Clinical Policy Title: Biofeedback for chronic pain

Clinical Policy Number: 03.03.06

Effective Date: June 1, 2015
Initial Review Date: February 19, 2014
Most Recent Review Date: February 15, 2017
Next Review Date: February 2018

Policy contains:
- Chronic primary headache disorders.
- Chronic non-malignant musculoskeletal pain.

Related policies:

CP# 03.03.01 Spinal cord stimulators for chronic pain
CP# 03.03.02 Intrathecal opioid therapy for chronic nonmalignant pain
CP# 03.03.03 Spinal surgeries
CP# 03.03.04 Spine pain — epidural steroid injections
CP# 03.03.08 Intravenous lidocaine infusion for neuropathic pain
CP# 03.02.07 Spine pain — facet joint injection
CP# 03.02.05 Spine pain — trigger point injection

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 biofeedback to be clinically proven and, therefore, medically necessary when all of the following criteria are met:

- One of the following indications:
  - Thermal or electromyographic (EMG) biofeedback, alone or in combination with other covered behavioral modalities, for treatment of migraine headache in individuals ages 16 years or older.
  - EMG biofeedback with or without relaxation therapy (where benefits apply) for treatment of tension-type headache (TTH) in children, adolescents, and adults.
• Appropriate pharmacotherapy is ineffective in treating chronic headache.
• Demonstrates motivation to actively participate in the treatment plan and responsiveness to the care plan requirements (e.g., practice and follow-through at home).
• Is capable of participating in the treatment plan (physically and cognitively).
• Has a condition that can be appropriately treated with biofeedback (i.e., there is no pathology to prevent success of the treatment).
• Biofeedback therapy is performed by a licensed health care professional with training in biofeedback.
• Biofeedback therapy consists of two treatment sessions per week, for up to 45 minutes per session.
• A trial of biofeedback training for up to four weeks is performed to determine if the individual is benefitting from treatment.
  – If the professional provider has determined that the individual appears to be benefitting from biofeedback or moving toward individual treatment goals after four weeks of biofeedback therapy, an additional four weeks of treatment may be prescribed. Sessions provided beyond this are considered not medically necessary, and, therefore, are not covered.
  – If the professional provider has determined that the individual does not appear to be benefitting from biofeedback or moving toward individual treatment goals after four weeks of biofeedback therapy, the use of biofeedback should be discontinued and an alternative treatment plan be proposed.

For Medicare members only:

Keystone First considers the use of biofeedback medically necessary for the following conditions:
• Muscle re-education of specific muscle groups, treatment of 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.
• The treatment of anorectal incontinence when the underlying cause is determined to be an ineffective anal sphincter squeeze function.
• The treatment of stress, urge, or persistent post-prostatectomy urinary incontinence and more conventional treatments (e.g., pharmacology, timed voiding, pelvic muscle exercises) have not been successful.
  – Biofeedback training is covered for the treatment of urinary incontinence only after patients have failed a documented trial of pelvic muscle exercise. A failed trial is defined as no clinically significant improvement in urinary incontinence after completing four weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.
Coverage for biofeedback training applies to services rendered by a practitioner in an office or other facility setting. Home use of biofeedback is not a covered service. Biofeedback training requires the continuous presence of the physician or qualified non-physician practitioner. Continuous presence requires one-on-one, face-to-face involvement between the patient and practitioner during training. Individuals selected for biofeedback training must:

- Have the ability to understand analog or digital signals using auditory or visual display.
- Be self-motivated to learn voluntary control through the observation of biofeedback and perform their personalized home exercise prescription, usually daily.

**Limitations:**

All other uses of biofeedback are not medically necessary including, but not limited to, for other primary chronic headache disorders, ordinary muscle tension states, or psychosomatic conditions.

The use of electroencephalography (EEG) biofeedback or in-home biofeedback devices is not medically necessary.

**Alternative covered services:**

- Physician office visits, pharmacotherapy, physical therapy, and behavioral health treatments within covered benefits.

**Background**

Musculoskeletal pain can be caused by disorders of the bones, joints, muscles, tendons, ligaments, bursae or a combination (International Association for the Study of Pain [IASP], 2014). The pain may be acute or chronic, regional or diffuse, and in musculoskeletal or associated neural tissues. Musculoskeletal pain affects all age groups. Individuals experience variable symptoms and consequences depending on the underlying cause of pain, resulting in significant suffering and disability for individual patients and their families. Diagnoses include peripheral neuropathies, inflammatory processes, sprains, strains, and arthritis. Other common conditions such as primary headache disorders, low back pain (LBP), or fibromyalgia may have no clear etiology (IASP, 2014).

The International Headache Society (IHS) defines primary headache disorders as headaches that exist independent from any other medical condition (IHS, 2014). The most common chronic forms include migraine, TTH, mixed migraine-TTH, and cluster headache. U.S. prevalence estimates of adults with chronic migraine or other severe headaches range from 16.2 percent to 22.7 percent, and head pain is a leading cause of emergency room visits (Smitherman, 2013).

Individuals with chronic musculoskeletal pain typically experience increased contractile resistance to pain upon stretching, pain with movement, fear of pain or reinjury, inadequate stretching technique,
and poor relaxation skills (Dieppe, 2013). Treatment depends on the underlying etiology and its severity. Management is typically multimodal, consisting of physical therapy, splinting or orthoses, nonsteroidal anti-inflammatory drugs (NSAIDs), reduction in workload, or increased rest. Often the cause of pain associated with these disorders is unknown, and conventional medical and surgical approaches fail to adequately address the pain and discomfort (IASP, 2014).

Since pain is a subjective and individual experience, biobehavioral pain techniques (i.e., relaxation techniques, cognitive-behavioral treatment [CBT] 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 (Kropp, 2013).

**Biofeedback:**

The Association for Applied Psychophysiology and Biofeedback (AAPB), the Biofeedback Certification International Alliance (BCIA), and the International Society for Neurofeedback and Research (ISNR) define biofeedback as “a process that enables an individual to learn how to change physiological activity for the purposes of improving health and performance” (AAPB, 2014). The goal of biofeedback treatment is to learn to actively change a normally involuntary physiologic function to 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 EMG, heart rate using electrocardiography (ECG), and brain wave activity using EEG, 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 nonpharmaceutical methods achieve pain relief (Sieberg, 2012).

The U.S. Food and Drug Administration (FDA) classifies biofeedback medical devices as 510(k) Class II with special controls medical devices, subject to certain limitations, and exempt from the premarket notification requirements (FDA, 2007). There are numerous biofeedback devices available from multiple manufacturers.

A license is not required to provide biofeedback training, although biofeedback therapists are often licensed in another healthcare field and practice according to those guidelines. The BCIA is the only certifying agency in the United States that establishes and maintains professional standards for the provision of biofeedback services, and certifies those who meet these standards (BCIA, 2014). Because of its potential effects on physiology, the AAPB recommends that biofeedback therapy involve a trained therapist, a motivated patient, and a monitoring instrument capable of providing accurate physiological information (AAPB, 2014).
Keystone First searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality (AHRQ) National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on December 13, 2016. Search terms were: "neurofeedback" (MeSH), "biofeedback, psychology" (MeSH), "pain" (MeSH), "pain management" (MeSH), "headache disorders" (MeSH), and "headache" (MeSH).

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**

We included the most recent or comprehensive systematic reviews with full text published since 2000. We included one additional systematic review by AHRQ, as it represented seminal research on migraine headache interventions at that time (Goslin, 1999). In all, 13 systematic reviews were included in this policy: five of primary headache disorders of the migraine or tension type (Barnes, 2011; Krishnan, 2009; Nestoriuc, 2008a and b; Goslin, 1999); one of fibromyalgia syndrome (Globbiewski, 2013); two of chronic knee pain (Macfarlane, 2012; Wasielewski, 2011); one of chronic LBP (Henschke, 2010); one of vulvodynia (Hayes, 2008); two of temporomandibular disorders (Aggarwal, 2011; McNeely, 2006); and one of multiple chronic pain indications (Hayes, 2004). No economic analyses were identified.

For primary headache disorders:

- There is moderate-quality evidence that EMG biofeedback, with or without relaxation is an effective treatment for chronic TTH 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 EMG biofeedback, thermal feedback alone, or less commonly used blood volume pulse (BVP) 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 EMG or thermal biofeedback as adjunctive treatment for migraine or TTH. Although effective, BVP biofeedback is rarely used. However, there was insufficient information for recommending which type of treatment to pursue for specific patients (Andrasik, 2010; Silberstein, 2000; Goslin, 1999).
- There is insufficient evidence of effectiveness for EEG 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, knee pain, LBP, vulvodynia, temporomandibular disorders, chronic pelvic pain, or repetitive motion injury.
- 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).

Policy updates:

We identified two new systematic reviews for this policy. They addressed treatments for fibromyalgia and chronic LBP (Daffada, 2015; Theadom, 2015). One new systematic review found inconclusive evidence to support sensory discrimination training (SDT), which is a sensorimotor training program based on the principles of neuroplasticity, for treatment of chronic LBP (Kaline, 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.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</thead>
<tbody>
<tr>
<td>Kaline (2016)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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</tbody>
</table>
| SDT for chronic LBP         | • Systematic review of six randomized controlled trials (RCTs) (257 total patients).  
                               • Overall quality: moderate with high risk of bias, variable protocols, and poor documentation of study design.  
                               • Inconsistent reduction in pain and function compared to another intervention, no treatment, or sham therapy, in the short or long term.  
                               • Results are inconclusive.                                                                                                                   |
| Daffada (2015)              | Key points:                                                                                                                                                      |
| Cortical remapping techniques for chronic LBP | • Systematic review of three RCTs, one randomized cross-over study, and one multiple-case study design.  
                                            • Overall quality: low with variation in treatment protocols and study details.                                                                 |
| Theadom (2015)              | Key points:                                                                                                                                                      |
| Cochrane review             | • Systematic review of 61 trials (4,234 predominantly female participants), biofeedback compared to usual care.                                                     |
| Mind and body therapy for fibromyalgia | • Overall quality: Very low.  
                                   • Results are inconclusive.                                                                                                                      |
| Glombiewski (2013)          | Key points:                                                                                                                                                      |
| Fibromyalgia syndrome       | • Meta-analysis of seven RCTs.  
                               • Quality of evidence: very low with high risk of bias.  
                               • Six to 22 sessions, 0.5 – 3 hours per session.  
                               • EMG-BF: reduced short-term pain, but not other outcomes. Long term effects unclear.                                                            |
| Macfarlane (2012)           | Key points:                                                                                                                                                      |
| EMG-assisted exercise for knee osteoarthritis | • Synthesis of two RCTs of EMG-assisted exercise for knee osteoarthritis.                                                                                  |
| Aggarwal (2011)             | Key points:                                                                                                                                                      |
| Cochrane review             | • Meta-analysis of 17 RCTs.  
                               • Quality of evidence: low with high risk of bias.  
                               • CBT either alone or in combination with biofeedback may improve long-term pain intensity, activity interference and depression. |
<p>| Barnes (2011)               | Key points:                                                                                                                                                      |
| Thermal biofeedback for migraine headaches in children | • Included RCTs in any language, &gt; 20 children, &gt; 80% follow-up.                                                                                             |
| Wasielewski (2011)          | Key points:                                                                                                                                                      |
| EMG biofeedback             | • Synthesis of eight RCTs.                                                                                                                                       |</p>
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| (EMG-BF) for quadriceps femoris for patellofemoral pain, post-operative pain or osteoarthritis. | • Quality of evidence: low to moderate with high risk of bias.  
• Results are inconclusive.                                                                                             |
| Henschke (2010) Cochrane review                                        | **Key points:**  
• Meta-analysis of six RCTs.  
• Overall quality: very low to low.  
• EMG-BF is more effective than wait list controls or progressive relaxation for short-term pain relief, but not for improving short-term function or intermediate- or long-term pain or functional status.  
• Results are inconclusive.                                                                                             |
| Krishnan (2009)                                                         | **Key points:**  
• Systematic review of two RCTs.  
• Low-quality evidence.  
• Results are inconclusive.                                                                                             |
| Nestoriuc (2008a) Biofeedback for headache disorders                    | **Key points:**  
• Meta-analysis of 94 RCTs, uncontrolled quasi-experimental designs, studies with ≥ four adult subjects (56 migraine, 45 TTH).  
• Quality of evidence: moderate.  
• Chronicity: migraine = 17.1 years, TTH = 14.8 years.  
• Migraine: thermal BF with either relaxation or EMG-BF was the most frequent modality followed by thermal-BF alone and BVP BF. TTH: 92% EMG-BF.  
• Migraine: mean number of sessions = 10.8 (3 – 24), mean duration = 43.5 (20 – 95) minutes.  
• TTH: mean number of sessions = 11.2 (6 – 20), mean duration = 42.6 (20 – 90) minutes.  
• Biofeedback produced significant improvements in headache frequency, perceived self-efficacy, symptoms of anxiety and depression, and medication consumption for both migraine and TTH for an average follow-up of 14 months in higher-quality analyses.  
• Biofeedback was more effective than waiting list and headache monitoring conditions in all cases, and EMG-BF was more effective than placebo and relaxation in TTH.                                                                 |
| Nestoriuc (2008b) Overlaps with Nestoriuc (2008a) Biofeedback for TTH  | **Key points:**  
• Meta-analysis of 21 pre-post studies, eight controlled clinical trials, 24 RCTs studies of chronic and episodic TTH.  
• Quality of evidence: moderate.  
• Predominately EMG BF over six to 20 sessions ($M = 10.8$, $SD = 4.1$), 20 – 90 minutes ($M = 41.4$, $SD = 15.3$) per session.  
• Overall, BF was more effective than headache monitoring, placebo, and relaxation therapies.  
• Biofeedback in combination with relaxation was the most effective treatment modality; effects were particularly large in children and adolescents.                                                                 |
| Hayes (2008)                                                           | **Key points:**  
• Meta-analysis of 94 RCTs, uncontrolled quasi-experimental designs, studies with ≥ four adult subjects (56 migraine, 45 TTH).  
• Quality of evidence: moderate.  
• Chronicity: migraine = 17.1 years, TTH = 14.8 years.  
• Migraine: thermal BF with either relaxation or EMG-BF was the most frequent modality followed by thermal-BF alone and BVP BF. TTH: 92% EMG-BF.  
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</table>
| **EMG-BF for vulvodynia**                    | • Synthesis of five studies (two RCTs, three case series).  
• Quality of evidence: low.  
• Biofeedback training is safe; no adverse events reported.  
• Case series reported pain relief and return to usual activities in adult women with EMG-BF. RCTs suggest EMG-BF is less effective than surgical therapy and at least equally effective than group CBT and topical therapy.  
• No definite patient selection criteria or optimal treatment protocols.  
• Results are inconclusive.                                                                                                                                               |
| **McNeely (2006)**                           | **Key points:**  
• Synthesis of two RCTs.  
• Quality of evidence: low, validity concerns, trials design, and reporting.  
• Results are inconclusive.                                                                                                                                              |
| **EMG-BF for TMD**                           | **Key points:**  
• Synthesis of RCTs, CCTs, and two meta-analyses.  
• Quality of evidence: low to moderate for chronic LBP, TMD, low for fibromyalgia and other chronic pain disorders.  
• Results are inconclusive in all age groups.                                                                                                                                 |
| **Hayes (2004)**                             | **Key points:**  
• Meta-analysis of 39 prospective controlled trials using thermal or EMG BF.  
• Quality of evidence: low, lack of double-blinding, scant single-blinding.  
• Average age: range 14 – 77 years, primarily adults, where reported.  
• Patients treated ≥ four weeks.  
• Migraine: relaxation training, thermal biofeedback combined with relaxation training, EMG-BF, and CBT are modestly effective versus wait-list control.  
• Thermal biofeedback with or without CBT had similar but nonsignificant effect versus other treatments, based on three studies.  
• Insufficient evidence for guiding treatment choice or supporting possible predictors of treatment response.                                                                 |
| **Goslin for AHRQ (1999)**                   | **Key points:**  
• Meta-analysis of 39 prospective controlled trials using thermal or EMG BF.  
• Quality of evidence: low, lack of double-blinding, scant single-blinding.  
• Average age: range 14 – 77 years, primarily adults, where reported.  
• Patients treated ≥ four weeks.  
• Migraine: relaxation training, thermal biofeedback combined with relaxation training, EMG-BF, and CBT are modestly effective versus wait-list control.  
• Thermal biofeedback with or without CBT had similar but nonsignificant effect versus other treatments, based on three studies.  
• Insufficient evidence for guiding treatment choice or supporting possible predictors of treatment response.                                                                 |

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


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


**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.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>90875</td>
<td>Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 30 minutes</td>
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<td>90876</td>
<td>Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes</td>
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<tr>
<td>90901</td>
<td>Biofeedback training by any modality</td>
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<table>
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<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
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<td>G43.001</td>
<td>Migraine without aura, not intractable, with status migrainosus</td>
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<tr>
<td>G43.009</td>
<td>Migraine without aura, not intractable, without status migrainosus</td>
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<td>G43.011</td>
<td>Migraine without aura, intractable, with status migrainosus</td>
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<td>G43.019</td>
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<td>G43.101</td>
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<td>G44.209</td>
<td>Tension-type headache, unspecified, not intractable</td>
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<td>G44.221</td>
<td>Chronic tension-type headache, intractable</td>
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<td>G44.229</td>
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<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
<th>Comments</th>
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