JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Medical Policy Manual** **Medical Policy**	*Policy Number*	CMS19.08
		Effective Date	02/01/2024
		Approval Date	11/21/2023
	Subject **Speech Devices**	*Supersesedes Date*	02/01/2023
		Page	1 of 8

This document applies to the following Participating Organizations:

Advantage MD	EHP	Johns Hopkins Health Plan of Virginia Inc. (JHHPVA)	Priority Partners
US Family Health Plan			

Keywords: SpeechEasy, SpeechVive

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I. ACTION

	New Policy	
X	Revising Policy Number	CMS19.08
	Superseding Policy Number	
	Retiring Policy Number	

II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

III. POLICY

For Advantage MD refer to: Medicare Coverage Database:

- No Local Coverage Determination (LCD) or National Coverage Determination (NCD) for SpeechEasy Device identified (Accessed October 17, 2023)
- No Local Coverage Determination (LCD) or National Coverage Determination (NCD) for SpeechVive Device identified (Accessed October 17, 2023)

For Employer Health Programs (EHP) refer to:

- Plan specific Summary Plan Descriptions (SPDs)

For Johns Hopkins Health Plan of Virginia LLC (JHHPVA) refer to: Medicare Coverage Database

- No Local Coverage Determination (LCD) or National Coverage Determination (NCD) identified (Accessed October 12, 2023)

For Priority Partners (PPMCO) refer to: Code of Maryland Regulations

- Code of Maryland Regulations (COMAR) 10.67.08.03 Nonbehavioral Health Fee-For-Service Benefits

For US Family Health Plan refer to: TRICARE Policy Manuals

- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 7, Section 8.1, Special Otorhinolaryngologic Services
- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 7, Section 23.1, Augmentative Communication Devices (ACDs)

IV. POLICY CRITERIA

A. Unless specific benefits are provided under the member's contract, JHHP considers speech aid devices used in the treatment of stuttering, Parkinson's Disease, or other indications experimental and investigational, as they do not meet Technology Evaluation Criteria (TEC) *(list not all-inclusive)*:

1. Altered auditory feedback devices: SpeechEasy®, SpeechEasyPD®, SmallTalk®
2. Speech volume modulation systems: SpeechVive®

V. DEFINITIONS

SmallTalk: an altered auditory feedback device that includes delayed auditory feedback (DAF), adjustable to normal or slow, and frequency-altered auditory feedback (FAF), intended to treat stuttering (Casa Futura, n.d.).

SpeechEasy® Devices: A small, inconspicuous speech device resembling hearing aids intended for the treatment of stuttering. The device works by digitally replaying the inividual's own words into their ear with a very slight delay (delayed auditory feedback) and alteration in frequency (frequency-shifted auditory feedback). The patient's brain perceives that it is speaking in unison with others, which may trigger a choral effect and suppress stuttering. The SpeachEasyPD device uses the same technology and is proposed to treat speech in individuals with Parkinson's disease. (SpeechEasy, 2023).

SpeechVive:® A wearable technology comprised of an ear-worn device, charging station and charging cord. The device plays a noise (multi-talker babble) only when an individual speaks. The noise elicits the Lombard Effect (use of noise to elicit louder and clearer speech spontaneously), automatically increasing the individual's vocal intensity, slowing their speech rate, and/or increasing the clarity of their speech. (CMS, 2022)

Technology Assessment: The systematic evaluation of the properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies, and interventions and their indirect, unintended consequences (World Health Organization, 2018).

Technology Evaluation Criteria (TEC): A service, device or supply must meet all the following criteria:

1. The technology must have final approval from the appropriate government regulatory bodies for intended use.
2. There must be sufficient scientific evidence-based studies to permit conclusions concerning the effect of the technology on health outcomes.
3. The technology must improve the member's net health outcome
4. The technology must be as beneficial as any established alternatives.
5. The improvement must be attainable outside the investigational setting.

VI. BACKGROUND

Stuttering is a disorder in which the fluency of speech is disrupted as certain sounds, syllables, and words are repeated or prolonged, affecting about three million individuals in the United States (NIDCD, 2017). The disorder usually occurs in young children as their speech develops (developmental stuttering). However, stuttering may also occur following trauma or injury to the head, or a stroke (neurogenic stuttering). While most children recover from stuttering, for some, the disorder may persist into adulthood. Treatments include various behavioral techniques depending on a number of factors such as age and communication goals. Speaking in unison with others (choral effect) has been known to increase fluency. Further, altering auditory feedback through techniques such as delayed auditory feedback (DAF) and frequency altered feedback (FAF) has been shown to improve speech dysfluencies. In DAF, the speaker's own vocal output is played back with a temporal lag; while in FAF, the frequency of the speaker's voice is modified and presented back to the speaker in near real-time (Malloy et al., 2022). As such, altered auditory feedback devices such as SpeechEasy® or SmallTalk® devices have been proposed as a treatment modality for stuttering and other speech dysfluencies. However, their efficacy has not been established in the peer-reviewed, published literature.

Most studies evaluating the efficacy of the SpeechEasy® as a stuttering treatment are uncontrolled studies with small sample sizes, short follow-up, and no direct comparisons of treatment efficacy with established behavioral techniques (Foundas et al., 2013; Gallop & Runyan, 2012; Pollard et al., 2009; Armson et al., 2008; O'Donnell et al., 2008; Armson et al., 2006). Studies generally compare the treatment efficacy of the auditory feedback device (SpeechEasy®) with unaltered feedback (control condition), yielding mixed results with studies either showing reduction in stuttering relative to baseline, no significant treatment effect, or no significant differences in stuttering frequency when wearing the device versus not. Gallup & Runyan evaluated the long-term efficacy (n=11) of the auditory feedback device among participants enrolled in the Pollard et al. study from months 13 to 59, and found no significant difference in stuttering frequency when wearing the device versus not wearing the device. A randomized clinical trial (n=16) reported by Ritto et al. (2016) compared the efficacy of SpeechEasy® (n=10) used daily over 6 months with behavioral techniques such as fluency shaping and stuttering modification (n=6) administered over a 12-week fluency promotion protocol. The authors reported no significant differences between the groups, with both treatment protocols achieving about 40% reduction in the number of stuttered syllables from baseline measures. Furthermore, no significant relapse was observed at 3 and 6 months following treatment, suggesting the SpeechEasy® device may be a viable alternative treatment for stuttering. While these findings may have potential implications for clinical utility, they have not been replicated in other studies and the study is limited by its small sample size and short follow-up. Further study is warranted.

The SmallTalk® auditory feedback device is commercially available and intended to reduce stuttering and improve fluency through delayed auditory feedback (DAF) and frequency-altered auditory feedback (FAF). A 2016 systematic review evaluating non-pharmacological treatments for stuttering included six studies utilizing auditory feedback devices combining DAF and FAF. Each of these studies were reported to have a high risk of bias. Unger et al. (2012) included use of the SmallTalk® device as researchers evaluated the immediate effects of altered auditory feedback (AAF) and one inactive condition (AAF parameters set to 0) on clinical attributes of stuttering during scripted and spontaneous speech. The study included a total of ten speech samples across four different experimental conditions (No Device, Inactive Condition, Device A, Device B). The resulting recorded speech samples were analyzed to detect changes in specific features of stuttering, including frequency, duration and the core behaviors of blocks, repetitions and prolongations. The authors concluded AAF significantly reduced, yet did not eliminate, stuttering during both scripted and spontaneous speech. However, the inactive condition also showed a significant improvement in speech fluency for participants with advanced stuttering severity ratings. During use of the devices, the most disfluencies remained during spontaneous speech. Overall, there is a paucity of studies evaluating the SmallTalk®device and further evidence is required to draw conclusions about its efficacy.

Dysarthria is common in Parkinson's disease (PD). It is estimated that 75% to 90% of patients with PD will develop voice and speech deficits, including reduced volume, a monotone, hoarse or strained voice quality, breathiness, difficulty with pronunciation, tremors, slurring, and using brief bursts of speech. These speech morbidities in PD are attributed to an impact on nerves and muscles of the larynx, throat, respiratory muscles, roof of the mouth, tongue, and lips; movement of facial muscles; and areas of the brain associated with hearing, voice, and speech processing (Hayes, 2020). Though data on voice-related quality of life in Parkinson's patients is limited, evidence suggests that speech disorders significantly impact these patients' lives and are likely associated with psychological distress and depression (Dashtipour et al., 2018).

Some studies indicate that noise masking or multi-talker background noise may improve speech in PD patients with hypophonia by leveraging an automatic brain response called the Lombard Effect. Thus, assistive auditory devices that incorporate the Lombard response have been developed to improve speech fluency in patients with PD (Adams et al., 2020). One such device,SpeechVive®, uses noise described as multi-talker babble to reportedly automatically increase vocal intensity, slow speech rate, and/or increase the clarity of speech (CMS, 2022).

Despite a scarcity of literature evaluating the effect of the SpeechVive® device on measures of speech performance in patients with Parkinson's disease, four such studies were identified (Richardson et al., 2022; Huber et al., 2019; Huber et al., 2016; Stathopoulos et al., 2014). Though each of these studies reported improvements in communication, such as increases in both vocal intensity and sound pressure level, many of these investigations were limited by small sample size, short follow-up, and a lack of controls. Overall, there remains an insufficient quantity of published, peer-reviewed human clinical data to evaluate the SpeechVive® for the management of speech disorders related to PD.

An UpToDate article on non-pharmacological management of Parkinson's disease (Fleisher, 2023) describes available alternate treatments for hypophonia in Parkinson's disease. Of these, two speech therapy techniques supported by small randomized trials are noted as potentialinterventions to improve speech volume in patients with Parkinson's disease. One technique emphasizes rhythm and intonation features of speech reinforced with visual feedback. The other technique, known as the Lee Silverman Voice Treatment [LSVT-LOUD], aims to increase vocal loudness to normal levels and delivers the treatment in an intensive, high-effort treatment plan. However, no guidance was provided for the use of the SpeechVive® or SpeechEasy® devices in the treatment of Parkinson's disease.

VII. CODING DISCLAIMER

CPT® Copyright the 2024 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.

Note: The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require preauthorization.

Adherence to the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits
Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Employer Health Programs (EHP): Specific Summary Plan Descriptions (SPDs) supersedes JHHP Medical Policy. If there are no criteria in the SPD, apply the Medical Policy criteria.
Johns Hopkins Health Plan of Virginia LLC (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.
US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

VIII. CODING INFORMATION

CPT®CODES ARE FOR INFORMATIONAL PURPOSES ONLY	
CPT ® CODES	**DESCRIPTION**
	NO CODES

HCPCS CODES ARE FOR INFORMATIONAL PURPOSES ONLY	
HCPCS	**DESCRIPTION**
E3000	Speech volume modulation system, any type, including all components and accessories

ICD-10 CODES ARE FOR INFORMATIONAL PURPOSES ONLY	
G20	Parkinson's disease
R47.1	Dysarthria and anarthria
R47.82	Fluency disorder in conditions classified elsewhere

IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

X. REFERENCES

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XI. APPROVALS

Historical Effective Dates: 01/14/1997, 10/22/2003, 10/22/2004, 10/21/2005, 10/10/2006, 03/03/2008, 03/02/2009, 06/04/2010, 08/23/2011, 09/07/2012, 12/05/2014, 03/03/2017, 08/03/2020, 11/16/2021, 02/01/2022, 02/01/2023, 02/01/2024