered DME.

4. The following devices, modifications and services do not meet the definition of a speech generating device and are not covered:

   a. Computers and tablets in general are not considered DME because they are useful in the absence of an illness or injury.
   b. Internet or phone services or any modification to a patient’s home to allow use of the speech generating device are not covered by Medicare because such services or modifications could be used for non-medical equipment such as standard phones or personal computers.
   c. 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 are not covered.
   d. 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 is not covered.
5. A speech generating device (SGD) **is covered** when all of the following criteria are met. If one or more of the above coverage criteria is not met, the SGD will be denied as not medically necessary.

   a. Prior to the delivery of the SGD, the patient 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 patient's medical condition is one resulting in a severe expressive speech impairment; and

   c. The patient'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 patient'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 patient's treating physician prior to ordering the device; and

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

6. **Accessories**

   a. Accessories are covered if the basic coverage criteria above for the base device are met and reasonable and necessary criteria for each accessory is clearly documented in the formal evaluation by the SLP.

   b. Alternative input devices are covered when a beneficiary 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.
c. Eye tracking and gaze interaction accessories for speech generating devices are covered when furnished to individuals with a demonstrated medical need for such accessories.

For additional coverage and coding information, see the DME MAC LCDs for Speech Generation Devices (L33739). Compliance with these policies is required where appropriate. (Accessed January 24, 2019)

II. DEFINITIONS

III. REFERENCES

See above

IV. REVISION HISTORY

04/01/2019 Updated policy introduction; added language to clarify:
- There are instances where [the Coverage Summary] may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG)
- In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5)

02/19/2019 Annual review with the following updates:
Guideline 3
- following language moved from “Note” section to align with referenced NCD:
  “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 a speech-generating device to be dedicated only to speech generation to be considered DME.”
- reference to “NCD for Speech Generating Devices (50.1)” moved to end of guideline 4.

Guideline 4 – remove the following language (duplicate CMS reference):
  “Also see the DME MAC LCDs for Speech Generation Devices (L33739). Compliance with these policies is required where appropriate.”

02/20/2018 Annual review; no updates.

02/14/2017 Annual review; with following updates:
Removed all reference to the “CMS Final Decision Memo for Speech Generating Devices (dated July 29, 2015)”, as the NCD has already been published.

02/16/2016 Annual review; with following updates:
- Guideline 1 and 2 Note – Replaced “The” with “If a” (to align with the NCD
Guideline 5 (Accessories)
  - Removed references to HCPCS codes E2599, E2500 and E2510
  - Added the language pertaining to alternative input devices and eye tracking and gaze interaction accessories based on the reference DME MAC LCDs for Speech Generation Devices (L33739)

09/15/2015  Updated the entire Coverage Summary guideline based on the revised NCD coverage language outlined in the CMS Final Decision Memo for Speech Generating Devices issue July 29, 2015.

02/17/2015  Annual review; with the following update:
Definitions of Speech Generating Devices - Added reference link to the NCD for Speech Generating Device (50.1).

10/21/2014  Removed detailed DME Face-to-Face Requirement information and replaced with a reference link to the DME, Prosthetics, Corrective Appliances/Orthotic and Medical Supplies Grid.

02/18/2014  Annual review; no updates.

08/20/2013  Added a note pertaining to the DME Face-to-Face Requirement in accordance with Section 6407 of the Affordable Care Act as defined in the 42 CFR 410.38(g).

02/19/2013  Annual review; no updates.

02/27/2012  Annual review; no updates.

02/21/2011  Annual review; no updates.