Temporomandibular Joint Disorders

Policy Number: 2022T0079II
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Instructions for Use

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Medicare Advantage Coverage Summary

- Dental Services, Oral Surgery and Treatment of Temporomandibular Joint (TMJ)

Coverage Rationale

See Benefit Considerations

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

- Arthrocentesis
- Arthroscopy
- Intra-articular injections of corticosteroids
- Trigger point injections
- Physical therapy
- Occlusal splint (stabilization and repositioning splints)
- Partial or total joint replacement

For medical necessity clinical coverage criteria, refer to the:

- InterQual® CP: Procedures:
  - Arthroscopy, Temporomandibular Joint (TMJ)
  - Discectomy, Temporomandibular Joint (TMJ)
  - Reconstruction, Temporomandibular Joint (TMJ)
- InterQual® Client Defined, CP: Procedures, Arthroplasty, Temporomandibular Joint (TMJ) (Custom) - UHG

Click here to view the InterQual® criteria.

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
- Low-load prolonged-duration stretch (LLPS) devices

- Multiple occlusal splints (i.e., daytime, and nighttime splints, maxillary and mandibular splints)

For information regarding intra-articular injections of sodium hyaluronate for temporomandibular joint disorders, refer to the Drug policy titled Sodium Hyaluronate.

For information regarding botulinum toxin injections for temporomandibular joint disorders, refer to the Drug Policy titled Botulinum Toxins A and B.

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
Temporomandibular Joint Disorders	

21050
21060
21198
21209
21240
21242
21243
21247
21299
E1399
	Medical notes documenting the following, when applicable:
	• 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:
	  ○ 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
	  ○ The physical and/or physiological abnormality has resulted in a functional deficit
	  ○ The functional deficit is recurrent or persistent in nature
	• Appropriate clinical studies addressing:
	  ○ The physical and/or physiological abnormality that confirm its presence
	  ○ The degree to which the abnormality is causing impairment
	  ○ Applicable TMJ radiological films and/or reports such as AP radiograph, panoramic radiograph, CT scans, and/or MRI
	• Treating physician's plan of care, including surgical treatment objectives, which must include the expected outcome for the improvement of the functional deficit
	• Prior therapies/treatments tried, failed, or contraindicated; include the dates and reason for discontinuation

Outpatient Surgical Procedures – Site of Service	
20552, 20553, 20605, 20606, 21010, 21070, 21198, 21209, 21247, 21299, 21499, 29800, 29804	Medical notes documenting the following, when applicable: • History • Physical examination, including patient weight and co-morbidities • Surgical plan • Physician privileging information related to the need for the use of the hospital outpatient department • American Society of Anesthesiologists (ASA) score, as applicable

*For code descriptions, refer to 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 orthopedic surgeons use to visualize, diagnose, and treat problems inside a joint (American Academy of Orthopedic 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
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
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
21198	Osteotomy, mandible, segmental
21209	Osteoplasty, facial bones; reduction
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

HCPCS Code	Description
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 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). Devices used for passive rehabilitation and prolonged duration stretching for mandibular hypomobility 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. These devices are used to treat mandibular hypomobility which may be due to scar tissue caused by radiation therapy for head and neck cancers, or temporomandibular joint dysfunction.

Benefit Considerations

The abbreviation “TMD” 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 a 2020 systematic review, Leung et al. assessed the evidence to determine if ultrasonography guided (USG) arthrocentesis provides better outcomes that conventional arthrocentesis for patients with temporomandibular disorder (TMD). Four small randomized controlled trials (RCT) with 144 patients were included in the final qualitative analysis. The articles selected were evaluated for study and patient characteristics, arthrocentesis procedure details, and treatment outcomes (post-operative pain, maximum mouth opening (MMO), procedure time, and attempts of needle positioning). The authors found no significant differences in pain reduction and improved MMO between sample groups receiving conventional arthrocentesis and USG-guided arthrocentesis, and both techniques are effective for treating patients with TMD to reduce pain and improve MMO. However, they found conflicting data in the attempts of needle positioning and procedure time and concluded that standardized treatment protocols and data from well-designed USG-guided arthrocentesis randomized clinical trials were lacking.

Öhrnell et al. (2019) conducted a prospective randomized controlled study to compare the clinical outcomes from noninvasive (conservative) and minimally invasive (arthrocentesis) treatments in patients with disk displacement without reduction (DDwoR). Twenty-four patients with clinically diagnosed symptomatic closed lock were randomized to a noninvasive (information, self-exercise, occlusal splints) intervention group and a minimally invasive (information, arthrocentesis with lavage, manipulation, postoperative self-exercise) intervention group. Maximal mouth opening (MMO) and pain (visual analogue scale [VAS]) were measured at baseline and at 3, 6, and 12 months after treatment. Both groups showed a successful outcome after 1 year. In the noninvasive group, the (mean ± SD) MMO value was 46.3 ± 7.2 mm, and the VAS score was 11 ± 17.1 in; and in the minimally invasive group, the MMO value was 42.7 ± 6.1 mm, and the VAS score was 10 ± 6.3. There were no significant differences between the 2 groups. Interestingly, a subgroup of patients who recovered spontaneously before treatment start had

significantly higher MMO values at baseline (P = .028). The authors concluded that outcomes with the 2 interventions (noninvasive and minimally invasive) are similar, and patients with a higher baseline MMO are more likely to experience spontaneous recovery. The sample size may however have been too small to detect a clinically significant difference between groups.

In a 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.

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.

Corticosteroid Injections

In a 2021 systematic review of randomized controlled trials Liapaki et al. investigated and compared injection of hyaluronic acid (HA), corticosteroids, and blood products and their abilities to improve maximum mouth opening (MMO) and decrease pain using the Visual Analog Scale (VAS) in patients with temporomandibular joint osteoarthritis (TMJOA). Nine studies (involving 434 patients) were included with a total of 32 patients receiving corticosteroid injections. All included studies used Ringer's lactate solution as the control. The results showed for TMJ pain, corticosteroid injection alone as well as corticosteroid plus arthrocentesis led to significant improvement in the VAS pain score at 6 and 12-month follow up. Arthrocentesis with Ringers lactate and normal saline also led to a significant improvement after 12 and 24 months. For MMO, arthrocentesis followed by corticosteroid injection significantly improved MMO after 12 months, while corticosteroid alone did not affect MMO significantly. The authors concluded that injectables and flushing of the joint with Ringer's lactate solution through arthrocentesis were able to significantly improve MMO and TMJ pain over a minimum follow-up period of 6 months, however it was not possible to show superiority of an injectable drug over Ringer's lactate. Based on these results, arthrocentesis contributes to improving MMO, by removing abraded, joint blocking, and inflammatory cell and extracellular matrix detritus, and perhaps may be an essential first step in the treatment of TMJOA when followed by an injectable. These conclusions are limited due to different protocols and follow-up periods; therefore, a meta-analysis was not possible. More randomized controlled trials addressing these limitations, with a similar methodology are needed.

Al-Moraissi et al. (2020a) conducted a systematic review and network meta-analysis of randomized clinical trials to identify the most effective treatment for pain reduction and improved mouth opening on arthrogenous temporomandibular joint disorders

(TMD's). Thirty-six studies compared pain, and 33 compared maximum mouth opening (MMO) and divided by length of follow up: short term (less than or equal to 5 months), and intermediate term (greater than 6 months to 4 years). Treatment compared included control/placebo, muscle exercises and occlusal splints, occlusal splint therapy alone, intraarticular injections of hyaluronic acid (HA) or corticosteroids (CS), arthrocentesis with and without HA, CS and platelet rich plasma (PRP) arthroscopy with or without HA and PRP, open joint surgery, and physiotherapy. With regard to intraarticular injections, the results showed that in the short term (less than or equal to 5 months) intra-articular injections of corticosteroids or hyaluronic acid achieved greater pain control than control/placebo, albeit the evident was very low quality. The results for the intermediate term (greater than or equal to 6 months) also showed statistically significant decrease in pain intensity with very low-quality evidence. For MMO, the results showed the most effective treatment for short and intermediate term improvement was arthroscopy procedures. The non-invasive procedures of occlusal splint therapy, physical therapy, conservative therapy, placebo/control provided significantly lower quality outcomes relative to pain and MMO. The authors concluded these results support a paradigm shift the treatment of arthrogenous TMD. There is new very low to moderate quality evidence indicating minimally invasive procedures, including CS injections, are significantly more effective than conservative treatments for both pain and improvement in MMO in the short and intermediate term, and recommend implementation as a first line treatment rather than the traditional concept of exhausting conservative treatment options. This study is limited by the inherent limitation of indirectness from network meta-analyses.

In a 2020 comparative randomized study, De Sousa et al. sought to compare the outcome of patients with TMJ arthralgia when submitted to four different treatment modalities. 80 patients were randomly distributed into 4 different treatment groups of 20 patients each, and all patients were given a nocturnal bite splint. One group was treated with the bite splint only, and the other 3 groups were injected with betamethasone, sodium hyaluronate or platelet rich plasma in addition to the splint. The authors assessed pain intensity and maximum pain free mouth opening. Patient were evaluated at the start of treatment, and again after one week, one month and six months. The results showed that maximum pain-free mouth opening improved in all the groups that made up the sample, with either a reduction in pain severity or with no pain. The group injected betamethasone improved more than the group without injection, but the sample size was too small to show a statistically significant difference in pain between groups. The group using the bite splint only showed the least improvement compared to the other three treatment groups. The authors concluded that all the treatments used caused a reduction in pain and increased pain-free mouth opening.

Davoudi et al. (2018) performed a systematic review to evaluate the advantages of administrating 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 research.

Gencer et al. (2014, included in the Al-Moraissi systematic review discussed above) 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 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 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 that steroid group had significantly better pain scores versus control (saline) group at 1st and 6th weeks and TX group at 6th weeks, however the HA group showed significantly better pain relief scores compared to the other groups. 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 all agents show effectiveness in reducing pain, with HA producing better pain relief scores when compared to the other anti-inflammatory agents studied.

Trigger Point Injections

Al-Moraissi et al. (2020c) conducted a network meta-analysis of randomized clinical trials comparing treatment outcomes of dry needling, acupuncture or wet needling using different substances (local anesthesia (LA), botulinum toxin-A (BTX-A), granisetron, platelet-rich plasma (PRP) or passive placebo versus real active placebo) to manage myofascial pain of the masticatory muscles. RCTs meeting the inclusion criteria were stratified according to the follow-up time: immediate post-treatment to 3 weeks, and 1 to 6 months post-treatment. Outcome variables were post-treatment pain intensity, increased mouth opening (MMO) and pressure threshold pain (PPT). The quality of evidence was rated according to Cochrane's tool for assessing risk of bias. Twenty-one RCTs involving 959 patients were included. The quality of evidence of the included studies was low or very low. There was a significant improvement of MMO after LA (MD = 3.65; CI: 1.18-6.1) and dry needling therapy (MD = 2.37; CI: 0.66-4) versus placebo. The three highest ranked treatments for short-term post-treatment pain reduction in TMD-M (1-20 days) were PRP (95.8%), followed by LA (62.5%) and dry needling (57.1%), whereas the three highest ranked treatments at intermediate-term follow-up (1-6 months) were LA (90.2%), dry needling (66.1%) and BTX-A (52.1%) (all very low-quality evidence). LA (96.4%) was the most effective treatment regarding the increase in MMO followed by dry needling (72.4%). The authors concluded that the effectiveness of needling therapy did not depend on needling type (dry or wet) or needling substance. The outcome of this network meta-analysis suggests that LA, BTX-A, granisetron and PRP hold some promise as injection therapies, but no definite conclusions can be drawn due to the low quality of evidence of the included studies. The findings are limited by the inherent indirectness of network meta-analyses.

Physical Therapy

In a 2020 systematic review and meta-analysis, Herrera- Valencia et al. sought to assess the medium- and long-term efficacy of manual therapy for temporomandibular joint disorders alone, or in combination with therapeutic exercises. Inclusion criteria were randomized controlled trials only, patients with any kind of temporomandibular disorder (mouth opening pain, mouth opening limitation, myofascial symptoms, non-reducing disc displacement, and chronic migraine), treatment included manual therapy in at least one of the experimental groups, a minimum of 3 months of follow-up, and pain must be one of the primary or secondary outcomes. Six studies met the inclusion criteria, 2 were considered low quality, and 4 were considered high quality, and totaled 304 patients. The results showed manual therapy to be an effective treatment in the medium term, but the effects decrease over time. However, when therapeutic exercise is added, the results can be maintained for a longer period of time.

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/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. 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. (2020b) conducted a systematic review and network meta-analysis of 48 randomized controlled trials 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 temporomandibular joint (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 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. 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 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

Biofeedback is a mind–body technique in which individuals learn how to modify their physiology for the purpose of improving physical, mental, emotional, and spiritual health. Clinical biofeedback may be used to manage disease symptoms as well as improve overall health and wellness (Frank et al.). 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 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.

Craniosacral Manipulation/Craniosacral Therapy

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. 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 therapy and low-load prolonged duration stretch (LLPS) devices are used for passive rehabilitation and prolonged duration stretching for mandibular hypomobility. These devices are considered unproven due to insufficient quality evidence of efficacy and safety for TMD.

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. 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 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). 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 case series 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). 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.

Clinical Practice Guidelines

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 November 2, 2021)

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 November 2, 2021)

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 November 11, 2021)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2022	**Coverage Rationale** • Removed references to specific InterQual® release dates; refer to the most current InterQual® criteria **Supporting Information** • Archived previous policy version 2022T0079HH

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 InterQual® criteria, 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.