Clinical Review Criteria
Jaw Motion Rehabilitation Device (Jaw Stretch Device)

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Criteria

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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</thead>
<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Article (LCA)</td>
<td>None</td>
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<tr>
<td>KPWA Medical Policy</td>
<td>Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, “Jaw Motion Rehabilitation Device,” for medical necessity determinations. Use the Non-Medicare criteria below.</td>
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For Non-Medicare Members

Jaw motion rehabilitation system is medically necessary to treat mandibular hypomobility when caused by radiation therapy in persons with head and neck cancer.

It is not medically necessary for any other indication, as there is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Trismus, defined as a tonic spasm of the muscles of mastication from diseases of the trigeminal nerve, is often used to describe mandibular hypomotility of any cause. Mandibular hypomotility is a common symptom in patients suffering from temporomandibular disorders as well as variety pathologies of the masticatory system. It may be related to intra- or extra-articular conditions such as synovitis, osteoarthritis, fibrosis, facial space infections, coronoid hyperplasia, fibrosis following radiation therapy, and tumors involving the head and neck regions. Patients with mandibular hypomotility experience limitations during eating, speaking, and with oral hygiene (Israel 1997, Cohen 2005, Melchers 2009).

The temporomandibular joint (TMJ) is a synovial joint that functions according to the same biological rules as other synovial joints and follows the same principles of joint motion and rehabilitation. Several manual, mechanical, and electromechanical approaches have been used for TMJ mobilization and increasing mouth opening. The most
common methods used are isometric and range of motion exercises, tongue depressor therapy, and mechanical stretching devices (Israel 1997).

The Therabite System (Therabite Corporation, Bryn Mawr, PA) is a handheld patient controlled, mechanical device with two mouthpieces that are inserted between the teeth of the upper and lower jaw. By squeezing the handles, the mouthpieces open and assist the opening of the mouth. The horse shoe-shaped surfaces on the arms come in contact with the teeth and spread the load across 10 anterior teeth in each jaw. This generates less force on the incisors than spatulas or screws and makes the Therabite appliance more comfortable to use. The force applied by squeezing and releasing the handle stretches the fibrosis intermittently. Maximum device opening can be adjusted between 25 and 45 mm using a single screw and can be sequentially increased by the patient or clinician. Similar to other exercise regimens and physiotherapy, the patient must be motivated and must use the device correctly and regularly. Adherence to exercise regimens has a positive effect on outcome, and poor adherence may be a barrier to treatment success (Buchbinder 1993, Gibbons 2007, Melchers 2009).

Medical Technology Assessment Committee (MTAC)

Jaw Motion Rehabilitation Device
04/16/2012: MTAC REVIEW

Evidence Conclusion: In a relatively small unblinded, randomized, controlled trial, Maloney and colleagues (2002) compared the effectiveness of a passive jaw motion device (Therabite) and wooden tongue depressors (WTD) in patients with temporomandibular joint and muscle disorders that did not respond to manual manipulation and bite plane therapy. The authors did not discuss the cause of mouth opening restriction. After undergoing manual manipulation of the mandible combined with flat bite plane therapy for 4 weeks, eligible patients were randomly assigned to one of three treatment groups: Therabite group, wooden tongue depressor group, or control group. Patients in the first 2 intervention groups received treatment for 4 weeks, and the control group received a total of 8 weeks of flat bite plane therapy only. The authors did not discuss compliance with therapy or completeness of follow-up. The results of the trial show that passive jaw motion therapy using Therabite was more effective than using wooden tongue depressor in reducing pain and increasing the maximum interincisal opening. In a smaller RCT, Buchbinder and colleagues (1993) compared the use of Therabite system plus unassisted exercise vs. tongue blade therapy plus unassisted exercise, or unassisted exercise only for 10 weeks in 21 patients with decreased interincisal opening secondary to radiation therapy after head and neck cancer resection. The initial average maximum interincisal opening (MO) was 21.6 mm. All three groups showed an initial increase in the MO in the first 4 weeks, after which there was only minimal further gain in the unassisted exercise group with or without tongue blade therapy. After 6 weeks of treatment, the net increase in MO in the Therabite group was significantly greater than either of the other 2 groups. In conclusion, evidence from two small RCTs suggest that passive jaw motion rehabilitation using Therabite device may be more effective than unassisted exercise, manual manipulation, and bite plane therapy with or without tongue blade therapy in reducing pain and improving maximum interincisal opening in patients with mandibular hypomobility.


The use of jaw motion rehabilitation device for mandibular hypomobility does not meet the Kaiser Permanente Medical Technology Assessment Criteria.
Codes
CPT: E1700, E1701, E1702