Treatment of Temporomandibular Joint Disorders (for Pennsylvania Only)

Policy Number: CS195PA.G
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Ü Instructions for Use

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Application

This Medical Policy only applies to the state of Pennsylvania. Any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis. Refer to Pennsylvania Exceptions, Pennsylvania Code, Title 55, Chapter 1101.

Coverage Rationale

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

- Arthrocentesis
- Intra-articular injections of corticosteroids
- Occlusal splint (stabilization and repositioning splints)
- Physical therapy
- Trigger point injections

The following TMJ surgical services are proven and medically necessary in certain circumstances. 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

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

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

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

Applicable Codes

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

CPT Code	Description
20552	Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)
20553	Injection(s); single or multiple trigger point(s), 3 or more muscles
20605	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); without ultrasound guidance
20606	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting
21010	Arthrotomy, temporomandibular joint
21050	Condylectomy, temporomandibular joint (separate procedure)
21060	Meniscectomy, partial or complete, temporomandibular joint (separate procedure)
21070	Coronoidectomy (separate procedure)
21085	Impression and custom preparation; oral surgical splint
21089	Unlisted maxillofacial prosthetic procedure
21110	Application of interdental fixation device for conditions other than fracture or dislocation, includes removal
21240	Arthroplasty, temporomandibular joint, with or without autograft (includes obtaining graft)
21242	Arthroplasty, temporomandibular joint, with allograft
21243	Arthroplasty, temporomandibular joint, with prosthetic joint replacement
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (e.g., for hemifacial microsomia)
21299	Unlisted craniofacial and maxillofacial procedure
21499	Unlisted musculoskeletal procedure, head
29800	Arthroscopy, temporomandibular joint, diagnostic, with or without synovial biopsy (separate procedure)
29804	Arthroscopy, temporomandibular joint, surgical
90901	Biofeedback training by any modality
97039	Unlisted modality (specify type and time if constant attendance)
97139	Unlisted therapeutic procedure (specify)

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

Description of Services

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

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

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

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

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

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

Clinical Evidence

Arthrocentesis

Corrêa-Silva et al. (2024) conducted a randomized, prospective clinical trial to compare the efficacy of arthrocentesis to occlusal splint therapy for the treatment of patients with anterior disc displacement with reduction and intermittent block (ADDwRIB) and anterior disc displacement without reduction and limited mouth opening (ADDw/oR). Twenty-four participants were included, 13 in group 1 (splint therapy) and 11 in group 2 (arthrocentesis). Participants were evaluated after 1, 2, 3, and 6 months for the clinical outcomes of pain, functionality, and psychosocial status. The results showed no statistically significant differences in pain outcomes between the two groups, however Group 2 had the maximum pain reduction at one month, which suggests arthrocentesis results in faster relief of pain. The results for mouth opening without pain, a statistically significant difference was observed between the groups, in which Group 1 had greater increase mouth opening at the end of 6 months. The authors concluded that these results show that both techniques used to treat ADDwRIB or ADDw/oR demonstrated similar results.

In a 2022 systematic review and network meta-analysis, Li et al. assessed the effectiveness of various treatments for disc displacement (DD) of the TMJ. After initial identification of 2,449 publications, twenty-six studies met the inclusion criteria. Post-therapeutic maximum mouth opening, and pain intensity were the outcomes of interest. Interventions groups were classified into seven grades and consisted of arthrocentesis, intra-articular injections with diverse drugs (sodium hyaluronate, opioids, non-steroidal anti-inflammatory drugs, platelet-rich plasma, or corticosteroids), occlusal splints, or a combination of the interventions. In comparison, the control groups were oral analgesics, self-exercise, muscle and joint massage, or health instruction for behavioral changes. The findings concluded most invasive treatments performed better than non-invasive treatments. Interventions of arthrocentesis + platelet rich plasma injection and platelet-rich plasma injection in Grade I showed the most improvement in both mouth opening and pain alleviation in patients with DD. The findings are limited by the indirect nature of network analyses. (Study by Öhrnell 2019, previously cited in this policy, is included in this systematic review).

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 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 were 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.

In a randomized clinical trial, Yilmaz et al. (2019) compared the effectiveness of hyaluronic acid (HA) injection and arthrocentesis plus HA injection for treating DD with reduction and DD without reduction. 90 participants aged 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, 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 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 participants, 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 participants with unilateral TMDs were treated by SPA. Thirty-eight of the, 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.

Arthroplasty

In a 2022 systematic review and meta-analysis, Mittal et al. evaluated the clinical outcomes of autogenous grafts for reconstruction arthroplasty (RA) in patients with TMJ ankylosis. A total of 35 studies (700 participants) were eligible and included in the analysis. The participants received various autogenous grafts which included costochondral grafts (CCG), coronoid, sternoclavicular joint (SCG), metatarsal, auricular, iliac crest and remnant condylar mass grafts. The authors concluded that CCG and coronoid grafts were the most favored autogenous grafts based on the reported outcomes of maximum incisor opening (MIO) with a clinically acceptable range (27.21–31.38 mm) and recurrence rates were

comparable for all types of grafts except for coronoid grafts which had the lowest recurrence rates of 2.98%. The researchers concluded single-arm studies and lack of comparative trials are limitations identified in this study.

In a prospective randomized clinical trial, Andrade et al. (2020) compared the effectiveness of interpositional arthroplasty using a dermis fat graft with gap arthroplasty (GA) in the management of TMJ ankylosis. A study of 22 patients who presented with ankylosis of the TMJ were treated with either plain gap arthroplasty or dermis fat arthroplasty. The reported outcome variables were mouth opening and pain on jaw exercises. The outcome variables were measured on day 5, day 14, at the end of one month, at six months, one year, two years, and three years. The results concluded a total of 20 patient reported outcomes as 2 patients failed to attend follow up visits. The researchers found a significant difference between the two groups on postoperative day 5 and at one year. The mean mouth opening was higher in the dermis fat group at day 5 ($p = 0.013$) and again at one year ($p = 0.018$). However, over a three-year period mouth opening in both groups did not differ significantly. The pain outcome variable, using the visual analogue scores, was lower in the dermis fat graft group with a significant difference on day 14 ($p = 0.029$). The groups showed similar results at the end of three years follow up. The researchers concluded that the two techniques have similar outcomes in the management of ankylosis of the TMJ. However, the study is limited due to a comparatively short follow-up and small sample size.

Mittal et al. (2019) performed a systematic review and meta-analysis comparing the clinical outcomes among various treatment of GA, interpositional gap arthroplasty (IGA), RA and distraction osteogenesis (DO). After applying exclusion criteria, 26 articles (1197 participants) were used in the data extraction and analysis. The primary outcome variable was recurrence rate, while secondary outcomes included MMO, and recurrence and MMO amongst autogenous grafts and alloplastic prosthetic implants. The higher recurrence rate was observed with GA compared to both IGA and RA ($p < 0.05$). Comparable results were obtained with IGA, RA and DO ($p > 0.05$). Regarding types of materials, alloplastic materials showed higher recurrence rate compared to autogenous materials ($p < 0.05$) when used for inter-positioning. For reconstruction, both autogenous grafts and alloplastic prosthetic implants gave similar results ($p > 0.05$). MMO's highest improvement resulted with IGA but in post-operative changes in MMO the differences were clinically similar in all other groups. No conclusions could be drafted for younger ages due to the paucity of studies. The authors concluded, for management of TMJ ankylosis, IGA with autogenous material and reconstruction using either autogenous grafts or total joint replacement by alloplastic prosthetic implants provides similar clinical outcomes. Limitations in the study included heterogenous studies and lack of randomization.

Corticosteroid Injections

In a 2021 systematic review of randomized controlled trials Liapaki et al. investigated and compared injection of HA, corticosteroids, and blood products and their abilities to improve MMO and decrease pain using the Visual Analog Scale (VAS) in patients with temporomandibular joint osteoarthritis (TMJOA). Nine studies (involving 434 participants) were included with a total of 32 participants 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 a 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 TMDs. Thirty-six studies compared pain, and 33 compared 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 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. (Publication by Gencer 2014, previously cited in this policy, is included in this systematic review).

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 participants were randomly distributed into 4 different treatment groups of 20 participants each, and all participants 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. Participants 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 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 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.

Trigger Point Injections

Al-Moraissi et al. (2020b) 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, 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 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 participants 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

Romeo et al. (2024) conducted a double blind randomized controlled trial to compare the efficacy of combining physical therapy with occlusal splint therapy (both included education) in 62 participants with myogenic TMDs. The primary outcome subjective pain measured by the Visual Analogue Scale (VAS) at rest (VAS rest), maximum mouth opening (VAS open) and while chewing gum (VAS chew). The secondary outcome was TMJ range of motion (TMJ ROM). Computer generation randomized 33 participants to the control group (occlusal splint and education) and 29 to the experimental group which added physical therapy to the occlusal splint and education interventions. Physical therapy intervention included the TMJ as well as cervical and thoracic spine and included mobilization with lateral and anterior glide traction, manipulation, soft tissue techniques as well as self-treatment at home that included massage and exercises. Follow up occurred at 3 and 6 months. The results showed that all measured outcomes were significantly improved when physical therapy is added to occlusal splint treatment, with follow up time having a more significant impact on VAS but not ROM. The authors concluded that the addition of physical therapy as part of multimodal treatment for

myogenic TMD is effective. No adverse effects were reported in either group. A dropout rate of more than 20% due to the Sars-Cov-2 pandemic and short follow up were limitations of this trial. Future research with longer follow up times will be needed to validate these findings and the impact of the intervention for the longer term.

In a 2022 systematic review, Asquini et al. evaluated the effectiveness of craniomandibular manual therapy (CMMT) on pain and range of motion (ROM) in patients with TMD. RCTs examining CMMT alone versus other treatments were included in this study. After screening a total of 2720 articles, 6 articles (293 participants) met the inclusion criteria. Two independent reviewers screened articles for inclusion, extracted data, assessed risk of bias, and evaluated the overall quality of evidence. The results showed all participants had a significant improvement in pain and MMO following CMMT in the mid-term, but two showed the superiority of CMMT compared to other interventions. The authors concluded the quality of evidence was low but clinicians planning to treat patients with TMD, may consider CMMT, in addition to other treatment modalities to reduce pain and improve MMO in the mid-term. Due to limitations of bias, heterogeneity, and small sample size future studies are warranted.

In a 2021 systematic review of the literature and meta-analysis, Zhang et al. compared the effects of exercise therapy and occlusal splint therapy on pain and mobility in patients with painful TMD. A total of 1,124 articles were initially identified, six studies met inclusion criteria. The six studies were RCTs and included 498 participants (251 occlusal splint therapy, 247 exercise therapy). The effectiveness of exercise therapy was found to be not superior to occlusal splint therapy for pain reduction in patients with painful TMD ($p = 0.08$; weighted standardized mean difference −0.29; 95% CI, −0.62 to 0.04). In maximum mouth-opening the results revealed occlusal splint therapy and exercise therapy was equivalent ($p = 0.51$; weighted standardized mean difference 0.12; 95% CI, −0.24 to 0.48) in patients with painful TMD. The researchers concluded there was no significant difference between occlusal splint therapy and exercise therapy for patients with painful TMD. Further research with additional RCTs is necessary to validate these findings due to small sample size and small overall standardized mean.

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 TMD alone, or in combination with therapeutic exercises. Inclusion criteria were RCTs only, patients with any kind of TMD (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 have been 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 participants. The results showed manual therapy to be an effective treatment in the medium term, but the effects decrease over time. However, when therapeutic exercise was added, the results could 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 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

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

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

treatment of TMDs. Multimodal therapy consisting of CT + HSS may produce the maximum improvement for TMD patients. This study is limited by the inherent limitation of indirectness from network meta-analyses.

Kuzmanovic et al. (2017, included in Al-Moraissi 2020c above) shared the results of a systematic review and meta-analysis of RCTs showing the short- and long-term effects of stabilization splints (SS) in treatment of TMDs, and to identify factors influencing its efficacy. MEDLINE, Web of Science and EMBASE were searched for RCTs comparing SS to non-occluding splint, occlusal oral appliances, physiotherapy, behavioral therapy, counseling, and no treatment. Random effects method was used to summarize outcomes. Subgroup analyses were carried out according to the use of Research Diagnostic Criteria (RDC/TMD) and TMDs origin. Strength of evidence was assessed by GRADE. Meta-regression was applied. Thirty-three eligible RCTs were included in this meta-analysis. In short term, SS presented positive overall effect on pain reduction and pain intensity. Important decrease of muscle tenderness and improvement of mouth opening were found. SS in comparison to oral appliances showed no difference. Meta-regression identified continuous use of SS during the day as a factor influencing efficacy. Long term results showed no difference in observed outcomes between groups. Low quality of evidence was found for primary outcomes. The authors concluded that SS presented short term benefit for patients with TMDs. In long term follow up, the effect is equalized with other therapeutic modalities. Further studies based on appropriate use of standardized criteria for patient recruitment and outcomes under assessment are needed to better define SS effect persistence in long term. (Publication by Fricton et al. 2010, which was previously cited in this policy is included in this systematic review)

Biofeedback

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

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

Shedden et al. (2013) conducted a RCT to evaluate the efficacy of biofeedback-based cognitive-behavioral treatment (BFB-CBT) versus dental treatment with occlusal splint (OS) and investigate changes in nocturnal masseter muscle activity (NMMA). Fifty-eight patients with chronic TMD were randomly assigned to receive either 8 weekly sessions of BFB-CBT or 8 weeks of OS treatment. Diagnoses were established using Research Diagnostic Criteria for TMD. Pain intensity and disability were defined as primary outcomes. Secondary outcomes included emotional functioning, pain coping, somatoform symptoms, treatment satisfaction, and adverse events. NMMA was assessed during 3 nights pretreatment and posttreatment with portable devices. Follow-up assessment took place 6 months after the treatment. The results showed both treatments resulted in significant reductions in pain intensity and disability, with similar amounts of clinically meaningful improvement (45% for BFB-CBT and 48% for OS). Patients receiving BFB-CBT showed significantly larger improvements in pain coping skills. Satisfaction with treatment and ratings of improvement were higher for BFB-CBT. Effects were stable over 6 months and tended to be larger in the BFB-CBT group for all outcomes. No significant changes were observed in NMMA. The authors concluded that the fact that BFB-CBT resulted in larger improvements in pain coping skills, and was well accepted by the patients, underlines the importance and feasibility of psychological treatments in the clinical management of TMD. Further research with randomized controlled trials is needed to validate these findings.

Craniosacral Manipulation/Craniosacral Therapy

Review of the medical literature did not identify quality evidence to support the efficacy of this therapy for the temporomandibular joint.

Jaw Mobility Mechanical Stretching Devices

Jaw mobility mechanical stretching devices for TMDs are considered unproven due to insufficient quality evidence of efficacy and safety. The published literature is limited to studies with small numbers of participants, short-term follow-up,

or large loss-to-follow-up. Furthermore, the findings of most studies are inconclusive or unfavorable. Compliance with these devices is limited and the impact on clinical outcomes cannot be established.

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

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

Kraaijenga et al. (2014) conducted an RCT to compare the application of the TheraBite®(TB) Jaw Motion Rehabilitation System with a standard physical therapy (PT) exercise regimen for the treatment of myogenic TMD. Patients with myogenic TMD were randomized for the use of the TB device or for standard PT. Mandibular function was assessed with the mandibular function impairment questionnaire (MFIQ). Pain was evaluated using a visual analog scale, and maximum inter-incisor (mouth) opening (MIO) was measured using the disposable TB range of motion scale. Of the 96 patients randomized (46 TB, 50 standard PT exercises), 38 actually started with the TB device and 41 with the standard PT exercises. After six-week follow-up, patients using the TB device reported a significantly greater functional improvement (MFIQ score) than the patients receiving regular PT exercises. At 6 weeks, no significant differences in pain, and active or passive MIO were found between the two groups. At 3 months, patients in both treatment groups did equally well, and showed a significant improvement in all parameters assessed. The authors concluded that this RCT on myogenic TMD treatment, comparing standard PT with passive jaw mobilization using the TheraBite Jaw Motion Rehabilitation System®, shows that both treatment modalities are equally effective in relieving myogenic TMD symptoms, but that the use of the TB device has the benefit of achieving a significantly greater functional improvement within the first week of treatment. Further research with RCTs is needed to validate these findings.

Epigenetic Appliances

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

Clinical Practice Guidelines

American Association for Dental, Oral, and Craniofacial Research (AADOCR)

Based on evidence from clinical trials as well as experimental and epidemiologic studies, the AADOCR (formerly known as American Association for Dental Research) 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 (AADOCR 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 Recommended Criteria for Orthognathic Surgery (2020), 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, refer to the following website (use product codes LZD and MPI): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed September 10, 2024)

Continuous passive motion (CPM) machines are approved as Class II devices by the FDA. Class II devices meet both the General Control requirements and Performance Standards established by the FDA. Additional information, under product code BXB, is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed September 10, 2024)

In March of 2023, the FDA issued a safety concern regarding jaw remodeling devices for adults. Further information can be found at the following website: https://www.fda.gov/medical-devices/safety-communications/evaluation-safety-concerns-certain-dental-devices-used-adults-fda-safety-communication. (Accessed September 10, 2024)

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Policy History/Revision Information

Date	Summary of Changes
04/01/2025	**Coverage Rationale** • Revised list of unproven and not medically necessary services: o Replaced "*passive rehabilitation therapy devices* (e.g., TheraBite Jaw Motion Rehabilitation System®) *and low-load prolonged-duration stretch devices* (e.g., Jaw Dynasplint® System)" with "*jaw mobility mechanical stretching devices* (e.g., Therabite Jaw Motion Rehabilitation System®, Jaw Dynasplint® System)" o Revised list of examples of epigenetic appliances; added "Advanced Lightwire Functional (ALF) appliances" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Archived previous policy version CS195PA.F

Instructions for Use

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

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