Treatment of Temporomandibular Joint Disorders (for Indiana Only)

Policy Number: CS195IN.05
Effective Date: April 1, 2025

Ü Instructions for Use

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Related Policies
None

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

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

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
- Jaw mobility mechanical stretching devices (e.g., TheraBite Jaw Motion Rehabilitation System®, Jaw Dynasplint® System)
- Multiple occlusal splints (i.e., daytime and nighttime splints, maxillary and mandibular splints)
- Epigenetic appliances [e.g., Homeoblock™, DNA® (Daytime/Nighttime appliance), Advanced Lightwire Functional (ALF) appliances]

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)
*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

CPT Code	Description
*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)

HCPCS Code	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 Prior Authorization and Notification: UnitedHealthcare Community Plan of Indiana.

Description of Services

Temporomandibular disorders (TMD) are a diverse, complex set of conditions that affect the temporomandibular joint (TMJ) and/or or the surrounding musculature. Symptoms include pain at rest and/or during jaw function, limited range of motion, and TMJ noises such as clicking, popping, and crepitus. Conditions may spontaneously resolve and reoccur or respond to conservative treatments such as non-steroidal anti-inflammatory drugs (NSAIDs), soft diet, jaw rest, moist heat, steroids, physical therapy, splints, muscle relaxants, and/or antidepressants. Failure of conservative methods may require the addition of injection therapy or surgery, including joint replacement. Experts recommend using the most conservative, reversible treatments possible (NICDR 2015).

Occlusal splints are used to treat myofascial pain dysfunction and TMJ disorders. Splint therapy consists of either a stabilization splint (also referred to as night guards or occlusal guards), or a mandibular repositioning splint/device. These are intended to reduce or eliminate clenching or bruxism (tooth grinding) and keep or reposition the jaw in a more relaxed position. Splints are made of a variety of materials and cover all or some teeth in an individual arch.

Myofascial trigger points are focal knots in a band of skeletal muscle caused by acute or repeated microtrauma which is common in disorders of the TMJ. Injections cause relaxation of the muscle fibers allowing lengthening of the muscle fiber, and removal of metabolite waste assisting in breaking the pain-tension cycle. This can be done as dry needling alone, or can be followed by an injection of corticosteroid, dextrose, or saline.

Craniosacral manipulation is also referred to as craniosacral therapy. It is a complimentary health approach purported to help a wide variety of conditions. The premise is that palpation of the cranium can detect small, rhythmic movement of the cranial bones which is attributed to cerebrospinal fluid pressure or arterial pressure. Treatment involves selective pressures being applied to these areas to manipulate the cranial bones to achieve a therapeutic result.

Jaw mobility devices are used for passive rehabilitation and prolonged duration stretching for mandibular hypomobility. These include devices such as the TheraBite® Jaw Motion Rehabilitation System, the Jaw Dynasplint® System, the OraStretch® Press Jaw Motion Rehab System, and the Therapacer™ Jaw Mobilizer.

Epigenetics is an area of science that examines how external factors affect gene activity without altering DNA sequence. Epigenetic appliances are intraoral devices similar to an orthodontic retainer in appearance. The premise is that when worn overnight, pressure is applied to the jaws resulting in expansion due to the stimulation of osteoblasts and osteoclasts. They are purported to help a wide variety of conditions including but not limited to TMJ disorders, sleep apnea, and chronic headaches.

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, included in Al-Moraissi 2020c above) 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. (Publication by Fricton et al. 2010, which was previously cited in this policy is included in this systematic review)

Biofeedback

There is insufficient quality evidence regarding biofeedback for the management of TMD and the effect on health outcomes cannot be established. Existing studies are of low quality with small sample sizes, short treatment and follow up times, and lack of protocol standardization.

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

Review of the medical literature did not identify quality evidence to support the efficacy of this therapy for the temporomandibular joint, and the effect on health outcomes cannot be established.

Jaw Mobility Mechanical Stretching Devices

Jaw mobility mechanical stretching devices for TMDs are considered unproven due to insufficient quality evidence of efficacy and safety. The published literature is limited to studies with small numbers of participants, short-term follow-up, or large loss-to-follow-up. Furthermore, the findings of most studies are inconclusive or unfavorable. Compliance with these devices is limited and the impact on clinical outcomes cannot be established.

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 patients with head and neck cancer 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.

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 RCTs is needed to validate these findings.

Epigenetic Appliances

Review of the medical literature did not identify quality evidence to support the efficacy of epigenetic appliances for the treatment of temporomandibular joint disorders and the effect on health outcomes cannot be established.

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 September 10, 2024)

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: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed September 10, 2024)

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: https://www.fda.gov/medical-devices/safety-communications/evaluation-safety-concerns-certain-dental-devices-used-adults-fda-safety-communication. (Accessed September 10, 2024)

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Policy History/Revision Information

Date	Summary of Changes
04/01/2025	**Related Policies** • Removed reference link to the Medical Benefit Drug Policy titled: o *Botulinum Toxins A and B (for Indiana Only)* o *Sodium Hyaluronate (for Indiana Only)Sodium Hyaluronate (for Indiana Only)* **Coverage Rationale** • Revised list of unproven and not medically necessary services: o Replaced "*passive rehabilitation therapy devices* (e.g., TheraBite Jaw Motion Rehabilitation System®) *and low-load prolonged-duration stretch devices* (e.g., Jaw Dynasplint® System)" with "*jaw mobility mechanical stretching devices* (e.g., TheraBite Jaw Motion Rehabilitation System®, Jaw Dynasplint® System)" o Revised list of examples of epigenetic appliances; added "Advanced Lightwire Functional (ALF) appliances" **Applicable Codes** • Added notation to indicate CPT codes 21240, 21242, and 21243 are not managed for medical necessity review for the state of Indiana at this time; refer to the most current *Prior Authorization and Notification List* for UnitedHealthcare Community Plan of Indiana • Removed notation indicating CPT codes 21110 and 29800 are not managed for medical necessity review for the state of Indiana at this time **Supporting Information** • Added *Description of Services* section • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS348IN.04

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.

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