This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
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<tr>
<td>• With chronic</td>
<td>• Electromyography biofeedback</td>
<td>• Pharmacologic treatment</td>
<td>• Symptoms</td>
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<td>pain</td>
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<td>• Nonpharmacologic treatment</td>
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<td>• Quality of life</td>
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<td>• Medication use</td>
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DESCRIPTION

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. Electromyography biofeedback has been evaluated as a method to reduce chronic or recurrent pain of musculoskeletal or psychosomatic origin.

SUMMARY OF EVIDENCE

For individuals who have chronic pain (including low back, knee, neck and shoulder, orofacial, and abdominal pain as well as fibromyalgia, osteoarthritis, systemic lupus erythematosus, and vulvar vestibulitis) who receive biofeedback, the evidence includes multiple randomized controlled trials (RCTs) for different pain syndromes. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. The results of these RCTs, some of which were sham-controlled, did not consistently report a benefit for biofeedback. Some RCTs reported improved outcomes with biofeedback, but these improvements were often of uncertain clinical significance or were not durable. Many other RCTs have found that biofeedback did not provide a significantly greater benefit in outcomes when it was used instead of or in addition to other conservative interventions such as exercise. Overall, the available RCTs were limited by small sample sizes and high dropout rates. This evidence base does not permit conclusions about the specific effects of biofeedback beyond the nonspecific effects of sham interventions, nor does it permit conclusions about the contribution of biofeedback beyond that of other conservative treatments for pain. The evidence is insufficient to determine the effects of the technology on health outcomes.
POLICY

Biofeedback as a treatment of chronic pain, including but not limited to low back pain, is investigational.

BACKGROUND

Treatment for chronic pain is often multimodal and typically includes psychological therapy. Psychological techniques vary but may include cognitive therapy, which teaches subjects the ability to cope with stressful stimuli by attempting to alter negative thought patterns and dysfunctional attitudes, and behavioral approaches to reduce muscle tension and break the pain cycle. Relaxation, using any of a variety of techniques including meditation or mental imagery, is considered a behavioral therapy that may be used alone or as a component of a cognitive-behavioral therapy program. Electromyography biofeedback has also been used for the treatment of chronic pain, on the assumption that the ability to reduce muscle tension will be improved through feedback of data to the patient regarding the degree of muscle tension. While some consider electromyography biofeedback to be a method used to obtain relaxation, others consider biofeedback to be distinct from other relaxation techniques.

Biofeedback provides physiologic information not normally available to the patient, with a concerted effort employed by the patient to use this feedback to help alter the physiologic process in some specific way. Biofeedback training is done either in individual or group sessions, alone or in combination with other behavioral therapies designed to teach relaxation. A typical program consists of 10 to 20 training sessions of 30 minutes each. Training sessions are performed in a quiet, nonstimulating environment. Patients are instructed to use mental imagery techniques to affect the physiologic variable being monitored, and feedback is provided for successful alteration of that physiologic parameter in the form of lights or tone, verbal praise, or other auditory or visual stimuli.

REGULATORY STATUS

Since 1976, a large number of biofeedback devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. Food and Drug Administration product code: HCC.

RELATED PROTOCOLS

Biofeedback as a Treatment of Fecal Incontinence or Constipation
Biofeedback as a Treatment of Headache
Biofeedback as a Treatment of Urinary Incontinence in Adults
Biofeedback for Miscellaneous Indications
Neurofeedback

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced
procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**REFERENCES**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.