Clinical Policy Title: Altered auditory feedback devices for speech dysfluency (stuttering)

Clinical Policy Number: 17.02.02

Effective Date: January 1, 2016
Initial Review Date: August 19, 2015
Most Recent Review Date: July 20, 2017
Next Review Date: July 2018

Related Policies:

CP# 15.02.05 Speech-generating devices.

ABOUT THIS POLICY: AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Pennsylvania considers the use of altered auditory feedback (AAF) devices for treatment of speech dysfluency (stuttering) to be investigational and, therefore, not medically necessary.

Limitations:

All other uses of AAF devices are not medically necessary.

Alternative covered services:

- Behavioral therapy.
Speech therapy for neurogenic stuttering.

**Background**

Speech dysfluency (stuttering or stammering) is involuntary breaks or interruptions in speech sounds that affect the flow of words (American Speech-Language-Hearing Association [ASHA], 2015; Prasse, 2008). It may be associated with anomalies of the Broca area of the left frontal lobe related to speech production (Kell, 2009). Dysfluency in verbal expression usually manifests as repetitions of sounds, syllables or words or as speech blocks or prolonged pauses between sounds and words. In more severe cases, symptoms may progress along with secondary behaviors such as eye blinking, jaw jerking and involuntary movements. Persons may develop strategies to avoid certain words, social interactions and other stressful situations. The burden of stuttering can affect a person’s self-esteem, self-image, quality of life, and academic and occupational relationships (Jones, 2014; Reilly, 2013; Prasse, 2008).

Stuttering occurs in persons of all ages, but it is most common in young children who are developing and learning language and speech. In most cases stuttering resolves by adulthood but may occur in up to one percent of adults (Prasse, 2008). Stuttering is classified as: developmental; acquired following a neurologic event; or, in rare cases, psychogenic in persons with a history of psychiatric illness or no known etiology. Developmental stuttering is the most common form. The etiology of developmental stuttering is unclear, but factors such as cognitive processing abilities, genetics, gender and environmental influences (e.g., social situations) may influence stuttering incidence. Assessment involves observation, interviewing and testing to establish the type and severity of stuttering, the impact on the patient and family, presence of secondary behaviors, the need for therapy and their coping behaviors (Prasse, 2008).

**Treatment:**

Treatment goals and strategies for children and adults vary. In young children, particularly those who are pre-school age, successful elimination of mild stuttering occurs in approximately 75 percent of cases, whereas the likelihood of eliminating stuttering behaviors decreases if they persist beyond age 8 years. In older children and adults who have more advanced forms of stuttering and secondary behaviors, treatment goals are generally not complete fluency. Rather, successful treatment may be defined by more modest decreases in stuttering frequency and duration, struggling to speak, avoidance behavior, and speaking anxiety, as well as improved social, educational, and occupational engagement (Prasse, 2008; Blomgren, 2013).

Modern treatment focuses on individualized behavioral approaches combined with education and training. In children, emphasis of treatment is on manipulating environmental factors (indirect approaches) and working exclusively on the speech of the child (direct approaches) (Blomgren, 2013). Indirect approaches facilitate speech fluency and communication rate by focusing on the parents or families of the stuttering child about how to modify their own speech and in their child's environment to model fluent speech.
Direct approaches focus on changing the person’s speech to facilitate fluency. They include speech modification and stuttering modification strategies to reduce disfluency rate, physical tension, secondary behaviors and communication attitudes. Nearly all current approaches to treating stuttering in children involve parental training. Techniques for mild stuttering include parental involvement (e.g., Lidcombe approach) and direct approaches (Blomgren, 2013; Prasse, 2008).

For more advanced forms of stuttering, therapy techniques are primarily compensatory (Blomgren, 2013; Prasse, 2008). Therapy generally emphasizes teaching new ways to manage and deal with the stuttering (stuttering management), changing core speech behavior that facilitates fluent speech (speech restructuring or reshaping), or a combination of the two. Stuttering management therapy may involve basic elements of cognitive behavioral therapy (CBT). Compensatory techniques must be used continuously to maintain improvement, and require a long-term strategy that includes teaching clients to be their own clinicians and offering opportunities for long-term therapeutic follow-up (Blomgren, 2013; ASHA, 2015).

Non-behavioral treatment approaches are also available. Drug therapy is emerging but, thus far, has proven ineffective in clinical studies (National Institute on Deafness and Other Communication Disorders [NIDCD], 2015). Electronic devices for the telephone and software for computers and smart phones have been developed to help control fluency. Perhaps the most longstanding devices are those that fit in or around the ear, much like a hearing aid, and manipulate auditory feedback to deliver a delayed or altered version of the wearer’s voice into the ear (The Stuttering Foundation, 2015).

**Regulatory status:**

The U.S. Food and Drug Administration (FDA) defines an anti-stammering device as one that electronically generates a noise when activated or when it senses the user’s speech to prevent the user from hearing the sounds of his or her own voice (21CFR874.5840). The device is used to minimize a user’s involuntary hesitative or repetitive speech. FDA classifies stuttering or anti-stammering devices as Class I devices. As such, these devices are exempt from premarket notification procedures. Several devices are marketed for use in the United States (FDA, 2015). This technique of manipulated or AAF is also known as delayed auditory feedback (DAF) and frequency-shifted auditory feedback.

Antistuttering devices that employ AAF are the focus of this policy.

**Searches**

AmeriHealth Caritas Pennsylvania searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
We conducted searches on June 8, 2016. Search terms were: “stuttering (MeSH)” and “feedback, sensory (MeSH),” and free-text terms “altered auditory feedback,” “delayed auditory feedback,” and “electronic fluency device.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews.**

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

AmeriHealth Caritas Pennsylvania identified one systematic review of the SpeechEasy® device (Janus Development Group Inc. Greenville, North Carolina) (Hayes, 2009), one narrative review of AAF devices (Lincoln, 2006), several small observational studies (Foundas, 2013; Ratyńska, 2012; Unger, 2012; Lincoln, 2010), and no guidelines or economic analyses for this policy. The evidence comprises several small uncontrolled case studies of the clinical use and effectiveness of AAF devices for the treatment of stuttering, primarily in adolescents and adults.

The evidence is insufficient to support the use of AAF devices for the treatment of stuttering. Results suggest an immediate reduction in stuttering frequency in some patients. However, the small sample sizes, short-term follow up, incomplete reporting of patient characteristics, and uncontrolled, non-randomized design of these studies limit the generalizability of the results. Critical knowledge about the effect of AAF during conversational speech and in everyday speaking situations is lacking, as is treatment durability. Knowledge of the correct levels of AAF for individuals and the characteristics of those likely to benefit from AAF also need to be established. Finally, the high rate of spontaneous recovery in children provides a statistical challenge for determining treatment effectiveness in that population.

**Policy updates:**

In 2017, we found one small randomized controlled trial (RCT) comparing AAF using SpeechEasy to behavioral techniques. Eighteen total adults participated in the study. Both groups achieved a comparable reduction in in number of stuttered syllables from baseline measures, with no significant
relapse after three or six months post-treatment. While encouraging, data on long-term outcomes and optimal patient characteristics are lacking. The evidence remains of low quality and insufficient to support the SpeechEasy device as a viable treatment option for stuttering. Therefore, no policy changes are warranted.

Summary of clinical evidence

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<tr>
<th>Citation</th>
<th>Content</th>
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<tbody>
<tr>
<td>Ritto (2016)</td>
<td><strong>Key points:</strong></td>
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| SpeechEasy in stuttering treatment | - An RCT comparing AAF using SpeechEasy to behavioral techniques:  
  - Group 1 = 10 men and one woman (mean age = 30.0 years) fitted with SpeechEasy with no additional training, used daily for six mos.  
  - Group 2 = six men and one woman (mean age = 35.6 years) received a 12-week fluency shaping and stuttering modification protocol.  
  - No statistically significant between-group differences (p > .05) in participants' stuttered syllables following treatment.  
  - Both groups achieved approximately 40% reduction in number of stuttered syllables from baseline measures, with no significant relapse after three or six months post-treatment. |
| Hayes (2009, update 2011) | **Key points:**                                                                                                                         |
| SpeechEasy® device | - Systematic review of five small, uncontrolled studies and one satisfaction survey.  
  - Overall quality: low with high risk of bias.  
  - Four studies performed in a speech laboratory indicated some patient benefit; one study in more realistic situations of daily life found no statistically significant improvement.  
  - Enrolled patients had large differences in stuttering severity, and limited or no long-term assessment.  
  - Results inconclusive. |

References

**Professional society guidelines/other:**

21CFR874.5840

FDA. Search of 510(k) Premarket Notification using product code KTH. FDA website.  


**Peer-reviewed references:**


**CMS National Coverage Determination (NCDs):**

No NCDs identified as of the writing of this policy.

**CMS Local Coverage Determinations (LCDs):**


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<td>Adult onset fluency disorder</td>
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<td>I69.223</td>
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