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, 2016
**Next Review Date:** July 2017

**Related Policies:**

CP# 15.02.05  Speech-generating devices.

**ABOUT THIS POLICY:** Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’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 Keystone First 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. Keystone First’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. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

**Coverage policy**

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

**Limitations:**

All other uses of altered auditory feedback 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 (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, American Speech-Language-Hearing Association [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 manipulating or altered auditory feedback (AAF) is also known as delayed auditory feedback (DAF) and frequency-shifted auditory feedback.

**Anti-stuttering devices that employ AAF are the focus of this policy.**

**Searches**

Keystone First searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
Agency for Healthcare Research and Quality's National Guideline Clearinghouse and other evidence-based practice centers.

The Centers for Medicare & Medicaid Services (CMS).

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**

Keystone First 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:**

None.

**Summary of clinical evidence**
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<tr>
<th>Citation</th>
<th>Content</th>
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| Hayes (2009, update 2011) | **Key points:**  
- 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. |

**Glossary**

**Altered auditory feedback (AAF)** — A collective term for conditions that involve electronically altering the speech signal so speakers perceive their voice differently from normal (Lincoln 2006). The precise reasons for the fluency-inducing effects of AAF are unknown.

**Delayed auditory feedback (DAF)** — A mechanism designed to slow the rate of speech. Using a device with DAF, the speaker must slow the rate of speech to prevent distortions in the speech heard through the device.

**Frequency-shifted auditory feedback (FAF)** — A mechanism designed to change the pitch at which the user hears his or her voice.

**Masking** — Introduction of white noise to reduce stuttering.

**Speech dysfluency (stuttering or stammering)** — A disturbance in the normal fluency and time patterning of speech that is inappropriate for the individual's age. This disturbance is characterized by frequent repetitions or prolongations of sounds or syllables, and may involve interjections, broken words, audible or silent blocking, circumlocutions, words produced with an excess of physical tension, and monosyllabic whole-word repetitions. **Stuttering** may occur as a developmental condition in childhood or as an acquired disorder associated with neurologic injury.

**Stuttering modification (traditional stuttering therapy)** — Reduces the severity of stuttering so speaking is performed without struggle by controlling primary symptoms, eliminating secondary behaviors and reducing the fear of overt stuttering.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**Clinical trials:**

Searched clinicaltrials.gov on June 22, 2015, using terms: stuttering OR stammering OR dysfluency OR "auditory feedback" OR speecheasy | Open Studies. Sixteen studies found. None relevant.

**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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