



Cigna Medical Coverage Policy

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Subject **Stuttering Treatment Devices**

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INSTRUCTIONS FOR USE

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Coverage Policy

Under many benefit plans, speech therapy is not covered for stuttering or dysfluency without evidence of an underlying medical condition or neurological disorder. In addition, many benefit plans specifically exclude services that are educational, training and behavioral training in nature. Stuttering treatment devices are considered training devices and, as such, are not covered under many plans.

Cigna does not cover stuttering treatment devices because they are considered experimental, investigational or unproven.

General Background

Stuttering, also referred to as stammering or dysfluency, is a speech disorder in which the normal flow of speech is disrupted by frequent repetitions or prolongations of speech sounds, syllables or words, or by an individual's inability to start a word. Developmental stuttering (DS) is the most common form of dysfluency and includes all cases that have gradual onset in childhood. Acquired stuttering in previously fluent individuals is much rarer than DS and may be neurogenic, resulting from brain damage associated with stroke or traumatic brain injury. Normal developmental dysfluency and early signs of stuttering are often difficult to differentiate. A speech evaluation is recommended for children who stutter longer than six months (Kirshner, 2008).

At present there is no cure for stuttering. Standard treatment for the disorder involves speech therapy with a variety of therapeutic approaches. Many programs for persistent stuttering focus on relearning how to speak or behavior modification. Treatment often includes educating parents about restructuring the child's environment to reduce episodes of stuttering. In some cases, medications such as haloperidol or risperidone are used.

Altered auditory feedback (AAF) devices have been proposed as a treatment method. The rationale for AAF lies in the observation that individuals who stutter tend to become more fluent when speaking in unison with others, a phenomenon called the choral effect. Delayed auditory feedback (DAF) delays the user's voice to his or her ears. Frequency-shifted auditory feedback (FAF) alters the pitch of the user's voice in his or her ears. Masking auditory feedback (MAF) synthesizes a sine wave that imitates vocal fold vibration which facilitates the fluency of speech. The masking sound is triggered by a laryngeal microphone and played back to the user via an earpiece. The underlying mechanisms that enhance fluency under AAF have not been identified. Many theories have been proposed such as distraction, auditory malfunctioning, or modified vocalization.

U.S. Food and Drug Administration (FDA)

The FDA categorizes stuttering or antistammering devices as Class I devices. As such, these devices are exempt from premarket notification procedures. The FDA defines an antistammering device as one that electronically generates a noise when activated or when it senses the user's speech and that is intended to prevent the user from hearing the sounds of his or her own voice. The device is used to minimize a user's involuntary hesitant or repetitive speech. Trade names for antistammering devices include: SpeechEasy® (Janus Development Group Inc., Greenville, NC); Fluency Master (National Medical Equipment Inc., New Hyde Park, NY); and Casa Futura's Pocket Speech Lab and Basic Fluency System (Casa Futura Technologies, Boulder, CO).

Stuttering Devices

The SpeechEasy device utilizes DAF and FAF to recreate and optimize the choral effect. The device is worn like a traditional hearing aid. When wearing a SpeechEasy device the user's words are digitally replayed in their ear with a very slight delay and frequency modification, which creates the illusion of speaking in unison with another person. This reportedly reduces stuttering in some individuals.

Auditory feedback provided by the Fluency Master antistuttering device involves the use of a small microphone placed near the larynx of the user. The microphone detects vocal tone vibrations which are amplified and sent to the user's earpiece. It is proposed that the amplification of vocal tone by the Fluency Master helps to control stuttering and improve fluency.

The Pocket Speech Lab utilizes all three types of AAF. In addition, vocal tension biofeedback analyzes the voice frequencies and amplitudes of the user. A green light indicates vocal relaxation and changes to red with increased vocal tension. This technique aims to train the user to speak with relaxed breathing and control of the muscles involved in speech. The Basic Fluency System uses DAF and FAF.

Literature Review

A number of small uncontrolled case studies (n=9–335) have reported on the clinical use and effectiveness of devices used for the treatment of stuttering (Foundas, et al., 2013; Ratyńska, et al., 2012; Unger, et al., 2012; Lincoln, et al., 2010; Armson and Kiefe, 2008; Stuart, et al., 2006; Armson, et al., 2006; Kalinowski, et al., 2004; Van Borsel, et al., 2004). Results of some studies have suggested that the use of these devices reduces stuttering frequency. However, the small sample sizes, short-term follow-up, and uncontrolled, nonrandomized design of these studies limit the generalizability of the results.

Bothe et al. (2006) conducted a systematic review of the evidence for behavioral, cognitive, and related treatments for developmental stuttering. There were no articles identified in the literature published between 1970 and 2005 specific to the SpeechEasy device that met the trial quality inclusion criterion established for this analysis (Bothe, et al., 2006).

Professional Societies/Organizations

The National Institute on Deafness and other Communication Disorders (NIDCD) states that some people who stutter use electronic devices to help control fluency. However, questions remain about how long such effects may last and whether people are able to easily use these devices in real-world situations. For these reasons, researchers are continuing to study the long-term effectiveness of these devices (NIDCD, 2010).

Use Outside of the US

No relevant information.

Summary

There is insufficient evidence in the published peer-reviewed scientific literature to conclude that stuttering devices are effective in the treatment of stuttering or dysfluency. The results of small, uncontrolled case series suggest that some individuals experience a decrease in stuttering while using altered auditory feedback (AAF) devices. However, well-designed prospective randomized, controlled clinical trials are needed to establish the long-term efficacy of these devices and to define their role in the treatment of stuttering when compared to standard treatment (e.g., speech therapy), or no treatment.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Experimental/Investigational/Unproven/Not Covered when used to report stuttering treatment devices:

HCPSC Codes	Description
E1399	Durable medical equipment, miscellaneous

*Current Procedural Terminology (CPT®) ©2013 American Medical Association: Chicago, IL.

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