

# Temporomandibular Joint Disorders

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[➔ Instructions for Use](#)

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## Coverage Rationale

[➔ See Benefit Considerations](#)

The following services are proven and medically necessary for treating disorders of the temporomandibular joint (TMJ):

- Arthrocentesis
- Injections of corticosteroids for rheumatoid arthritis related disorders
- Trigger point injections
- Physical therapy
- Occlusal splints (stabilization and repositioning splints)
- Sodium Hyaluronate for disc displacement and osteoarthritis
- Partial or total joint replacement when other treatments have failed

For medical necessity clinical coverage criteria for the following services, refer to MCG™ Care Guidelines, 24<sup>th</sup> edition, 2020:

- Arthroplasty-Temporomandibular Joint Arthroplasty, ACG: A-0523 (AC)
- Arthroscopy-Temporomandibular Joint Arthroscopy, ACG: A-0492 (AC)
- Arthrotomy- Temporomandibular Joint Arthrotomy, ACG: A-0522 (AC); Temporomandibular Joint Modified Condylotomy, ACG: A-0521 (AC)

Click [here](#) to view the MCG™ Care Guidelines.

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

- Biofeedback
- Craniosacral manipulation
- Passive rehabilitation therapy
- Low-load prolonged-duration stretch (LLPS) devices

## Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT/HCPCS Codes*	Required Clinical Information
<b>Temporomandibular Joint Disorders</b>	
21240 21242 E1399	<p>Medical notes documenting all of the following:</p> <ul style="list-style-type: none"> <li>● Comprehensive physician office notes identifying with the history of the medical condition(s) requiring treatment or surgical intervention; this documentation must include all of the following: <ul style="list-style-type: none"> <li>○ A well-defined physical and/or physiological abnormality (e.g., congenital abnormality, functional, or skeletal impairments) resulting in a medical condition that has required or requires treatment</li> <li>○ The physical and/or physiological abnormality has resulted in a functional deficit</li> <li>○ The functional deficit is recurrent or persistent in nature</li> </ul> </li> <li>● Appropriate clinical studies addressing: <ul style="list-style-type: none"> <li>○ The physical and/or physiological abnormality that confirm its presence</li> <li>○ The degree to which the abnormality is causing impairment</li> <li>○ Applicable TMJ radiological films and/or reports such as AP radiograph, panoramic radiograph, CT scans, and/or MRI</li> </ul> </li> <li>● Treating physician's plan of care, including surgical treatment objectives, which must include the expected outcome for the improvement of the functional deficit</li> <li>● History of previous non-surgical and surgical treatment</li> </ul>
<b>Outpatient Surgical Procedures – Site of Service</b>	
20605 20606 21010 29800 29804	<p>Medical notes documenting all of the following:</p> <ul style="list-style-type: none"> <li>● History</li> <li>● Physical examination, including patient weight and co-morbidities</li> <li>● Surgical plan</li> <li>● Physician privileging information related to the need for the use of the hospital outpatient department</li> <li>● American Society of Anesthesiologists (ASA) score, as applicable</li> </ul>

\*For code descriptions, see the [Applicable Codes](#) section.

## Definitions

**Arthroplasty:** Surgery to relieve pain and restore range of motion by realigning or reconstructing a joint (Medical Dictionary for the Health Professions and Nursing).

**Arthroscopy:** A surgical procedure orthopaedic surgeons use to visualize, diagnose, and treat problems inside a joint (American Academy of Orthopaedic Surgeons [AAOS]).

**Arthrotomy:** Cutting into a joint (Medical Dictionary for the Health Professions and Nursing).

**Condyle:** The smooth surface area at the end of a bone, forming part of a joint (Medical Dictionary for the Health Professions and Nursing).

**Condylotomy:** Incision or surgical division of a condyle (Medical Dictionary for the Health Professions and Nursing).

## 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 the member specific benefit plan document 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
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)
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
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)

*CPT® is a registered trademark of the American Medical Association*

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

## Description of Services

Temporomandibular disorders (TMD) are a diverse, complex set of conditions that affect the temporomandibular joint (TMJ) and/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. Many of the underlying causes of TMJ dysfunction are unknown, and treatments may be nonspecific and palliative. 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 (NICDR 2015).

Devices used for passive rehabilitation and prolonged duration stretching for mandibular hypomobility include devices such as the Therabite® Jaw Motion Rehabilitation System and The Jaw Dynasplint® System.

## Benefit Considerations

The abbreviation “TMJ” is used throughout this document to represent Temporomandibular Disorder, also known as Temporomandibular Joint Disorder, Temporomandibular Joint Syndrome or Temporomandibular Joint Dysfunction.

Many benefit documents have explicit exclusions for services to diagnose and treat temporomandibular joint (TMJ) disease whether medical or dental in nature. Before using this policy, check the member specific benefit plan document and any federal or state mandates, if applicable.

## Clinical Evidence

### Arthrocentesis

In this randomized clinical trial, Yilmaz et al. (2019) compared the effectiveness of hyaluronic acid (HA) injection and arthrocentesis plus HA injection for treating disc displacement with reduction and disc displacement without reduction. 90 participants age 15-82 years were divided into 2 main groups: group I which included participants with the disc displacement with reduction and group II which included disc displacement without reduction. The primary outcome variable was maximum pain on chewing, while secondary outcomes included maximum pain at rest, maximum non-assisted and assisted mouth opening, chewing efficiency, temporomandibular joint (TMJ) sounds, quality of life, treatment tolerability, and treatment effectiveness. At the six-month follow-up, improvements were recorded. Notably, arthrocentesis plus HA in group I showed superior improvement in chewing efficiency ( $p = 0.041$ ) and quality of life ( $p = 0.047$ ) compared to single HA; in group II arthrocentesis plus HA showed superior improvement in quality of life ( $p = 0.004$ ) compared to single HA. The authors concluded both procedures successfully improved the symptoms of both groups of patients, but arthrocentesis plus HA injection seemed superior. Limitations of this study were the low number of patients and lack of patient masking to treatment assignment.

Bouchard et al. (2017) performed a systematic review of the literature and meta-analysis of randomized controlled trials (RCTs) comparing TMJ lavage (arthrocentesis) with conservative measures in reducing pain and improving jaw motion. Two independent reviewers identified RCTs, and data extracted from the selected studies included population characteristics, interventions, outcomes, and funding sources. Risk of bias was assessed with the Cochrane Collaboration risk assessment tool for RCTs. Five studies, for a total of 308 patients, were included and results showed a reduction in pain in the intervention group at 6 months and 3 months, but not at 1 month. No difference in mouth opening was observed at the same intervals. The authors concluded that given the relatively small number of patients, the high risk of bias in 3 studies, and the statistical and clinical heterogeneity of the included studies, the use of TMJ lavage for the treatment of temporomandibular disorders should be recommended with caution because of the lack of strong evidence to support its use.

Nitzan et al. (2017) conducted a case series to evaluate the long-term outcome of arthrocentesis in patients with symptomatic temporomandibular joint (TMJ) osteoarthritis that was unresponsive to nonsurgical interventions. Seventy-nine patients (83 joints) with symptomatic TMJ osteoarthritis that had not responded to nonsurgical interventions and who underwent arthrocentesis were included in this study (67 female patients, 12 male patients aged 13 to 70). Demographic, clinical, and radiologic data, including assessment of pain, dysfunction, improvement, and satisfaction, and maximal mouth opening were analyzed. The patients were followed for  $56.9 \pm 6.7$  months. The results showed Sixty-four (81%) reacted favorably to arthrocentesis. For these patients, maximal mouth opening increased from  $26.3 \pm 0.8$  to  $39.24 \pm 0.9$  mm. Pain and dysfunction scores decreased from  $6.92 \pm 0.2$  to  $2.36 \pm 0.3$  and from  $7.37 \pm 0.2$  to  $2.24 \pm 0.4$  respectively. The authors concluded that for most patients, arthrocentesis offers long-term favorable outcomes for symptomatic TMJ osteoarthritis that has not responded to nonsurgical treatments and otherwise would have required surgical arthroplasty. Severity of preoperative clinical and computerized tomographic findings is not predictive for the success of arthrocentesis. The findings are however limited by a lack of comparison group.

Şentürk et al. (2017) conducted a study to evaluate the long-term effects of the single-puncture arthrocentesis (SPA) technique. Forty-two patients with unilateral temporomandibular joint disorders (TMDs) were treated by SPA. Thirty-eight of these patients completed 1-24 months of follow-up (short-term group) and 21 completed 11 months or longer of follow-up (long-term group).

The two groups were evaluated statistically for pain (visual analogue scale), maximum mouth opening, lateral excursion, and protrusion. Both follow-up duration groups showed significant improvements when compared to baseline levels for almost all of the outcome variables. The authors concluded that single puncture temporomandibular joint arthrocentesis is an effective treatment method over both the short and long term.

## TMJ Artificial Prostheses

The TMJ Concepts is a permanent, custom-made orthopedic implant intended to restore lower jaw function and relieve pain in patients. A 2019 ECRI custom product brief for TMJ Concepts Prostheses identifies the evidence as somewhat favorable for the device. A meta-analysis of cohort studies of three implants indicates that TMJ Concepts implants improve TMJ pain and motion range and provide similar outcomes for decreased pain and improved function, diet, and maximal incisal opening compared to other TMJ implants. Limitations include low-quality studies at high risk of bias which provide insufficient data to compare TMJ Concepts with autografts or to characterize their safety profile. Larger, multicenter randomized controlled trials are needed to address these gaps.

Sadhev et al. (2018) conducted a retrospective review to describe the clinical variables in patients after alloplastic TMJ reconstruction (TJR) performed at Massachusetts General Hospital from 2000 to 2015. The aim of this study was to assess changes in pain and range of motion (ROM), as well as postoperative complications and comorbidities. Clinical variables included primary diagnosis; number of previous surgical procedures and comorbidities. Data were obtained from 95 patients undergoing a total of 108 surgical procedures, with an average follow-up period of  $4.48 \pm 3.38$  years. The results showed the following: The most common primary indications for TJR were ankylosis (44%) and inflammatory disease (23%). The maximum interincisal opening improved by a mean of  $7.7 \pm 10.27$  mm, and pain decreased by a mean of  $1.5 \pm 3.29$  points on a visual analog scale. Transient facial nerve palsy (25%) was the most common postoperative complication; however, long-term complications were rare. The most frequent comorbidities were psychiatric disorders (56%) and gastrointestinal disease (46%). Psychiatric patients had similar preoperative pain scores ( $6.0 \pm 2.90$ ) but significantly higher postoperative pain scores ( $4.7 \pm 2.58$ ) compared with nonpsychiatric patients. Twenty-eight percent of patients had prior failed TMJ implant materials, specifically Proplast-Teflon (Vitek, Houston, TX). These patients were significantly older ( $50.4 \pm 8.26$  years) and had smaller preoperative ROM ( $21.7 \pm 8.85$  mm) and smaller postoperative ROM ( $28.3 \pm 9.59$  mm). The authors concluded that patients showed a statistically significant increase in ROM and reduction in pain. TJR is an effective treatment option in patients with limited mouth opening or severe pain.

Johnson et al. (2017) conducted a systematic review and bias adjusted meta-analysis to determine which prosthesis has resulted in the best outcomes after total temporomandibular joint replacement (TMJR). A comprehensive electronic search was undertaken in September 2015. Inclusion criteria encompassed studies that described one of the three current TMJR systems and that had pre- and postoperative data on at least two of the following TMJR indications: pain, diet, function, and maximum inter-incisal opening (MIO). Sixteen papers were included in the systematic review, reporting 10 retrospective studies and six prospective studies (no randomized controlled or case-controlled trials). A total 312 patients with 505 TMJ Concepts prostheses, 728 patients with 1048 Biomet prostheses, and 125 patients with 196 Nexus prostheses were included in the analysis. There was no real difference between the various TMJR systems in terms of pain or diet scores. Function scores improved with the TMJ Concepts, but this was the only prosthesis for which data were available. Biomet prostheses appeared to have a greater increase in MIO mean gain compared to TMJ Concepts and Nexus prostheses; however, this was heavily biased by one study. Without this study, there was no real difference in MIO. The authors concluded that the prostheses are similar, but most data are available for the TMJ Concepts prosthesis, with results being favourable.

Gerbino et al. (2017) conducted a retrospective study of 14 years of experience in total alloplastic reconstruction of the TMJ using stock and custom Biomet prostheses. 38 patients (55 joints) who underwent single-stage alloplastic total joint replacement from January 2000 to October 2014 were enrolled in the study. The subjective and objective variables were as follows: TMJ pain, diet, jaw function, maximum interincisal opening (MIO), quality of life and occlusion. The minimum follow-up was 12 months. Of the patients, 25 underwent Biomet total joint reconstruction system with stock prosthesis, 12 patients underwent total joint reconstruction system with custom made (patient matched) prosthesis, and 1 patient underwent bilateral total joint reconstruction using stock system on one side and custom system on the other side. The following adverse events and complications were recorded: bleeding, 2 cases; malocclusion, 1 case; postoperative infection with prosthesis removal, 1 case; heterotopic bone formation, 1 case; and contralateral TMJ overload in unilateral cases, 1 case. The occlusion was habitual unchanged in 29 of 38 cases. In 1 patient occlusion worsened with less stable functional contact. The patient refused postoperative orthodontic treatment. In 8 patients, a concomitant orthognathic procedure was planned in order to improve the occlusion. In all these patients, the occlusion improved. Quality of life and MIO relevantly improved in all cases. The authors

concluded that this study supports the use of total joint reconstruction for end-stage TMJ disease. Both stock and custom implants allow consistent results, but there are precise indications for the use of custom implants.

The purpose of a 2-year prospective study conducted by Gonzalez-Perez et al. (2015) was to investigate outcomes achieved with a stock temporomandibular joint (TMJ) replacement system in the management of end-stage TMJ disorders. Fifty-two patients with severe disease requiring reconstruction (36 unilateral/16 bilateral) were operated on consecutively. The mean follow-up period from initial TMJ symptoms to TMJ replacement surgery was 5 years (range 1–8 years). Clinical evaluations were carried out on preoperative day 1, and at months 3, 6, 12, and 24 following the TMJ replacement. Pain intensity changes (preoperative vs. current) were measured using a visual analogue scale (VAS, 10 cm) ranging from 0 to 10, with higher scores indicating more severe pain. Jaw opening was evaluated with a TheraBite scale between the incisal edges of the upper and lower central incisors. Over the 2 years of postoperative follow-up, there was a significant reduction in pain for 25 patients with TMJ replacement (48% of the patients studied); these patients reported a pain reduction of over 80% (in comparison with the preoperative pain values). Twelve of these 25 patients (23% of the cases) were in the '100%' pain reduction category, because the postoperative pain score was 0 (absence of pain). Many of the patients (71%) experienced mouth opening improvement of 100%. The authors concluded that the results of this study support the surgical placement of stock TMJ prostheses and show that the approach is efficacious and safe, reduces pain, and improves maximum mouth opening movement. This study also found that patients with a poorer functional status prior to treatment obtained the best final outcomes. Improvements persisted for 2 years following completion of the treatment.

A National Institute for Health and Care Excellence (NICE) report states that current evidence on the efficacy and safety of total prosthetic replacement of the temporomandibular joint is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. The procedure should be carried out only by clinicians with specific training and experience in total prosthetic replacement of the temporomandibular joint (NICE, 2014).

In a 3-year follow-up study of a 10-year multicenter clinical trial of patients implanted with the Biomet Microfixation TMJ Replacement Systems, Giannakopoulos et al., (2012) found that there was statistically significant improvement in pain level, jaw function, and incisal opening. Although there were complications necessitating the removal of 14 of 442 implants (3.2%), there were no device-related mechanical failures.

## Injections

### *Corticosteroids*

Davoudi et al. (2018) performed a systematic review to evaluate the advantages of administering corticosteroid (CS) during arthrocentesis. A data search was performed through December of 2017. After initial identification of 2,067 articles, seven studies were considered eligible based on inclusion and exclusion criteria. The following data was collected for each study: author, year, study design, participants (age and gender), method of TMD diagnosis, administered CS and dosage, the monitoring tests before and after arthrocentesis, and clinically significant outcomes. Limitations included the heterogeneous gathered data which prevented a meta-analysis and inability to compare other lavage agents such as hyaluronic acid (HA). The authors concluded arthrocentesis of TMJ with CS seemed have similar findings to other therapeutic drugs utilized, with no significant differences. More randomized control trials on this subject in comparison to other methods are suggested for future researches.

Gencer et al. (2014) conducted a controlled study comparing the efficacy of intra-articular injections of three different agents with well-known anti-inflammatory properties. A total of 100 patients who were diagnosed as temporomandibular joint disorder, but not specifically rheumatoid arthritis related TMJ, in the Department of Otolaryngology at Bozok University School of Medicine were prospectively studied. Patients with symptoms of jaw pain, limited or painful jaw movement, clicking or grating within the joint, were evaluated with temporomandibular CT to investigate the presence of cartilage or capsule degeneration. In the study group there were 55 female and 45 male patients who were non-responders to conventional anti-inflammatory treatment for TMJ complaints. The patients were randomly divided into four groups consisting of a control group and three different groups who underwent intra-articular injection of one given anti-inflammatory agent for each group. Saline solution was injected into the intra-articular space in the control group, and one of three anti-inflammatory agents including hyaluronic acid (HA), betamethasone (CS) and tenoxicam (TX) were administered intra-articularly under ultrasonographic guidance. Following the completion of injections, the changes in subjective symptoms were compared with visual analogue scales, (VAS) scores at 1st and 6th weeks' follow-up visits between the four groups. The results showed that the HA group did significantly better pain relief scores compared to the other groups at 1st and 6th weeks. TX and CS groups' pain scores were better than control group

values. The pain relief effect of TX was noted to decrease significantly between the 1st and 6th week. The same pattern was not observed in HA, CS and control (saline) groups between 1st and 6th week. The authors concluded that HA produced better pain relief scores when compared to the other anti-inflammatory agents studied. The main disadvantage of HA is its relatively higher cost. Despite the lower VAS scores, intra-articular TX and CS may be assessed as more economic alternatives to intra-articular HA injections.

### ***Trigger Point Injections***

Machado et al. (2018) completed a systematic review to evaluate the effectiveness of dry needling and injection with different substances in temporomandibular myofascial pain. Electronic databases PubMed, EMBASE, CENTRAL/ Cochrane, Lilacs, Scopus, Web of Science and CAPES Catalog of Dissertations were searched for randomized clinical trials. From 7128 eligible studies, 137 were selected for full-text analysis and 18 RCTs were included in this review. Due to the heterogeneity of the primary studies it was not possible to perform a meta-analysis. The narrative analysis of the results showed that most of the studies had methodological limitations and biases that compromised the quality of the findings. The authors concluded that dry needling and local anaesthetic injections seem promising, but there is a need to conduct further randomized clinical trials, with larger samples and longer follow-up times, to evaluate the real effectiveness of the technique and evaluated substances.

### **Physical Therapy**

Shimada et al. (2019) performed a focused review on the effects of exercise therapy for the management of painful temporomandibular disorders (TMDs). A painful TMD condition such as myalgia and arthralgia can be managed by exercise therapy and exercise therapy is defined as a regimen or plan of physical activities designed and prescribed or specific therapeutic goals. In this review the authors use the following exercise modalities from the Guide Book of Orofacial Pain for Diagnosis and Treatment: mobilization exercise, muscle strengthening exercise (resistance training), and coordination exercise and postural exercise. The authors found exercise therapy appeared to have a significant effect on both pain intensity and jaw mobility. Mobilisation exercise including manual therapy, passive jaw mobilisation with oral appliances and voluntary jaw exercise appeared to be a promising option for painful TMD conditions such as myalgia and arthralgia. This review addressed not only the effects of exercise therapy on various clinical conditions of painful TMD shown in the past, but also an urgent need for consensus among dentists and clinicians in terms of the management of each condition, as well as terminology.

Improvement of strength, mobility and range of motion (ROM) are just a few objectives of physiotherapy. Shousha et al. (2018) compared the effects of a short-term conservative physiotherapy program versus those of occlusive splinting on pain and ROM in cases of Temporomandibular Joint (TMJ) Dysfunction. This single-blinded randomized controlled study included 112 male and female participants aged 15–27 years. Conservative physiotherapy was provided to one group for 15 minutes/three times a week by a physiotherapist while the other group received standard occlusive splinting by a dentist with adjustments as necessary; both groups were treated for six weeks. Pain outcome measures were assessed by the visual analogue scale and TMJ ROM measured with the TMJ opening index. The significant improvements were in favor of the conservative physiotherapy group for both ROM and pain level. The authors concluded conservative physiotherapy would be a better initial treatment option than occlusal splints. Limitations of the study include the lack of a follow up period and the inability to blind the patient groups to treatment due to the nature of the study.

### **Occlusal Splints**

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. These splints are intended to reduce or eliminate clenching or bruxism (tooth grinding) and keep or reposition the jaw in a more relaxed position.

Tolevski-Meshkova et al. (2019) conducted a longitudinal retrospective case series assessing effectiveness, efficiency, and feasibility of a systematic protocol for the choice and management of occlusal splints (OA) in the treatment of temporomandibular disorders (TMDs). The study spanned over one year with 337 individuals diagnosed with TMD. In order to evaluate the results in the medium term, a sample of 100 patients was selected among those that completed treatment for at least one year. The authors concluded joint and muscle pain, joint noises and mandibular mobility all improved with the use of the occlusal splints. Limitations of the study included using a select variety of occlusal devices and not all types and long-term follow up studies are needed.

Kuzmanovic et al. (2017) shared the results of a 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 randomized controlled trials (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. The effect estimates were expressed as odds ratio (OR) or standardized mean difference (SMD) with 95% confidence interval. 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.

Hasegawa et al. (2017) conducted a case series to evaluate the relationship between displacement of the mandibular condyle/disc due to occlusal splint insertion with splint therapy and changes in discomfort of the temporomandibular joint (TMJ), and to clarify the relationships between the outcomes over time of temporomandibular discomfort and TMJ magnetic resonance imaging (MRI) findings at the initiation of splint therapy. A total of 75 patients admitted to hospital with discomfort around the TMJ were evaluated. A visual analogue scale for TMJ discomfort was administered during visits for approximately 3 months following the initiation of splint therapy. At the start of splint therapy, magnetic resonance imaging (MRI) was performed with and without splint insertion, and condyle and disc movements were evaluated. Disc balance, disc position and function, disc configuration, joint effusion, osteoarthritis, and bone marrow were evaluated. Linear regression and multiple regression analyses were used to clarify relationships between changes in discomfort and the factors evaluated. The results showed no significant correlation between TMJ discomfort and condyle/disc movement with splint insertion. TMJ discomfort was significantly relieved by splint therapy regardless of temporomandibular MRI findings. Unilateral anterior disc displacement and marked or extensive joint effusion fluid were significantly improved with splint therapy. The authors concluded that discomfort tended to remit with splint therapy regardless of temporomandibular MRI findings. Improvement of TMJ discomfort appears more likely to occur in patients with unilateral anterior disc displacement and with an apparent organic disorder, such as a joint effusion.

Fricton et al. (2010) conducted a systematic review with meta-analysis of randomized controlled trials (RCTs) assessing the efficacy of intraoral orthopedic appliances for reducing pain in patients with temporomandibular disorders (TMD) compared to placebo, no treatment or other treatments. A total of 47 publications citing 44 randomized controlled trials (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

Shedden et al. (2013) conducted a randomized controlled trial 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.

Biofeedback has been found to be useful for management of episodic or recurrent migraine or tension type headaches in pediatric patients. Turk et al. (1993) found that biofeedback provided sustained TMJ pain control, but the study protocol also included stress management techniques making it difficult to evaluate the weight of the contribution of biofeedback to the reduced pain levels.

Biofeedback is a technique to help gain control over involuntary bodily functions such as heart rate and blood pressure and been suggested to help many conditions such as anxiety, high blood pressure, headaches and chronic pain. It is thought that by harnessing the power of the mind and becoming aware of what's going on inside one's own body, more control can be gained over the body's overall health. While one RCT suggests that biofeedback may have an effect similar to a proven treatment (splints), it doesn't provide support that this approach is superior to established treatment and insufficient evidence to consider biofeedback as proven for TMJ.

## **Craniosacral Manipulation**

A 2017 Hayes report states that overall, no benefit of Craniosacral Therapy (CST) was found in all studies that included a control comparison group, although some beneficial effects of CST were found compared with baseline. A range of patient diagnoses and outcome measures were included across studies, making it difficult to determine whether CST might influence these variables differently. The quality of evidence available is considered very low.

Craniosacral manipulation is an alternate form of therapy most often used by massage therapists, chiropractors and osteopath providers to help with migraines, neck pain, fibromyalgia, and TMJ pain. Health care professionals use a gentle touch to manipulate joints in the spine, pelvis, head and neck. This service is considered unproven for TMD and the quality of evidence is low with additional research needed.

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

Lee et al (2018) conducted a randomised, open-label, controlled, three-centre 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. This study was to compare the effectiveness and cost of the Therabite® and wooden spatulas. The authors studied compliance with exercises and health-related QoL, assessed cost using three health economics measures, and conducted semistructured interviews with patients. Patients were randomised 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). Completion rates for the three economic measures were good. 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 study to investigate the influence of isolated temporomandibular joint (TMJ) manual therapy on pain and range of motion (ROM) of the TMJ and cervical spine including flexion-rotation test (FRT) in people suffering chronic pain arising from chronic arthralgic temporomandibular disorder (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 Visual Analogue Scale (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 a randomized controlled clinical trial (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 temporomandibular 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, 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 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.

Passive rehabilitation therapy and low-load prolonged duration stretch (LLPS) devices are used for passive rehabilitation and prolonged duration stretching for mandibular hypomobility. Examples of these devices include but are not limited to the Dynasplint, TheraBite Jaw Motion Rehabilitation System and the OraStretch® press. These devices are considered unproven due to insufficient evidence and efficacy for TMD.

## Professional Societies

### *American Association for Dental Research (AADR)*

Based on evidence from clinical trials as well as experimental and epidemiologic studies, the AADR strongly recommends that, unless there are specific and justifiable indications to the contrary, treatment of temporomandibular disorder (TMD) patients initially should be based on the use of conservative, reversible and evidence-based therapeutic modalities. Studies of the natural history of many TMDs suggest that they tend to improve or resolve over time. While no specific therapies have been proven to be uniformly effective, many of the conservative modalities have proven to be at least as effective in providing symptomatic relief as most forms of invasive treatment. Because those modalities do not produce irreversible changes, they present much less risk of producing harm (AADR 2015).

## ***American Association of Oral and Maxillofacial Surgeons (AAOMS)***

In the most recent Parameters of Care, the AAOMS makes the following statement regarding surgical procedures of the TMJ: “Surgical intervention for internal derangement is indicated only when nonsurgical therapy has been ineffective, and pain and/or dysfunction are moderate to severe. Surgery is not indicated for asymptomatic or minimally symptomatic patients. Surgery also is not indicated for preventive reasons in patients without pain and with satisfactory function. Pretreatment therapeutic goals are determined individually for each patient” (AAOMS 2017).

Additionally, the AAOMS Criteria for Orthognathic Surgery (2017), subsection on Facial Skeletal Discrepancies Associated with Documented Temporomandibular Joint Pathology states the following: "In some patients, skeletal malocclusion and TMJ dysfunction may be correlated. While some types of malocclusion have been more commonly implicated, a variety of deformities have been reported to be associated with TMJ symptoms. The rationale for proceeding with surgery to correct skeletal-dental deformities is based on common reports of significant improvement in joint and muscle symptoms after a variety of orthognathic procedures. The literature reports that approximately 80% of patients show improvement of pre-operative symptoms after orthognathic surgery. Prior to performing an orthognathic procedure on such patients, non-surgical therapies should be attempted, including those procedures and treatments that mimic the effects of occlusal alteration.”

## **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, see the following website (use product codes LZD and MPI): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>. (Accessed March 2, 2020)

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 March 2, 2020)

Bone anchored devices are approved as Class II devices by the FDA and are intended for fixation of suture (soft tissue) to bone. Additional information, under product code MAI or MBI, is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed March 2, 2020)

## **Centers for Medicare and Medicaid Services (CMS)**

Medicare does not have a National Coverage Determination (NCD) for arthrocentesis related to the treatment of temporomandibular joint (TMJ) disorders. Local Coverage Determinations (LCDs) do not exist at this time.

Medicare covers the manipulation of the occipitocervical or temporomandibular regions of the head when indicated for conditions affecting those portions of the head and neck. See the NCD for Manipulation (150.1). LCDs specific to this procedure for the treatment of TMJ disorder do not exist at this time.

Medicare does not have an NCD specific to occlusal splints (stabilization and repositioning splints) for the treatment of TMJ disorders. LCDs exist; see the LCDs for [Oral Maxillofacial Prosthesis](#).

Medicare does not have an NCD for physical therapy and biofeedback used to treat TMJ disorders. LCDs exist; see the LCDs for [Outpatient Physical Therapy](#).

Medicare does not have NCDs specific for the following treatments for TMJ disorder. LCDs specific for these treatments for TMJ disorder do not exist at this at this time.

- Arthroplasty
- Arthroscopy
- Arthrotomy
- Craniosacral Manipulation
- Injections of Corticosteroids for Rheumatoid Arthritis Related Disorders

- Low-load Prolonged-Duration Stretch (LLPS) Devices
- Partial or Total Joint Replacement When Other Treatments Failed
- Passive Rehabilitation Therapy
- Sodium Hyaluronate for disc displacement and osteoarthritis
- Trigger Point Injections

For additional information, see the following:

- [Medicare Benefit Policy Manual, Chapter 15, §150.1 – Treatment of Temporomandibular Joint Syndrome](#)
- [Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals](#)
- [Medicare Benefit Policy Manual, Chapter 15, §100 - Surgical Dressings, Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations](#)

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## Policy History/Revision Information

Date	Summary of Changes
11/01/2020	<b>Related Policies</b> <ul style="list-style-type: none"><li>Added reference link to the Utilization Review Guideline titled <i>Outpatient Surgical Procedures – Site of Service</i></li></ul>
08/01/2020	<b>Template Update</b> <ul style="list-style-type: none"><li>Reformatted policy; transferred content to new template</li></ul>
05/01/2020	<b>Documentation Requirements</b> <ul style="list-style-type: none"><li>Updated required clinical information for temporomandibular joint disorders</li></ul> <b>Supporting Information</b> <ul style="list-style-type: none"><li>Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li><li>Archived previous policy version 2020T0079BB</li></ul>

## Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. 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.