Jaw Motion Rehabilitation Systems

Policy
*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

Note: Some plans exclude coverage of jaw stretch devices as equipment available over the counter without a prescription. Please check benefit plan descriptions.

I. Aetna considers jaw motion rehabilitation system (e.g., the Therabite Jaw Motion Rehabilitation System, and the OraStretch press) medically necessary to treat mandibular hypomobility caused by radiation in persons with head and neck cancers.

II. Aetna considers jaw motion rehabilitation system (e.g., the Therabite Jaw Motion Rehabilitation System, and the OraStretch press) experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature, including any of the following conditions (not an all-inclusive list):

- Closed lock treatment
- Facial burns
- Mandibular coronoid hyperplasia
- Non-surgical temporomandibular joint (TMJ) dysfunction
- Oral burns
- Orofacial pain
Post-surgical TMJ rehabilitation
Rehabilitation following facial trauma
Stroke
Treacher Collins syndrome
Trismus (including prophylactic training for the prevention of radiotherapy-induced trismus).

See

CPB 0405 - Mechanical Stretching Devices for Contracture and Joint Stiffness
also (0405.html)
on the use of dynamic splinting for the treatment of trismus.

Background

Most head and neck cancers are treated with surgery, radiation, or a combination of the 2 modalities. The choice of treatment depends primarily on the anatomic site, extent and histologic grading of the tumor, and the presence of infection. Modern reconstructive techniques permit cancer patients, especially those with head and neck malignancies, to undergo more immediate reconstruction and thereby achieve better functional outcomes while still progressing through multimodality treatment in a timely manner. However, the more aggressive the cancer therapy, the more it places patients at risk for oral complications related to treatment.

One of the major complications from therapeutic administration of ionizing radiation to the head and neck is mandibular hypomobility -- a reduction in mandibular range of motion (ROM) caused by radiation-induced scarring and contraction of soft tissues surrounding the jaw. Clinically, the severity of mandibular hypomobility is related to the radiation dose, volume of tissue treated, and age of the patient.

Mandibular hypomobility is treated by stretching the scar tissue. Methods commonly used to stretch the scar tissue and increase mandibular ROM include: (i) oral opening exercises; (ii) stacking tongue blades between the molars; (iii) continuous passive motion of the jaw; and/or (iv) stretching the jaw using custom-made mechanical devices. One such custom-made device is the Therabite, a threaded screw-type instrument that is placed between the teeth and turned to gradually open the jaw, much like a car jack. Preliminary evidence indicates that the Therabite is more effective than other modalities in maintaining
and/or improving mandibular ROM in irradiated patients. There are, however, inadequate outcomes data comparing the Therabite to more conventional methods to support the use of Therabite for any other condition. Orabite is another brand of jaw stretch device that is not longer on the market.

Melchers and associates (2009) examined the factors that may influence Therabite exercise adherence, how these interrelate and provided aims for interventions to increase adherence. These researchers performed a multi-center, formal-evaluative qualitative retrospective study. A total of 21 patients treated for head-neck cancer were interviewed in semi-structured, in-depth interviews. Internal motivation to exercise, the perceived effect, self-discipline and having a clear exercise goal influenced Therabite exercise adherence positively. Perceiving no effect, limitation in Therabite opening range and reaching the exercise goal or a plateau in mouth opening were negative influences. Pain, anxiety and physiotherapists could influence adherence both positively and negatively. Based on the results, a model for Therabite exercise adherence was proposed. It is important to signal and evaluate the factors that negatively influencing Therabite adherence, especially before there is a perceived effect. The authors stated that research is needed to examine why some patients do not achieve results despite high exercise adherence, to identify effective exercise regimens and to assess proposed interventions aimed to increase Therabite exercise adherence.

Shulman et al (2008) retrospectively evaluated the effect of the Dynasplint Trismus System (DTS; Dynasplint Systems Inc., Severna Park, MD) for patients who were recently diagnosed with trismus following radiation therapy, dental treatment, oral surgery, or following a neural pathology such as a stroke. These researchers reviewed 48 patient histories (treated in 2006 to 2007), and divided into 4 cohort groups (radiation therapy for head/neck cancer, dental treatment, oral surgery, or stroke), to measure the efficacy of this treatment's modality. Patients were prescribed the DTS after diagnosis of trismus based on examination that showed less than 40 mm maximal interincisal (opening) distance (MID). The DTS uses low-load, prolonged-duration stretch with replicable, dynamic tension to achieve longer time at end range (of motion). Each patient used this device for 20 to 30 mins, 3 times per day. This cohort case series showed that there was a statistically significant difference within all patient groups (p < 0.0001; t = 10.3289), but there was not a significant difference between groups (p = 0.374). The biomechanical modality of DTS with a low-load, prolonged-duration stretch was attributed to the success in reducing contracture in this study. This improved range of motion,
allowing patients to regain the eating, hygiene and speaking patterns they had before developing trismus. The main drawbacks of this study were the lack of a control group and small sample size. The authors stated that "future studies should include a randomized, controlled, crossover study of this unit to compare the efficacy of treating trismus, and a case/control study could evaluate prevention of trimus with the DTS".

In a case report, Shulman et al (2009) described the use of dynamic splinting to reduce trismus that occurred in a patient following multiple dental procedures. A 26-year old man was referred for severe trismus and pain following 3 dental procedures on the lower right molars. The patient presented with MID of only 5-mm and mastication muscle spasticity. Following physical therapy (i.e., massage, moist heat, neuromuscular electrical stimulation, and ultrasound) 3 times per week for 2 months and additional treatment of dynamic splinting for 4 weeks (TID), the patient increased his MID to 52 mm and returned to normal eating and speaking. The main drawbacks of this study were (i) it was a single-case report, and (ii) lack of follow-up.

In a retrospective, cohort study, Stubblefield et al (2010) examined the effectiveness of a dynamic jaw opening device as part of a multi-modal treatment strategy for trismus in patients with head and neck cancer (n = 20). All patients underwent assessment by a board-certified physiatrist and were referred to physical therapy for delivery of the DTS and instructed to progress use of the DTS to 30 mins 3 times a day. Additional modalities for the treatment of trismus including pain medications and botulinum toxin injections were prescribed as clinically indicated. Main outcome measures included change in MID as documented in the medical record. The use of the DTS as part of multi-modal therapy including physical therapy, pain medications, and botulinum toxin injections as deemed clinically appropriate resulted in an overall improvement of the MID from 16.5 mm to 23.5 mm (p < 0.001). Patients who could comply with the treatment recommendations for DTS treatment did better than those who could not, with an improvement of the MID from 16 mm to 27 mm (p < 0.001) versus 17 mm to 22 mm (p = 0.88). The authors concluded that the DTS is a safe and effective component of a multi-modal strategy for improving trismus associated with head and neck cancer and its treatment. Moreover, they stated that further investigation is needed to determine the relative effectiveness of the treatment modalities available for trismus including physical therapy and other jaw stretching devices. This was a retrospective pilot study with a small sample size (n = 20); and its finding were confounded by the use of other modalities. Furthermore, the authors...
stated that "a large randomized prospective trial that directly compares DTS with TheraBite and each to physical therapy and a non-treatment group for both acute and chronic trismus patients would be potentially illuminating".

Loorents et al (2014) noted that radiotherapy-induced trismus (RTIT) is a debilitating condition without any proven effective treatment. These researchers investigated the effectiveness of prophylactic training to prevent RTIT during and up to 12 months after completed RT in patients with head and neck cancer (HNC); they also examined the incidence of RTIT. A total of 66 consecutive patients from 2 RT clinics in Sweden were randomized into one of two groups: (i) training with TheraBite® Jaw Motion Rehabilitation System™ or (ii) a control group. Maximum interincisal openings (MIO) were recorded at baseline and once-weekly during treatment, 3, 6 and 12 months after completed RT. Training frequency was recorded by patients in a log book. There were no significant differences in MIO between the intervention and control groups at any of the measurement points. Patients in both groups maintained their normal variation in MIO at 12 months after completed RT. A small group of patients in the control group had a 17 % mean decrease in MIO by week 6 compared to baseline and improved their MIO by using the training program. There was a significant mean difference in MIO from baseline to week 6 (3 mm, \( p = 0.018 \)), and month 6 (2.7 mm, \( p = 0.04 \)), for patients receiving 3D conformal radiotherapy.

There was a significant difference in MIO between patients treated with RT and concurrent chemotherapy compared to patients with RT only at 12 months (\( p = 0.033 \)). The authors concluded that patients with HNC undergoing high-dose RT do not need to be burdened with an intense prophylactic training program during RT and up to 12 months after completed RT. Measurements of MIO during RT and up to 12 months after completed RT are recommended to identify a small risk group who are an exception and may need a training program.

In a prospective randomized controlled trial (RCT), Kraaijenga et al (2014) compared the application of the TheraBite (TB) Jaw Motion Rehabilitation System with a standard physical therapy (PT) exercise regimen for the treatment of myogenic temporo-mandibular disorder (TMD). Myogenic TMD patients were randomized for the use of the TB device or for standard PT. Mandibular function was assessed with the mandibular function impairment questionnaire (MFIQ). Pain was evaluated using a visual analog scale (VAS), and MIO was measured using the disposable TB ROM scale. Of the 96 patients randomized (46 TB, 50 standard PT exercises), 38 actually started with the TB device and 41 with the standard PT exercises. After 6-week follow-up, patients using the TB device reported a
significantly greater functional improvement (MFIQ score) than the patients receiving regular PT exercises ($p=0.0050$). At 6 weeks, no significant differences in pain, and active or passive MIO were found between the 2 groups. At 3 months, patients in both treatment groups did equally well, and showed a significant improvement in all parameters assessed. The authors concluded that this RCT on myogenic TMD treatment, comparing standard PT with passive jaw mobilization using the TheraBite Jaw Motion Rehabilitation System, showed that both treatment modalities are equally effective in relieving myogenic TMD symptoms, but that the use of the TB device has the benefit of achieving a significantly greater functional improvement within the first week of treatment. The major drawbacks of this study were its small sample size ($n = 36$ receiving TB), lack of blinded assessment of outcomes, and short-term follow-up (6 weeks); and there were no significant differences in pain, and active or passive MIO between the TB and standard PT groups at 6 weeks.

**Trismus:**

In a prospective study, Montalvo and colleagues (2017) examined the impact of structured exercise with TheraBite on trismus, trismus-related symptomatology, and health-related quality of life (HRQL) in patients with HNC. A total of 15 patients with trismus (MIO less than or equal to 35 mm) after oncologic treatment for HNC, underwent a 10-week exercise program with the TheraBite device and were followed regularly. Time between oncologic treatment and start of TheraBite exercise ranged from 0.7 to 14.8 years (average of 6.2); MIO, trismus-related symptoms, and HRQL was assessed before and after exercise and after 6 months. A significant improvement in MIO was observed post-exercise (3.5 mm, 15.3 %, $p = 0.0002$) and after 6-month of follow-up (4.7 mm, 22.1 %, $p = 0.0029$). A statistically significant correlation was found between increased MIO and fewer trismus-related symptoms. The authors concluded that exercise with TheraBite improved MIO and trismus-related symptoms in patients with trismus secondary to HNC; structured exercise with the TheraBite appeared to be beneficial for patients with trismus independent of time since oncologic treatment. These finding from a small ($n = 15$) uncontrolled study need to be validated by well-designed studies.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

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<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tr>
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<td>Other CPT codes related to the CPB:</td>
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<tr>
<td>Code</td>
<td>Code Description</td>
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<tr>
<td>95851</td>
<td>Range of motion measurements and report (separate procedure); each extremity, (excluding hand) or each trunk section (spine)</td>
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<tr>
<td>97110</td>
<td>Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility</td>
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<tr>
<td>97530</td>
<td>Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes</td>
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<tr>
<td>97535</td>
<td>Self care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes</td>
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HCPCS codes covered if selection criteria are met:

- E1700 Jaw motion rehabilitation system  
- E1701 Replacement cushions for jaw motion rehabilitation system, package of six  
- E1702 Replacement measuring scales for jaw motion rehabilitation system, package of 200

ICD-10 codes covered if selection criteria are met:

- C76.0 Malignant neoplasm of head, face and neck  
- M26.69 Other specified disorders of temporomandibular joint  
- Z92.3 Personal history of irradiation

ICD-10 codes not covered for indications listed in the CPB: (not all-inclusive):

- Numerous options Burn and corrosion of head, face and neck, sequela [Codes not listed due to expanded specificity]  
- G45.0 - G45.2, G45.4 - G45.9 Transient cerebral ischemic attacks and related syndromes  
- I60.00 - I67.2, I67.4 - I69.998 Cerebrovascular diseases  
- M26.03 Mandibular hyperplasia [coronoid]  
- M26.601 - M26.609 Temporomandibular joint disorders  
- Q75.4 Mandibulofacial dysostosis [Treacher Collins Syndrome]  
- R25.2 Abnormal involuntary movements [trismus]
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<tr>
<th>Code</th>
<th>Code Description</th>
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<tr>
<td>S00.00x+</td>
<td>Injuries to the head</td>
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<tr>
<td>S09.93x+</td>
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<tr>
<td>T20.00x+</td>
<td>Burn and corrosion of head, face and neck</td>
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<tr>
<td>T20.79x+</td>
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The above policy is based on the following references:


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Amendment to
Aetna Clinical Policy Bulletin Number: 0412 Jaw Motion Rehabilitation Systems

There are no amendments for Medicaid.