Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	**Submission Date**: 7/1/2024
Policy Number: ccp.1188	**Effective Date:** 1/2016 **Revision Date:** June 1, 2024
Policy Name: Altered auditory feedback devices for speech dysfluency (stuttering)	

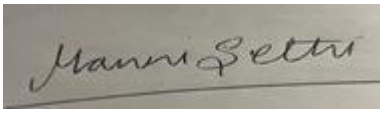
Type of Submission – Check all that apply:

New Policy
X Revised Policy*
Annual Review – No Revisions
Statewide PDL

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Keystone First
Family of Health Plans

Altered auditory feedback devices for speech dysfluency (stuttering)

Clinical Policy ID: CCP.1188

Recent review date: 6/2024

Next review date: 10/2025

Policy contains: Altered auditory feedback; anti-stuttering devices; assistive device; speech dysfluency; SpeechEasy.

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, on a case by case basis, 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

Altered auditory feedback devices for treatment of speech dysfluency (stuttering) is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

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, 2021; Prasse, 2008; Sander, 2019). 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; Prasse, 2008; Reilly, 2013).

Stuttering occurs in persons of all ages, but it is most common in young children who are developing and learning language and speech. Life span incidence of stuttering is estimated at 5% (Yairi, 2013) . 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.

Treatment

Treatment goals and strategies for children and adults vary, depending on age and severity. In milder cases, complete elimination of stuttering may be the goal, whereas in advanced forms, 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 may be the objective (Blomgren, 2013; Prasse, 2008).

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.

For more advanced forms of stuttering, therapy techniques are primarily compensatory (Blomgren, 2013; Prasse, 2008). Compensatory techniques must be used continuously to maintain improvement and require a long-term strategy of teaching clients to be their own clinicians and offering opportunities for long-term therapeutic follow-up (American Speech-Language-Hearing Association, 2021; Blomgren, 2013). Electronic devices for the telephone and software for computers and smart phones have been developed to help control fluency. Among 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 (Alm, 2022).

Regulatory status

The U.S. Food and Drug Administration 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. The U.S. Food and Drug Administration (2021) 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. This technique of manipulated or altered auditory feedback is also known as delayed auditory feedback and frequency-shifted auditory feedback.

Findings

We identified one narrative review of altered auditory feedback devices (Lincoln, 2006), several small observational studies (Foundas, 2013; Lincoln, 2010; Ratyńska, 2012; Unger, 2012), and no guidelines or economic analyses for this policy. The evidence comprises several small uncontrolled case studies of the clinical use and effectiveness of altered auditory feedback devices for the treatment of stuttering, primarily in adolescents and adults.

The evidence is insufficient to support the use of altered auditory feedback 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 altered auditory feedback during conversational speech and in everyday speaking situations is lacking, as is treatment durability. Knowledge of the correct levels of altered auditory feedback for individuals and the characteristics of those likely to benefit from altered auditory feedback 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.

In 2017, we found one small randomized controlled trial comparing altered auditory feedback 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.

In 2018, we added no new information.

In 2019, we identified no newly published, relevant literature to add to the policy. The policy ID was changed from CP# 17.02.02 to CCP.1188.

In 2020, we identified no newly published, relevant literature to add to the policy.

In 2021, we added one systematic review and meta-analysis (Connery, 2021) of nine randomized controlled trials examining the effectiveness of several nonpharmacological stuttering therapies. One of the trials evaluated the SpeechEasy device. The meta-analysis highlighted no significant pooled difference between intervention and comparator groups in improving communication and psychosocial functioning. The results confirm previous findings and require no policy changes. In 2022, we added no new information to the policy.

In 2022, we added no new information to the policy.

In 2023, we added a scoping review of 23 studies of altered auditory feedback that found measures of speech (including stuttering) in children over age four generally compensated in the opposite direction of manipulation, however, but perhaps not as effectively as in adults (Coughler, 2022). We also removed Centers for Medicare & Medicaid Services citations and references.

In 2024, we identified no newly published, relevant literature to add to the policy.

References

On May 12, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “stuttering” (MeSH), “feedback, sensory” (MeSH), “altered auditory feedback,” “delayed auditory feedback,” and “electronic fluency device.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

21CFR874.5840.

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Policy updates

8/2015: initial review date and clinical policy effective date: 1/2016

8/2016: Policy references updated.

8/2017: Policy references updated.

8/2018: Policy references updated.

6/2019: Policy references updated. Policy ID changed.

6/2020: Policy references updated.

6/2021: Policy references updated.

6/2022: Policy references updated.

6/2023: Policy references updated.

6/2024: Policy references updated.