



May 29, 2015

SUBMITTED ELECTRONICALLY via CAGinquiries@cms.hhs.gov

Dr. Subash Duggirala
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1614-P
P.O. Box 8016
Baltimore, MD 21244

RE: National Coverage Determination 50.1: Speech-Generating Devices (SGDs)

Dear Dr. Duggirala:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (“ITEM”) Coalition wish to extend our sincere thanks and appreciation for the draft reconsideration of the National Coverage Determination 50.1: Speech-Generating Devices (SGDs), which was published on April 29, 2015.

The ITEM Coalition is a national consumer and clinician-led coalition advocating for access to and coverage of assistive devices and technologies for persons of all ages with injuries, illnesses, disabilities and chronic conditions. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including such conditions as multiple sclerosis, paralysis, hearing and speech impairments, cerebral palsy, visual impairments, spinal cord injuries, brain injury, stroke, spina bifida, myositis, limb loss, Osteogenesis Imperfecta (“OI”), and other life-altering conditions.

We write first and foremost to thank you and the CMS staff that worked on the NCD reconsideration and produced the proposed, revised NCD. SGDs are critical to meet the needs of a relatively small number of individuals with severe or complex speech, language or communication impairments who, without SGDs, are unable to meet their daily communication needs. For these individuals, SGD are necessary to protect life, safety, health, independence, family and social roles, and most generally, basic human dignity.

The ITEM Coalition is very pleased with—and supportive of—the following revisions:

- The removal of the word “dedicated” as a characterization of a speech-generating device because it reflects contemporary design and capabilities of SGD technology and allows

beneficiaries to maximize their use of this technology to improve communication and quality of life;

- The recognition of email, text, and phone messages as forms of communication essential for persons with severe speech impairments;
- The inclusion of Internet capabilities to download updates, such as vocabulary expansion and other covered communication components;
- The allowance of additional, non-covered features of SGDs, such as video communication, as options at the cost of the Medicare beneficiary.

The language used in the revised NCD addresses many of the concerns originally expressed by ITEM and will ensure access to SGDs by Medicare beneficiaries with the most complex communication needs. We view these changes as an important step in the right direction for present and future beneficiaries in need of SGDs.

While it is clear that the intent of the policy is to ensure full and appropriate access to SGDs, ITEM recommends the following revisions for greater clarity. We maintain that these revisions will help to establish the NCD as a long-term policy that is able to withstand technological and interpretative changes over time.

- The terminology “functional speaking” or “functional speaking communication” is not recognized within the speech-language-hearing profession in this context, nor is it consistent with the new and appropriate inclusion of email in the revised NCD. Because candidates for SGDs have lost the ability to use speech to meet their functional and medical communication needs, ITEM recommends the use of the term “functional communication” in lieu of “functional speaking communication.” We understand that the term, “functional communication needs” is a common phrase used by speech language pathologists, and is thereby the preferred terminology. This does not change the meaning of the statement or expand the coverage, and is consistent with the use of the SGD for both speech-generation and email purposes.
- As previously stated, the ITEM Coalition appreciates the removal of the word “dedicated” with respect to the function of a SGD. We also recommend that CMS incorporate the following sentence from the analysis portion of the Decision Memorandum into the text of the NCD: *“As long as the 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.”*
- Because the issuance of the Advanced Beneficiary Notice (ABN) is voluntary, ITEM recommends adding “voluntary” prior to the ABN reference, or replacing “ABN” with the generic term “notice.” This edit to the NCD will prevent confusion from the contractors, suppliers, and patients regarding the necessity for an ABN when the features are clearly outside the scope of the Medicare-covered SGD benefit.

- Given the history of misinterpretation by the CMS contractors, ITEM is concerned about the absence of a statement addressing mounting technologies and/or accessories. We strongly encourage CMS to add the following language to ensure continued coverage:

“Reasonable and necessary accessories for speech generating devices include access technology and mounting accessories used by patients with limited mobility. These accessories include, but are not limited to: eye-tracking, switches, pointers, scanners and table or wheelchair mounting hardware.”

- ITEM requests that CMS resolve to revisit its current reimbursement policies with respect to not covering a laptop computer, desktop computer or a personal digital assistant (PDA) as an SGD. These devices can serve primarily as assistive technology for individuals with severe speech impairments and can be procured in many instances at a lower cost than other SGDs on the market. The rapid technological innovation in this field suggests that CMS should be open in the future to revisiting this decision and considering in its calculus additional advancements in technology.
- ITEM recommends that CMS issue the revised NCD for SGDs in final form as soon as possible. The uncertainty and confusion that arose in 2014 regarding SGD coverage and allowable features will not be resolved until this revised NCD is adopted as final administrative guidance.

Capped Rental

Using the “capped rental” methodology to reimburse SGDs continues to be an overarching issue that inhibits access to consistent communication for SGD users. The draft NCD will help to ensure that Medicare beneficiaries have the ability to upgrade SGDs; however, there are still significant concerns directly related to the capped rental policy. Legislation has passed the U.S. Senate that exempts SGDs from capped rental and a similar bill is pending in the House. But this exemption would expire on October 1, 2018. Whether through this NCD or another mechanism, CMS should revisit its decision to reimburse SGDs as capped rental and permit the beneficiary to choose to purchase his or her SGD on a one-time, lump-sum basis.

In addition, it is unclear whether upgrades are permitted during the capped rental period, particularly for rentals that were initiated prior to the anticipated revised NCD. At this time, there is still no definitive resolution regarding coverage of additional SGD features and accessories during the capped-rental period and we urge CMS to clarify this in its final NCD.

Eye-Tracking Accessories

ITEM notes that CMS did not address in the draft NCD the ongoing rejection of claims for SGD eye-tracking accessories. CMS’ failure to cover SGD eye-tracking accessories has caused—and continues to cause—undue harm to Medicare beneficiaries with severe or complex speech, language or communication impairments who are unable otherwise to meet their daily communication needs. ITEM asks CMS to please consider resolving these coverage issues as soon as possible, again, in the context of the final version of the NCD or through other mechanisms available to CMS.

The ITEM Coalition applauds CMS for the draft NCD and the consideration given to public comments and concerns. We welcome the opportunity to work with you to further discuss and implement changes to the SGD NCD that will preserve Medicare beneficiary access to this critical assistive technology. If you have any questions, please contact the ITEM Steering Committee (listed below) or the ITEM Coalition via email at Peter.Thomas@ppsv.com or 202-466-6550. Thank you for your consideration of our comments.

Sincerely,

ITEM Coalition Steering Committee Members

Mark Richert, American Foundation for the Blind (MRichert@afb.net)

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Endorsing Organizations

American Academy of Physical Medicine & Rehabilitation

American Association on Health and Disability

American Cochlear Implant Alliance

American Congress of Rehabilitation Medicine

American Foundation for the Blind

American Medical Rehabilitation Providers Association

American Occupational Therapy Association

American Speech-Language-Hearing Association

American Therapeutic Recreation Association

Association for Education and Rehabilitation of the Blind and Visually Impaired

Association of Assistive Technology Act Programs

Association of University Centers on Disabilities

ACCSES

Brain Injury Association of America

Caregiver Action Network

Christopher and Dana Reeve Foundation

Clinician Task Force

Easter Seals

Institute for Matching Person & Technology

Lakeshore Foundation

National Association of State Head Injury Administrators

National Disability Rights Network

National Multiple Sclerosis Society

Paralyzed Veterans of America

Perkins

United Spinal Association

The Arc of the United States