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 Community Health Choices	**Submission Date**: 3/1/2024
Policy Number: ccp.1151	**Effective Date:** 6/2015 **Revision Date:** February 1, 2024
Policy Name: Biofeedback for chronic pain	

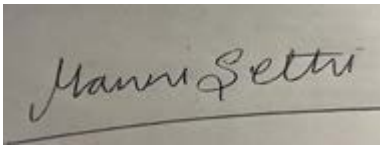
Type of Submission – Check all that apply:

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
Community HealthChoices

Biofeedback for chronic pain

Clinical Policy ID: CCP.1151

Recent review date: 2/2024

Next review date: 6/2025

Policy contains: Non-malignant musculoskeletal pain; primary headache disorders.

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' 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 Community HealthChoices 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 Community HealthChoices' 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 Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

Biofeedback is clinically proven and, therefore, may be medically necessary for the treatment of any of the following indications:

- Thermal or electromyography biofeedback, alone or in combination with behavioral modalities, for treatment of migraine headache in individuals ages 16 years or older (Andrasik, 2010; Goslin, 1999; Nestoriuc, 2008b; Silberstein, 2000).
- Electromyography biofeedback with or without relaxation therapy for treatment of tension-type headache in children, adolescents, and adults (Barnes, 2011; Goslin, 1999; Nestoriuc, 2008b).
- Electromyography biofeedback for treatment of chronic low back pain (Qaseem, 2017; Sielski, 2017).
- Electromyography biofeedback for muscle re-education of specific muscle groups or treatment of either pathological (disease-based) muscle abnormalities of spasticity or incapacitating muscle spasm or weakness, when more conventional treatments (e.g., heat, cold, massage, exercise, support) have not been successful (Castelnuovo, 2016).

Members must meet all of the following criteria:

- Demonstrated motivation to actively participate in the treatment plan and responsiveness to the care plan requirements (e.g., practice and follow-through at home).
- Are capable of participating in the treatment plan (physically and cognitively).
- Have a condition that can be appropriately treated with biofeedback (i.e., there is no pathology to prevent success of the treatment).
- The biofeedback therapy is performed by a licensed health care professional with training in biofeedback.

Limitations

All other uses of biofeedback are not medically necessary.

Alternative covered services

Physician office visits, pharmacotherapy, physical therapy, and behavioral health treatments.

Background

Pain is a subjective and individual experience, and biobehavioral pain techniques (i.e., relaxation techniques, cognitive-behavioral treatment, and biofeedback) have been proposed to modulate pain processing and reduce pain (Kropp, 2013). Biobehavioral treatment strategies focus on “unlearning” of pain and on modification of pain triggers and conditions that reinforce and maintain pain.

Biomechanical and physiological responses are the two groups used in biofeedback. The body’s activity and movement are measured via biomechanical techniques using simple or complex sensors. Physiologic activity is measured by differing means. Electromyography is the frequently used to measure muscle movement, but other modes are used to measure heart, lung, and skin activity. Different forms of biofeedback have been used as an adjunct to physical therapy for greater than 50 years. It has demonstrated benefit for neuromuscular diseases, stroke sequelae and orthopedic surgery. As the methodology advances more complex task-oriented goals like walking and grasping objects become a reality. The most common biofeedback use, aside from neuromuscular retraining, is the treatment of chronic pain, anxiety, and incontinence, by impacting the sympathetic nervous system response (Malik, 2023).

Biofeedback therapy may be medically necessary when it promotes the visual, auditory or any evidence of improvement in certain types of bodily functions that are either under involuntary or voluntary control to alleviate an abnormal bodily condition. It is successful in achieving this is based on the principle that a desired response learned by the member following the receipt of being educated, can and will affect a desired physiological response. Patients need to be able to understand analog and digital signals received from an auditory or visual display. They must be self-motivated to perform, via observation learning, those techniques prescribed for them and personalize their training as needed at home usually on a daily basis (Malik, 2023).

The goal of biofeedback treatment is to learn to actively change a normally involuntary physiologic function into a desired direction, by feeding the function back visually or acoustically so it can be perceived consciously by the subject (Kropp, 2013). The effects of biofeedback can be measured by monitoring skin temperature, skin conductance, galvanic skin response, muscle tension using electromyography, heart rate using electrocardiography, and brain wave activity using electroencephalography, also known as neurofeedback. While the mechanisms by which biofeedback acts to control pain or prevent the onset of headache are not understood completely, the cognitive processes of attention, expectancy, and memory may help to understand how non-pharmaceutical methods achieve pain relief (Sieberg, 2012).

A professional license is not required to provide biofeedback training, although biofeedback therapists are often licensed in another healthcare field and practice according to those guidelines. Because of its potential effects on physiology, the Association for Applied Psychophysiology and Biofeedback (2020) recommends that biofeedback therapy involve a trained therapist, a motivated patient, and a monitoring instrument capable of providing accurate physiological information.

Findings

We included the most recent or comprehensive systematic reviews with full text published since 2000. We included one additional systematic review, as it represented seminal research on migraine headache

interventions at that time (Goslin, 1999). In all, 10 systematic reviews were included in this policy: four of primary headache disorders of the migraine or tension type (Barnes, 2011; Goslin, 1999; Nestoriuc, 2008a, 2008b); one of fibromyalgia syndrome (Glombiewski, 2013); two of chronic knee pain (Macfarlane, 2012; Wasielewski, 2011); one of chronic low back pain (Henschke, 2010); and one of temporomandibular disorders (Aggarwal, 2011). No economic analyses were identified.

For primary headache disorders (Barnes, 2011; Goslin, 1999; Nestoriuc, 2008a, 2008b):

- There is moderate-quality evidence that electromyography biofeedback, with or without relaxation is an effective treatment for chronic tension-type headache in all age groups, but especially in children and adolescents. Treatment comprised an average of 11 sessions lasting approximately 40 – 45 minutes in a clinical setting. Treatments resulted in significant reductions in headache frequency, intensity, and headache-index and moderate reductions in muscle tension, self-efficacy, anxiety, depression, and pain medication use.
- There is moderate-quality evidence that thermal biofeedback with either relaxation or electromyography biofeedback, thermal feedback alone, or the less commonly used blood volume pulse feedback are effective treatments for chronic migraine headache in individuals ages 16 and older. Treatment comprised an average of 11 sessions lasting approximately 40 – 45 minutes, primarily in a clinical setting, and may have included home training reinforcement. Treatment resulted in significant improvements in frequency, intensity, duration, headache index, and self-efficacy. Smaller but still significant reductions in medication consumption, depression, and anxiety were also found.
- There is insufficient evidence to support the effectiveness of any biofeedback modality as treatment for migraine headaches in individuals ages 15 years and younger.
- While adverse effects of biofeedback have not been reviewed systematically or reported consistently in the research literature, it is generally regarded as a safe treatment alternative.
- There is insufficient evidence to support the effectiveness of biofeedback as treatment for other primary headache disorders.
- Evidence-based guidelines support the use of electromyography or thermal biofeedback as adjunctive treatment for migraine or tension-type headache. Although effective, blood volume pulse biofeedback is rarely used. However, there was insufficient information for recommending which type of treatment to pursue for specific patients (Andrasik, 2010; Goslin, 1999; Silberstein, 2000).
- There is insufficient evidence of effectiveness for electroencephalography biofeedback in headache disorders (Andrasik, 2010).

For other chronic non-malignant pain disorders, there is insufficient evidence to support the effectiveness of any biofeedback modality as treatment for fibromyalgia syndrome (Glombiewski, 2013), chronic knee pain (Macfarlane, 2012; Wasielewski, 2011), chronic low back pain (Henschke, 2010), or temporomandibular disorders (Aggarwal, 2011). Few evidence-based guidelines exist that include or recommend biofeedback for these specific chronic pain disorders. One guideline did not support the use of biofeedback for low back disorders (American College of Occupational and Environmental Medicine, 2011).

In 2017, we identified two new systematic reviews for this policy. They addressed treatments for fibromyalgia and chronic low back pain (Daffada, 2015; Theadom, 2015). One new systematic review found inconclusive evidence to support sensory discrimination training, which is a sensorimotor training program based on the principles of neuroplasticity, for treatment of chronic low back pain (Kalin, 2016). Results for the effectiveness of biofeedback compared to usual care were inconclusive due to poor-quality evidence. These results do not change the conclusions from the original policy. Therefore, no changes to the policy are warranted.

In 2018, we identified a meta-analysis (Sielski, 2017), a cost-effectiveness analysis (Haines, 2017), and an evidence-based guideline (Qaseem, 2017) addressing biofeedback treatment for acute, subacute, or chronic low

back pain. The new information supports electromyography biofeedback as an initial non-pharmacologic treatment option for chronic low back pain. The policy was changed to reflect these findings.

Two other evidence-based guidelines present recommendations for biofeedback in persons with musculoskeletal pain. The European League Against Rheumatism made a weak recommendation against biofeedback for fibromyalgia due to insufficient evidence of effectiveness (Macfarlane, 2017). The Italian Consensus Conference on Pain in Neuro-rehabilitation provided recommendations for treating various types of neuromuscular pain, but only tension-type headache and migraine were supported by high quality evidence; all other indications were based on case reports, small case series, or expert opinion (Castelnuovo, 2016). Both guidelines provide conflicting recommendations on biofeedback in fibromyalgia. For other musculoskeletal indications, there remains insufficient evidence of effectiveness to support biofeedback as a first-line treatment option. It may offer some pain relief when other standard of care therapies fail. The policy was changed to consider electromyography biofeedback in such instances.

A systematic review of 37 out of 651 quantitative studies including adult females, males and children, was performed to evaluate biofeedback evidence used for chronic pelvic pain and confirmed it as an effective treatment option for ano-rectal disorders, chronic prostatitis and female pelvic pain disorders in addition to improving quality of life (Wagner, 2022).

In 2019, we added no new information to the policy and made no policy changes. The policy ID was changed from CP# 03.03.06 to CCP.1151.

In 2020, we added the results of several systematic reviews and meta-analyses of biofeedback interventions for treating chronic pain conditions that require no changes to the policy (Aggarwal, 2019; Amatya, 2018; Bidonde, 2019; Oliveira, 2018).

In 2021, we removed one older reference and added two systematic reviews and meta-analyses (Bernier, 2020; Patel, 2020), which confirm previous findings and warrant no changes to the policy.

In 2022, we added more conditions, updated and added references to reflect the most current data and identified no new relevant research for the policy.

In 2023, we described how biofeedback works, included more current data which supported previous findings. No changes are warranted to the policy.

In 2024, we removed urinary and fecal incontinence from the coverage section, due to a lack of evidence supporting efficacy. We removed the reference to the Centers for Medicare & Medicaid Services. No changes are warranted to the policy.

We also added the following reviews:

- A focused systematic review/meta-analysis of 29 articles (n = 1,342) showed significant improvement in the intensity of headaches after electromyography/biofeedback, compared with controls. Authors state that the treatment is especially useful in patients who are unable to undergo drug therapy (Cinnera, 2023).
- A network meta-analysis of 45 randomized controlled trials (n = 3,379) determined that of seven types of physical factor therapies for pain relief for patients with post-stroke shoulder-hand syndrome, biofeedback plus rehabilitation therapies demonstrated the greatest improvement. (Feng, 2023).

References

On November 6, 2023, 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 “neurofeedback” (MeSH), “biofeedback, psychology” (MeSH), “pain” (MeSH), “pain management” (MeSH), “headache disorders” (MeSH), and “headache” (MeSH), “musculoskeletal diseases/rehabilitation” (MeSH), and “musculoskeletal diseases/therapy” (MeSH) 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.

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Policy updates

2/2014: initial review date and clinical policy effective date: 6/2015

2/2017: Policy references updated.

2/2018: Policy references updated. Policy changed.

2/2019: Policy references updated. Policy ID changed.

2/2020: Policy references updated.

2/2021: Policy references updated.

2/2022: Policy references updated.

2/2023: Policy references updated.

2/2024: Policy references updated.