



# Treatment of Temporomandibular Joint Disorders (for Indiana Only)

Policy Number: CS195IN.04 Effective Date: March 1, 2024

Ü Instructions for Use

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#### **Related Policies**

- Botulinum Toxins A and B (for Indiana Only)
- Sodium Hyaluronate (for Indiana Only)

# **Application**

This Medical Policy only applies to the state of Indiana.

# **Coverage Rationale**

For medical necessity clinical coverage criteria, refer to the <u>Indiana Health Coverage Programs Provider Reference Module:</u> <u>Surgical Services</u>.

The following services are unproven and not medically necessary for treating disorders of the temporomandibular joint (TMJ) due to insufficient evidence of efficacy (this list is not all-inclusive):

- Biofeedback
- Craniosacral manipulation/therapy
- Passive rehabilitation therapy devices (e.g., TheraBite Jaw Motion Rehabilitation System\*)
- Low-load prolonged-duration stretch devices (e.g., The Jaw Dynasplint® System)
- Multiple occlusal splints (i.e., daytime and nighttime splints, maxillary and mandibular splints)
- Epigenetic appliances [e.g., Homeoblock<sup>™</sup>, DNA (Daytime/Nighttime Appliance)<sup>®</sup>]

# **Applicable Codes**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
*20552	Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)

CPT Code	<b>Description</b>
*20553	Injection(s); single or multiple trigger point(s), 3 or more muscles
*20605	Arthrocentesis, aspiration and/or injection, intermediate joint, or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); without ultrasound guidance
*20606	Arthrocentesis, aspiration and/or injection, intermediate joint, or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting
*21010	Arthrotomy, temporomandibular joint
*21050	Condylectomy, temporomandibular joint (separate procedure)
*21060	Meniscectomy, partial or complete, temporomandibular joint (separate procedure)
*21070	Coronoidectomy (separate procedure)
*21085	Impression and custom preparation; oral surgical splint
*21089	Unlisted maxillofacial prosthetic procedure
*21110	Application of interdental fixation device for conditions other than fracture or dislocation, includes removal
21240	Arthroplasty, temporomandibular joint, with or without autograft (includes obtaining graft)
21242	Arthroplasty, temporomandibular joint, with allograft
*21243	Arthroplasty, temporomandibular joint, with prosthetic joint replacement
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (e.g., for hemifacial microsomia)
21299	Unlisted craniofacial and maxillofacial procedure
*21499	Unlisted musculoskeletal procedure, head
*29800	Arthroscopy, temporomandibular joint, diagnostic, with or without synovial biopsy (separate procedure)
*29804	Arthroscopy, temporomandibular joint, surgical
*90901	Biofeedback training by any modality
97039	Unlisted modality (specify type and time if constant attendance)
97139	Unlisted therapeutic procedure (specify)

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<b>HCPCS Code</b>	Description
*E0746	Electromyography (EMG), biofeedback device
*E1399	Durable medical equipment, miscellaneous
*E1700	Jaw motion rehabilitation system
*E1701	Replacement cushions for jaw motion rehabilitation system, package of 6
*E1702	Replacement measuring scales for jaw motion rehabilitation system, package of 200

**Note**: Codes labeled with an asterisk (\*) are not managed for medical necessity review for the state of Indiana at the time this policy became effective. Refer to the most up to date prior authorization list for Indiana at <a href="Prior Authorization and Notification: UnitedHealthcare Community Plan of Indiana">Prior Authorization and Notification: UnitedHealthcare Community Plan of Indiana</a>.

## **Clinical Evidence**

#### **Occlusal Splints**

There are no published studies addressing the treatment of TMJ disorders with more than one splint at a time (i.e., am/pm appliances; maxillary/mandibular appliances), therefore it is not possible to conclude if more than one device has a beneficial effect on health outcomes.

Al-Moraissi et al. (2020c) conducted a systematic review and network meta-analysis of 48 RCTs to assess the effectiveness of various types of occlusal splint therapy in the management of temporomandibular disorders and rank them according to their effectiveness. Predictor variables were control, non-occluding splint, hard stabilization splint (HSS), soft stabilization splint (SSS), prefabricated splint, mini-anterior splint, anterior repositioning splint (ARS), and counseling therapy (CT) with or without HSS. Outcome variables were pain improvement, posttreatment pain intensity, improvement in mouth opening, and disappearance of TMJ sounds. The results indicated that when compared to a control for arthrogenous disorders, very low to low quality evidence showed there was a significant decrease in pain after the use of an ARS, mini anterior splints and HSS alone. Moderate quality evidence showed improvement with CT and HSS combined. For myogenous disorders, very low-quality evidence showed improvement with mini anterior splints, SSS and moderate evidence for CT alone, CT + HSS and HSS alone. The authors concluded that based on this network meta-analysis, there is moderate to very low-quality evidence confirming the effectiveness of occlusal splint therapy in the treatment of TMDs. Multimodal therapy consisting of CT + HSS may produce the maximum improvement for TMD patients. This study is limited by the inherent limitation of indirectness from network meta-analyses.

Kuzmanovic et al. (2017) shared the results of a systematic review and meta-analysis of RCTs showing the short- and long-term effects of stabilization splints (SS) in treatment of TMDs, and to identify factors influencing its efficacy. MEDLINE, Web of Science and EMBASE were searched for RCTs comparing SS to non-occluding splint, occlusal oral appliances, physiotherapy, behavioral therapy, counseling, and no treatment. Random effects method was used to summarize outcomes. Subgroup analyses were carried out according to the use of Research Diagnostic Criteria (RDC/TMD) and TMDs origin. Strength of evidence was assessed by GRADE. Meta-regression was applied. Thirty-three eligible RCTs were included in this meta-analysis. In short term, SS presented positive overall effect on pain reduction and pain intensity. Important decrease of muscle tenderness and improvement of mouth opening were found. SS in comparison to oral appliances showed no difference. Meta-regression identified continuous use of SS during the day as a factor influencing efficacy. Long term results showed no difference in observed outcomes between groups. Low quality of evidence was found for primary outcomes. The authors concluded that SS presented short term benefit for patients with TMDs. In long term follow up, the effect is equalized with other therapeutic modalities. Further studies based on appropriate use of standardized criteria for patient recruitment and outcomes under assessment are needed to better define SS effect persistence in long term.

Fricton et al. (2010) conducted a systematic review with meta-analysis of RCTs assessing the efficacy of intraoral orthopedic appliances for reducing pain in patients with TMD compared to placebo, no treatment, or other treatments. A total of 47 publications citing 44 RCTs (n = 2,218) were included. Ten RCTs were included in two meta-analyses. In the first meta-analysis of seven studies (n = 385), a hard stabilization appliance was found to improve TMD pain compared to non-occluding appliance. In the second meta-analysis of three studies (n = 216), a hard stabilization appliance was found to improve TMD pain compared to no-treatment controls. The quality of the studies was moderate. The authors concluded that hard stabilization appliances, when adjusted properly, have good evidence of modest efficacy in the treatment of TMD pain compared to non-occluding appliances and no treatment. Other types of appliances, including soft stabilization appliances, anterior positioning appliances and anterior bite appliances, have some RCT evidence of efficacy in reducing TMD pain. However, the potential for adverse events with these appliances is higher and suggests the need for close monitoring in their use.

#### **Biofeedback**

There is insufficient quality evidence regarding biofeedback for the management of TMD.

In a 2020 systematic review, Florjanski et al. evaluated the efficiency of biofeedback in masticatory muscle activity management. This review included 10 study designs: crossover studies, single-blinded, randomized clinical trials. Participants suffered from TMD-related muscle pain, myofascial pain sleep bruxism, awake bruxism and in one case the type of bruxism was not defined. The studies were divided into two groups, depending on the type of biofeedback intervention used: biofeedback training and contingent electrical stimulation. For biofeedback training, patients received audio, visual, and vibratory signals making them aware of mastication muscle activity and encouraging them to perform certain actions to disrupt the activity. The authors concluded that while this systematic review presents research over the past 21 years, the quality of the evidence in the majority of the studies is generally low quality due to small sample sizes, short treatment and follow up times, and lack of protocol standardization, but do show a significant correlation between biofeedback usage and reduction of muscle activity, and that biofeedback can be useful in decreasing masticatory muscle activity.

Shedden et al. (2013) conducted a RCT to evaluate the efficacy of biofeedback-based cognitive-behavioral treatment (BFB-CBT) versus dental treatment with occlusal splint (OS) and investigate changes in nocturnal masseter muscle activity (NMMA).

Fifty-eight patients with chronic TMD were randomly assigned to receive either 8 weekly sessions of BFB-CBT or 8 weeks of OS treatment. Diagnoses were established using Research Diagnostic Criteria for TMD. Pain intensity and disability were defined as primary outcomes. Secondary outcomes included emotional functioning, pain coping, somatoform symptoms, treatment satisfaction, and adverse events. NMMA was assessed during 3 nights pretreatment and posttreatment with portable devices. Follow-up assessment took place 6 months after the treatment. The results showed both treatments resulted in significant reductions in pain intensity and disability, with similar amounts of clinically meaningful improvement (45% for BFB-CBT and 48% for OS). Patients receiving BFB-CBT showed significantly larger improvements in pain coping skills. Satisfaction with treatment and ratings of improvement were higher for BFB-CBT. Effects were stable over 6 months and tended to be larger in the BFB-CBT group for all outcomes. No significant changes were observed in NMMA. The authors concluded that the fact that BFB-CBT resulted in larger improvements in pain coping skills, and was well accepted by the patients, underlines the importance and feasibility of psychological treatments in the clinical management of TMD. Further research with randomized controlled trials is needed to validate these findings.

#### Craniosacral Manipulation/Craniosacral Therapy

There is no quality evidence to support the efficacy of this therapy for the temporomandibular joint.

#### Passive Rehabilitation Therapy and Low-Load Prolonged Duration Stretch (LLPS) Devices

Passive rehabilitation and LLPS are considered unproven due to insufficient quality evidence of efficacy and safety for TMDs.

Lee et al (2018) conducted a randomized, open-label, controlled, three-center feasibility study to compare the efficacy of the Therabite® jaw motion rehabilitation system (Atos Medical) with that of wooden spatulas to relieve and prevent trismus in patients who have had radiotherapy for stage three and four oral and oropharyngeal cancer. Secondary aims were to assess the feasibility and the impact of exercise on health-related quality of life (QoL), and the use of health services after treatment. The authors studied compliance with exercises and health related QoL, and conducted semi-structured interviews with patients. Patients were randomized into two groups: the Therabite® group (n = 37) and the wooden spatula group (n = 34). All patients had some sense of jaw tightening before the study started. Mean mouth opening after six months increased in both groups, but the difference between the groups was not significant (p = 0.39). The authors concluded there was no significant difference between the two groups in frequency of contact with care services or in QoL. Exercises during and after radiotherapy can ameliorate trismus in patients with stage three and four oral and oropharyngeal cancers, but differences between groups in efficacy, compliance, QoL, or use of hospital or community health services, were not significant. Furthermore, the findings from this specific population may not apply to all patients with TMJ.

Zatarain et al. (2018) conducted a study to assess the feasibility of incorporating the use of the Jaw Dynasplint into a standard program of self-care for the prevention of trismus in head and neck cancer patients undergoing primary or adjuvant radiation. Study participants (n = 40) were randomized using a permuted block design to conventional stretching or stretching plus use of the Jaw Dynasplint 3 times per day for 30 minutes. Patients were instructed to record maximum interincisal opening each day as well as logging use of the Jaw Dynasplint. The results showed 6 months after initiation of the preventative regimen, 50% of patients in the Dynasplint arm and 75% in the conventional stretching arm remained on their assigned therapy. Trismus was diagnosed in 2 patients in the control arm and in 4 patients in the Dynasplint arm. Only 25% (95% confidence interval = 11.1, 46.9) of patients in the Dynasplint arm used the device as prescribed. The authors concluded that the addition of the Jaw Dynasplint therapy decreased compliance compared with conventional stretching, and it is unlikely that the regimen will prove efficacious as a preventative measure due to low compliance.

Grondin et al. (2017) conducted a case series to investigate the influence of isolated TMJ manual therapy on pain and ROM of the TMJ and cervical spine including flexion-rotation test (FRT) in people suffering chronic pain arising from chronic arthralgic TMD. An experienced clinician managed a case series of 12 patients with TMD (mean duration 28.6 months ±26.9). The intervention comprised four-weekly sessions of transverse medial accessory TMJ mobilization and advice. Patients were examined prior to and one-week following the intervention period. Outcome measures included jaw disability, jaw pain measured by VAS, maximal mouth opening ROM, cervical ROM including FRT, and pain during cervical movement. A paired t-test revealed significant improvement following the intervention in disability, VAS pain score at rest and at maximum mouth opening, jaw opening ROM, FRT ROM to the left and right. In contrast, no significant change was identified for total cervical ROM (p = 0.905). After the intervention, five patients (41.66%) had no pain at rest or at maximal mouth opening, and all had a negative FRT. The effect sizes indicate a moderate to strong, clinically significant effect for all variables apart from total cervical ROM. The authors concluded that while a case series cannot identify a cause-and-effect relationship, these results provide

preliminary evidence for the influence of TMJ manual therapy on measures of TMD including pain, as well as upper but not whole cervical movement and associated pain in patients with a diagnosis of TMJ arthralgia. Further research with larger patient samples and randomized controlled trials are needed to validate these findings. The significance of this study is also limited by a short follow-up period.

Kraaijenga et al. (2014) conducted an RCT to compare the application of the TheraBite® (TB) Jaw Motion Rehabilitation System with a standard physical therapy (PT) exercise regimen for the treatment of myogenic TMD. Patients with myogenic TMD 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, and maximum inter-incisor (mouth) opening (MIO) was measured using the disposable TB range of motion 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 six-week follow-up, patients using the TB device reported a significantly greater functional improvement (MFIQ score) than the patients receiving regular PT exercises. At 6 weeks, no significant differences in pain, and active or passive MIO were found between the two 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®, shows 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. Further research with randomized controlled trials is needed to validate these findings.

In a retrospective cohort study of twenty patients, Stubblefield et al. (2010) evaluated the effectiveness of a dynamic jaw opening device for treating trismus in patients with head and neck cancer. The authors compared the 15 participants who complied with the intervention to the 5 that did not comply. They conclude that the use of the Dynasplint Trismus System (DTS) as part of multimodal therapy including physical therapy, pain medications and botulinum toxin injections resulted in an overall improvement of the maximal interincisal distance (MID). Further prospective controlled clinical trials that directly compare DTS to other treatment modalities are needed.

#### **Epigenetic Appliances**

Research shows that there is no quality evidence to support the efficacy of epigenetic appliances for the treatment of temporomandibular joint disorders.

# **U.S. Food and Drug Administration (FDA)**

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA regulates temporomandibular joint prostheses as Class III devices which require premarket approval (PMA). For a complete list of approved products, refer to the following website (use product codes LZD and MPI): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed July 19, 2023)

Continuous passive motion (CPM) machines are approved as Class II devices by the FDA. Class II devices meet both the General Control requirements and Performance Standards established by the FDA. Additional information, under product code BXB, is available at: <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm</a>. (Accessed July 19, 2023)

In March of 2023, the FDA issued a safety concern regarding jaw remodeling devices for adults. Further information can be found at the following website: <a href="https://www.fda.gov/medical-devices/safety-communications/evaluation-safety-concerns-certain-devices-used-adults-fda-safety-communication">https://www.fda.gov/medical-devices/safety-communication-safety-concerns-certain-devices-used-adults-fda-safety-communication</a>. (Accessed August 9, 2023)

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# **Policy History/Revision Information**

Date	Summary of Changes
05/01/2024	<ul> <li>Related Policies</li> <li>Removed reference link to the Medical Policy titled Orthognathic (Jaw) Surgery (for Indiana Only) (retired May. 1, 2024)</li> </ul>
03/01/2024	<ul> <li>Title Change</li> <li>Previously titled Temporomandibular Joint Disorders (for Indiana Only)</li> <li>Coverage Rationale</li> <li>Revised list of unproven and not medically necessary services/devices:         <ul> <li>Added "epigenetic appliances [e.g., Homeoblock™, DNA (Daytime/Nighttime Appliance)*]"</li> <li>Replaced:</li> <li>"Passive rehabilitation therapy" with "passive rehabilitation therapy devices (e.g., TheraBite Jaw Motion Rehabilitation System*)"</li> <li>"Low-load prolonged-duration stretch devices" with "low-load prolonged-duration stretch devices (e.g., The Jaw Dynasplint* System)"</li> </ul> </li> <li>Supporting Information</li> <li>Updated Clinical Evidence and FDA sections to reflect the most current information</li> <li>Archived previous policy version CS348IN.03</li> </ul>

## **Instructions for Use**

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.