



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Therabite[®] Jaw Motion Rehabilitation System[™]

Effective Date 7/15/2009
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Coverage Policy Number 0186

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Hyperlink to Related Coverage Policies

Continuous Passive Motion (CPM) Devices
Temporomandibular Joint (TMJ) Disorder
Surgery

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

CIGNA does not cover the Therabite[®] Jaw Motion Rehabilitation System[™] because it is considered experimental, investigational or unproven.

General Background

Mandibular or jaw hypomobility is a condition in which normal range of motion of the temporomandibular joint (TMJ) is lacking. Mandibular hypomobility causes pain when the maxilla and mandible are separated, prevents patients from chewing or eating normally, and may impair speech and oral hygiene. Jaw hypomobility has numerous causes, including internal derangement of the TMJ, degenerative joint disease, muscle atrophy due to stroke, and trismus (spastic contraction of the muscles of mastication). Jaw hypomobility may also be caused by tumor invasion of the masticatory muscles and/or the TMJ, or by radiotherapy, if the masticatory muscles and/or TMJ are included in the field of radiation. In some cases, both tumor invasion and damage from radiotherapy are present.

Physical therapy modalities used in the rehabilitation of other joints, such as active and passive range of motion, ultrasound and application of heat, have also been used to treat TMJ hypomobility. Passive rehabilitation therapy for TMJ hypomobility has traditionally included manual unassisted stretching and stacking of tongue blades between the molars to increase the size of the interincisal opening. Passive rehabilitation is generally part of a physical therapy program for TMJ hypomobility, but it must also be employed daily outside of physical

therapy. Continuous passive motion (CPM) devices have been proposed to treat jaw hypomobility, and custom-made mechanical devices have also been developed to provide passive rehabilitation. One such device is the Therabite® Jaw Motion Rehabilitation System™.

The Therabite system is a patient-operated device used for passive rehabilitation therapy of the TMJ. The Therabite system is a hand-held device that consists of padded bite plates attached to a scissors-like unit. The patient inserts the mouthpiece and squeezes a lever, moving the mouthpiece downward. The prescribed degree of opening is set using a range-setting adjustment based on the prescribed maximum incisal opening. The patient uses the fine-adjustment knob to regulate opening speed and distance. The mouth opening is stretched for several seconds at a time. The process is repeated five to 10 times, several times a day. The Therabite system has been proposed as a patient-operated therapy to treat jaw hypomobility related to trismus, TMJ, post-surgical TMJ, trauma and radiation therapy, and mandibular coronoid hyperplasia.

U.S. Food and Drug Administration (FDA)

The Therabite system is listed in the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health database as a Class I device without a requirement for approval through the Premarket Approval (PMA) or 510(k) process.

Literature Review

Cohen et al. (2005) evaluated the use of Therabite in the early postoperative management of trismus in seven patients who underwent resection and reconstruction for head and neck cancer. Patients were given a Therabite device, instructed in its proper use, and began using the device within six weeks following surgery. All patients were instructed to perform six repetitions holding the mouth open for six seconds each time, six times daily. Maximum interincisor opening was measured by a gauge provided with the device at the start of use and at the most recent postoperative visit. Follow-up ranged from 12 to 48 weeks after surgery. The average maximum interincisor opening was 30 mm (range 21–38 mm) at the last visit, with an average gain of 10 mm (range 1–21 mm). Two patients were lost to follow-up. Four of five patients reported minimal or no limitation on overall quality of life relative to jaw opening. The authors concluded that the Therabite mechanical stretching device is effective and safe for the management of trismus in a select group of patients. These results cannot be generalized, however, due to the study design and small number of patients.

Maloney et al. (2002) conducted a randomized controlled trial that included 46 patients with TMJ disease. This study evaluated the use of Therabite and an intraoral appliance (n=17), the use of tongue depressors in conjunction with an intraoral appliance (n=12), and an intraoral appliance only (n=17). The Therabite group showed increased jaw mobility and decreased pain compared to the group using intraoral appliances alone. The use of tongue depressors had little effect. This trial was also very small, with unblinded evaluations and a follow-up period of only four weeks.

A systematic review of the effectiveness of physical therapy interventions for TMJ disorders concluded that the results of the review support the use of active and passive oral exercises as effective interventions to reduce symptoms, but more information on the exercise prescription is necessary to allow for replication in clinical settings. The authors advised that findings must be interpreted with caution, since most studies were of poor methodological quality. The Therabite system is described in the review as a mechanical aid that provides passive stretch to the TMJ, but no recommendation for use of the device is made (McNeely, et al., 2006).

Summary

There are very few published studies in the medical literature that evaluate the use of Therabite or of passive rehabilitation of the TMJ using any device. There is insufficient evidence in the peer-reviewed clinical literature to demonstrate the safety and efficacy of the Therabite Jaw Motion Rehabilitation System to provide passive rehabilitation as compared to traditional methods of treating jaw hypomobility. The few studies that have been done are small with findings that cannot be generalized.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
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-9-CM Diagnosis Codes	Description
	Multiple/Varied

***Current Procedural Terminology (CPT®) ©2008 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	07/15/2008	0186	Therabite [®] Jaw Motion Rehabilitation System [™]

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