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.

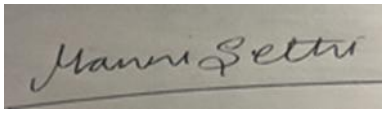
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 7/1/2025
Policy Number: CCP.1188	Effective Date: 1/1/2016 Revision Date: 6/2025
Policy Name: Altered auditory feedback devices for speech dysfluency (stuttering)	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

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

Please provide any clarifying information for the policy below:

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

Altered auditory feedback devices for speech dysfluency (stuttering)

Clinical Policy ID: CCP.1188

Recent review date: 6/2025

Next review date: 10/2026

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

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP'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- CHIP, 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- CHIP'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- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP'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, 2025; Sander, 2019). 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 (American Speech-Language-Hearing Association, 2025).

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 (American Speech-Language-Hearing Association, 2025).

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).

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). 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, 2025; 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. The device is used to minimize a user's involuntary hesitative or repetitive speech. It is classified as a Class I device, which is exempt from premarket notification procedures (21CFR874.5840). Several devices are marketed for use in the United States (U.S. Food and Drug Administration, 2025). This technique of manipulated or altered auditory feedback is also known as delayed auditory feedback and frequency-shifted auditory feedback.

Findings

Guidelines

We identified no guidelines that addressed altered auditory feedback devices for the treatment of speech dysfluency.

According to the American Speech-Language-Hearing Association (2025), treatment for fluency disorders is highly individualized. Selection of treatment approaches and materials are multifactorial with a person-centered

focus on function, taking into consideration the individual's age, preferences, and needs within the context of family and community. Altered auditory feedback devices are not mentioned specifically as an intervention.

Evidence review

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 may be achieved 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. While most of the studies addressed stuttering interventions in early childhood, limited evidence exists for altered auditory feedback and only for school-aged children and adults.

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.

Several systematic reviews have examined the efficacy altered auditory feedback devices for stuttering. A comprehensive systematic review analyzed devices that alter the way a person who stutters hears their own speech under a variety of conditions including reading, monologue, and conversation (either in person or via the telephone). Six of the studies reported on use of the SpeechEasy device in adolescents and adults in laboratory, clinical, and naturalistic contexts, and three of the papers examined longer-term outcomes. None used a control group design. Follow-up periods ranged up to 59 months with sample sizes ranging from seven to 31 participants. All studies reported some degree of effectiveness for this intervention in terms of reducing stuttering, but five out of the six papers were assessed as being at higher risk of bias, with only one judged to have a lower risk of bias (Baxter, 2016).

One systematic review and meta-analysis (Connery, 2021) identified the first randomized controlled trial (Ritto, 2016) of the SpeechEasy device. In the Ritto trial, ten participants (mean age 30.0 years) using a SpeechEasy device daily for six months with no additional speech training were compared to six participants (mean age 35.6 years) who underwent a 12-week fluency promotion protocol with techniques based on both fluency shaping and stuttering modification. The meta-analysis highlighted no significant pooled difference between intervention and comparator groups in improving communication and psychosocial functioning.

Systematic reviews published after 2021 confirmed these earlier findings and the need for further investigation. Speech restructuring treatments may reduce stuttering, when measured by the percentage of syllables stuttered to measure changes in speech fluency, but do not address the psychological aspects of stuttering, such as social anxiety. Hybrid treatments that deal with the multifaceted nature of stuttering, including speech modification and methods targeting psychological and social effects of stuttering, should be considered for all age groups (Johnson, 2023; Laiho, 2022).

In 2017, we updated the references. 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 updated the references and made no policy changes.

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

In 2023, we updated the references and removed Centers for Medicare & Medicaid Services citations and references. No policy changes are warranted.

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

In 2025, we updated the references and reorganized the findings section with no policy changes warranted.

References

On April 9, 2025, 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. Antistammering device.

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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.

6/2025: Policy references updated.