

TEMPOROMANDIBULAR JOINT DISORDERS

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Related Policies
<ul style="list-style-type: none"> • Botulinum Toxins A and B • Manipulation Under Anesthesia • Manipulative Therapy • Orthognathic (Jaw) Surgery • Sodium Hyaluronate • Supply Policy

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

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

CONDITIONS OF COVERAGE

Applicable Lines of Business/ Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General benefits package
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes ¹
Precertification with Medical Director Review Required	Yes ¹
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	All
Special Considerations	¹ Oxford's Dental Department will review requests for services to be rendered by practitioners of the following specialties: oral surgery, oral/maxillofacial surgery, general or pediatric dentistry, endodontics, periodontics, and orthodontics. All other specialties require review by Oxford's Medical Management Department (Medical Director or their designee).

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

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

Many benefit documents have explicit exclusions for services to diagnose and treat temporomandibular joint (TMJ) disease whether medical or dental in nature. Also, dental services are typically excluded from benefit coverage under most Certificates of Coverage and many Summary Plan Descriptions. Such dental services include, but are not limited to, bite plates, occlusal equilibration, study models, dentures, crowns, bridges, fillings, orthodontics, X-rays of individual teeth and/or tomograms. However, some states mandate benefit coverage for treatment of TMJ disorders. In such instances, state mandates take precedence over the member specific benefit plan document. In all cases, state mandates and the member specific benefit plan document must be reviewed in order to determine member specific benefit coverage for treatment of TMJ disorders.

Indications for Coverage

When a plan covers TMJ services, the following are eligible:

Diagnostic Procedures:

- Evaluations, consultations (including pain management consultations), office visits and examinations
- Diagnostic testing (e.g., panoramic x-ray, arthrography) (Please note that advanced imaging [MRI, CT scan, etc.] is subject to current utilization review guidelines and the applicable notification process.)

Surgical and Non-Surgical Procedures

- Arthrocentesis, TMJ
- Arthroplasty, TMJ
- Arthroscopy, TMJ
- Arthrotomy, TMJ
- TMJ splints / biteplates (includes dental casts; refer to the reimbursement policy titled [Supply Policy](#))
- Trigger point injections
- Sodium hyaluronate for TMJ disorders (refer to the clinical policy titled [Sodium Hyaluronate](#))
- Injections of corticosteroids (see [Coverage Rationale](#) below)
- Physical therapy for TMJ disorders
- FDA approved TMJ prosthetic replacement (These may be covered when all other treatment has failed; this is subject to clinical review.)

Coverage Limitations and Exclusions

When a plan excludes coverage for TMJ disorders, all services are excluded from coverage regardless of whether the underlying cause is due to medical or dental reasons or conditions. The TMJ exclusion applies to all provider types (i.e., MD, DO, DC, DMD, DDS, etc.).

When a plan does not cover TMJ services, the following are not covered. Note that certain services listed below are not covered even for plans that cover TMJ services. The following is not an all-inclusive list.

- Unproven services for TMJ disorders
- Acupuncture for TMJ disorders (See [Additional Information](#) below)
- TMJ prosthetic replacement
- Arthrocentesis, TMJ
- Arthroplasty, TMJ
- Arthroscopy, TMJ
- Arthrotomy, TMJ
- Biofeedback for TMJ disorders (Not covered even when plan covers TMJ services; also see [Coverage Rationale](#) below)
- Chiropractic treatment for TMJ disorders (See [Additional Information](#) below)
- Computerized mandibular scan or jaw tracking for TMJ disorders (Not covered even when plan covers TMJ services)
- Craniosacral therapy/manipulation for TMJ disorders (Not covered even when plan covers TMJ services; also see [Coverage Rationale](#) below)
- Dental braces or other orthodontics for TMJ disorders (Not covered even when plan covers TMJ services)
- Dental casts for TMJ disorders
- Dental restoration work (crowns, bridges) for TMJ disorders (Not covered even when plan covers TMJ services)
- Diagnostic testing (e.g., panoramic x-ray, arthrography) for TMJ disorders
- Doppler analysis for TMJ disorders (Not covered even when plan covers TMJ services)
- Evaluations (consultations, office visits, examinations) for TMJ disorders

- Injections of corticosteroids for TMJ disorders
- Mental health counseling for TMJ disorders (Not covered even when plan covers TMJ services; see [Additional Information](#) below)
- Occlusal adjustment/grinding down teeth for TMJ disorders (Not covered even when plan covers TMJ services)
- Physical therapy for TMJ disorders
- Surface electromyography for TMJ disorders (Not covered even when plan covers TMJ services)
- TMJ splints/biteplates
- Trigger point injections for TMJ disorders
- Sodium hyaluronate for TMJ disorders
- Vibration analysis for TMJ disorders (Not covered even when plan covers TMJ services)

Additional Information

Please note the following clarifications:

- Acupuncture for TMJ disorders is not covered even if a plan has an acupuncture benefit. *Rationale:* TMJ exclusion overrides the acupuncture benefit.
- Manipulative treatment for TMJ disorders (chiropractic or osteopathic) is not covered even if a plan has a manipulative treatment benefit. *Rationale:* TMJ exclusion overrides the manipulative treatment benefit.
- Services to treat dislocation of the mandible/jaw are considered eligible for coverage as is any other dislocation. This includes coverage for surgical stabilization of the joint that may be required, particularly if repeated jaw dislocations occur. The diagnosis in such cases would be dislocation (i.e., not TMJ syndrome) and therefore would NOT be applicable to an exclusion for TMJ services.
- For mental health service, please refer to member specific benefit plan documents for possible mental health benefits.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

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

- Arthrocentesis
- Arthroplasty [For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 22nd edition, 2018, Temporomandibular Joint Arthroplasty, ACG: A-0523 (AC)]
- Arthroscopy (with or without FDA approved bone anchor devices)
- Arthrotomy/open joint surgery (with or without FDA approved bone anchor devices)
- Injections of corticosteroids for rheumatoid arthritis-related TMJ disorders
- Physical therapy
- Stabilization and repositioning splint therapy (This does not include low-load prolonged-duration stretch (LLPS) devices discussed below)

Partial or total joint replacement with an artificial prosthesis is proven and/or medically necessary for treating disorders of the temporomandibular joint (TMJ) when all other treatments have failed.

The following services are unproven and/or not medically necessary for treating disorders of the temporomandibular joint (TMJ):

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

There are limited studies evaluating biofeedback for the treatment of musculoskeletal pain, including TMJ pain. Well-designed randomized, blinded and placebo-controlled outcome studies published on craniosacral manipulation for TMJ are not available.

While there are some data from several randomized trials and case series studies that certain types of passive rehabilitation techniques may improve jaw mobility early in recovery in patients who have undergone TMJ surgery, or have lost jaw mobility due to TMJ derangement or to contracture following radiation therapy, these studies all included very small numbers of patients, and did not provide blinded assessment of outcomes, long-term follow-up, or information on optimal treatment protocols.

Further prospective controlled clinical trials that directly compare LLPS devices to other treatment modalities are needed.

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 may apply.

CPT Code	Description
20605	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); without ultrasound guidance
20606	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting
21010	Arthrotomy, temporomandibular joint
21050	Condylectomy, temporomandibular joint (separate procedure)
21060	Meniscectomy, partial or complete, temporomandibular joint (separate procedure)
21085	Impression and custom preparation; oral surgical splint
21089	Unlisted maxillofacial prosthetic procedure
21110	Application of interdental fixation device for conditions other than fracture or dislocation, includes removal
21240	Arthroplasty, temporomandibular joint, with or without autograft (includes obtaining graft)
21242	Arthroplasty, temporomandibular joint, with allograft
21243	Arthroplasty, temporomandibular joint, with prosthetic joint replacement
29800	Arthroscopy, temporomandibular joint, diagnostic, with or without synovial biopsy (separate procedure)
29804	Arthroscopy, temporomandibular joint, surgical
90901	Biofeedback training by any modality
97039	Unlisted modality (specify type and time if constant attendance)
97139	Unlisted therapeutic procedure (specify)

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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 six
E1702	Replacement measuring scales for jaw motion rehabilitation system, package of 200

DESCRIPTION OF SERVICES

Temporomandibular disorders (TMD) are a diverse, complex set of conditions that affect the temporomandibular joint (TMJ) and/or the surrounding musculature. Symptoms include pain at rest and/or during jaw function, limited range of motion and TMJ noises such as clicking, popping and crepitus. Many of the underlying causes of TMJ dysfunction are unknown, and treatments may be nonspecific and palliative. Conditions may spontaneously resolve and reoccur, or

respond to conservative treatments such as non-steroidal anti-inflammatory drugs (NSAIDs), soft diet, jaw rest, moist heat, steroids, physical therapy, splints, muscle relaxants and/or antidepressants. Failure of conservative methods may require the addition of injection therapy or surgery. (NICDR 2015)

Devices used for passive rehabilitation of the TMJ include continuous passive motion (CPM) devices such as the Therabite Jaw Motion Rehabilitation System.

CLINICAL EVIDENCE

Temporomandibular Joint Disorders

Arthrocentesis

Arthrocentesis, puncture of a joint space with a needle to remove accumulated fluid, may also include irrigating the temporomandibular joint. This is the simplest and least involved of the invasive surgical options. It is performed under local anesthesia using two needles placed into the joint spaces to inject and withdraw Ringer's lactate solution. Increased pressure within the joint may be used in an attempt to lyse adhesions. Steroids or hyaluronic acid (HA) may be injected to prevent inflammation or lubricate the joint. The mandible may also be manipulated to complete the process of freeing the disc.

In a Cochrane review, Guo et al. (2009) assessed the effectiveness and complications of arthrocentesis and lavage for the treatment of temporomandibular joint disorders compared with controlled interventions. Two randomized controlled trials (RCTs) were included in the review. The two trials, including 81 patients with temporomandibular joint disorders, compared arthrocentesis with arthroscopy. No statistically significant difference was found between the interventions in terms of pain. However, a statistically significant difference in favor of arthroscopy was found in maximum incisal opening (MIO). Mild and transient adverse reactions such as discomfort or pain at the injection site were reported in both groups. No data about quality of life were reported. The authors concluded that there is insufficient, consistent evidence to either support or refute the use of arthrocentesis and lavage for treating patients with temporomandibular joint disorders. Further high quality RCTs of arthrocentesis need to be conducted before firm conclusions with regard to its effectiveness can be drawn.

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

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.

Arthroscopy

Arthroscopy (direct joint visualization by means of an arthroscope), a minimally invasive procedure performed under general anesthesia, can be used for both diagnostic and treatment procedures. Treatment involves lysis of adhesions and lavage of the joint space, but debridement, capsular stretch and arthroplasty (surgery to repair, reshape or reconstruct a diseased joint) may also be performed. In general, arthroscopy is one of the recommended treatments for patients with a demonstrable intra-articular condition such as disc displacement (with or without reduction), who have had prior conservative treatment for a period of time without relief.

Al-Moraissi et al. (2015) performed a systematic review with meta-analysis to assess the clinical outcomes of the following three surgical methods for the management of internal derangement of the temporomandibular joint (TMJ): arthroscopic lysis and lavage (ALL), arthroscopic surgery (AS), and open surgery (OS). Seven publications were identified: three randomized controlled trials (RCTs), two controlled clinical trials (CCTs), and two retrospective studies. A total of 227 patients were enrolled in the five studies comparing OS (n = 112) to AS (n = 115) with a

follow-up period of 1 to 5 years. A total of 657 patients were enrolled in two studies comparing ALL (n = 326) to AS (n = 331) with a follow-up period of 1–2 years. The results of the meta-analysis showed that the use of OS is superior to AS in pain reduction, with comparable maximal inter-incisal opening (MIO), jaw function, and clinical findings (clicking, joint tenderness, and crepitation). In addition, the results of the present study showed that ALL provides greater improvement in MIO and comparable pain reduction when compared to AS. There was a significant improvement in joint movement for patients managed with AS. The authors concluded that although the results of the meta-analysis showed a trend towards better outcomes with OS for pain reduction and improvement of jaw function, AS is a safe technique associated with only mild and transient complications, with a more rapid patient recovery. They acknowledged that the variation in open-joint surgeries and different levels of joint pathology may have had an effect on the results of the present study. Hyaluronic acid injections were used in two studies and this may have further enhanced the effect of arthroscopic surgery.

In a Cochrane review, Rigon et al. (2011) assessed the effectiveness of arthroscopy for the management of temporomandibular disorders (TMDs). Seven randomized controlled clinical trials (n=349) of arthroscopy for treating TMDs were included. The authors reported that both arthroscopy and nonsurgical treatments reduced pain after 6 months. When compared with arthroscopy, open surgery was more effective at reducing pain after 12 months. There were no differences in mandibular functionality or in other outcomes in clinical evaluations. Arthroscopy led to greater improvement in maximum interincisal opening after 12 months than arthrocentesis; however, there was no difference in pain.

Breik et al (2016) conducted a retrospective cohort study with the purpose of evaluating the medium to long-term outcomes of TMJ arthroscopic lysis and lavage and determine factors associated with progression to open surgery. The single operator series was performed over a 6-year period from 2006 to 2012. The variables of gender, age and category were compared to evaluate factors associated with success of arthroscopy and progression to open surgery. The data were analysed via Kaplan Meier method for time-to event analyses and Chi-squared tests for trend analyses. Pre-operative and post-operative Visual analogue scores and maximum inter-incisal opening results were analysed with the Student's t-test. A total of 167 patients and 216 joints underwent arthroscopy with a mean follow up of 6.9 years. Overall 77.7% of joints had a successful result and required no further surgery. There was no gender difference with respect to progression to surgery. Males underwent open surgery after a mean of 6.2 months from Arthroscopy and Females after a mean of 15.6 months from Arthroscopy. The highest failure rate between age groups was in the 21-30 year age group. There was a statistically significant rate of progression to open surgery depending on the classification at the time of arthroscopy, with all patients with category 4 and 5 disease progressing to open surgery. The authors concluded Arthroscopic lysis and lavage of the TMJ is a reliable and effective operation for patients with early stage (i.e., Categories 1, 2 and 3) disorders of the TMJ. Patients with more advanced joint disease (i.e., Categories 4 & 5) gained only temporary relief from TMJ arthroscopy and often progress to open TMJ surgery.

Arthrotomy

Open surgery techniques such as arthrotomy (cutting into a joint) are more invasive, and are performed under general anesthesia. A preauricular incision is usually used, and then an incision in the temporal fascia exposes articular capsule and superior joint space, or an incision in the collateral ligament allows access to the inferior joint space. Prophylactic antibiotics and/or steroids may be administered.

Miloro et al. (2017) conducted a retrospective cohort study to assess the effectiveness of discectomy without replacement in improving jaw function and decreasing pain. Subjects with internal derangement underwent discectomy without replacement by one surgeon at a single academic medical center. The primary predictor variables were preoperative maximal incisal opening (MIO) and Helkimo Clinical Dysfunction Index (CDI) score. The primary outcome variable was postoperative MIO and CDI score. A paired student's t-test assessed the difference between pre- and post-operative MIO and CDI scores. Preoperatively, all patients had severe dysfunction (TMJ locking or severe TMJ or muscle pain). Postoperatively 14 of 17 subjects (82%) showed marked improvement in mandibular function, and reduction in pain characterized as clinically symptom-free or only small dysfunction. The author's concluded that discectomy without replacement is effective in improving MIO based upon improvement in objective and subjective assessments.

TMJ Artificial Prostheses

TMJ prostheses fully or partially replace the articulating structures of the TMJ anatomy. Partial replacement is typically done by resurfacing the joint fossa with a metallic implant and total replacement uses a metallic condyle that articulates against a polyethylene or metallic fossa.

Johnson et al. (2017) conducted a systematic review and bias adjusted meta-analysis to determine which prosthesis has resulted in the best outcomes after total temporomandibular joint replacement (TMJR). A comprehensive electronic search was undertaken in September 2015. Inclusion criteria encompassed studies that described one of the three current TMJR systems and that had pre- and postoperative data on at least two of the following TMJR indications: pain, diet, function, and maximum inter-incisal opening (MIO). Sixteen papers were included in the

systematic review, reporting 10 retrospective studies and six prospective studies (no randomized controlled or case-controlled trials). A total 312 patients with 505 TMJ Concepts prostheses, 728 patients with 1048 Biomet prostheses, and 125 patients with 196 Nexus prostheses were included in the analysis. There was no real difference between the various TMJR systems in terms of pain or diet scores. Function scores improved with the TMJ Concepts, but this was the only prosthesis for which data were available. Biomet prostheses appeared to have a greater increase in MIO mean gain compared to TMJ Concepts and Nexus prostheses; however this was heavily biased by one study. Without this study, there was no real difference in MIO. The authors concluded that the prostheses are similar, but most data are available for the TMJ Concepts prosthesis, with results being favourable.

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

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

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

In a prospective long-term analysis of 131 consecutive patients who had undergone alloplastic replacement of 132 mandibular condyle(s) for reconstruction after disarticulation for pathology or trauma, Marx et al. (2008) reported follow-up time ranged from 3.4 to 18.6 years with an average of 7.8 years. A total of 13 (9.8%) patients developed minor complications including pain (2/132, 1.5%), loose plate (2/132, 1.5%), limited jaw opening (4/132, 3.0%), and plate exposures all of which were in irradiated patients (6/132, 4.5%). One patient (0.8%) who also was irradiated developed an erosion into the external auditory meatus with pain. None developed an erosion into the middle cranial fossa. The authors concluded alloplastic replacement of the mandibular condyle with a metallic condyle on a rigid reconstruction plate functioning against a natural disc or a soft tissue graft in the temporal fossa after disarticulation for pathology or trauma provides long-term stability with minimal complications (a total complication incidence of 10.6%).

In a prospective cohort study of 36 patients with osteoarthritis of the temporomandibular joint, Keller et al. (2012) concluded that temporomandibular joint hemiarthroplasty with a custom metal fossa/eminence prosthesis provides satisfactory clinical and functional outcomes when used for advanced osteoarthritis in patients with focal joint pain secondary to computed tomographically documented joint pathology.

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

Injections

Injection of anti-inflammatory agents (corticosteroids) into the TMJ joint spaces is a minimally invasive therapy for TMJ disorders.

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

Physical Therapy

Physical therapy modalities such as exercises, heat, jaw mobilization, ultrasound etc., have been used to treat the muscular component of myofascial pain of the masticatory muscles and TMJ disorders.

The aim of a systematic study and meta-analysis performed by Armijo-Olivo et al. (2016) was to summarize evidence from and evaluate the methodological quality of randomized controlled trials that examined the effectiveness of manual therapy (MT) and therapeutic exercise interventions compared with other active interventions or standard care for treatment of temporomandibular disorders (TMD). Electronic data searches of 6 databases were performed, in addition to a manual search. Randomized controlled trials involving adults with TMD that compared any type of MT intervention (e.g., mobilization, manipulation) or exercise therapy with a placebo intervention, controlled comparison intervention, or standard care were included. The main outcomes of this systematic review were pain, range of motion, and oral function. Forty-eight studies met the inclusion criteria and were analyzed. The authors concluded that although the quality of the evidence was low, the results of the systematic review are consistent with previous reviews, showing positive effects when using exercises to treat myogenous and arthrogenous TMD. In particular, interventions including exercises to correct head and neck posture and active and passive oral exercises can be effective for reducing musculoskeletal pain and improving oromotor function. Manual therapy alone or in combination with exercises shows promising effects. Manual therapy targeted to the cervical spine decreased pain and increased mouth range of motion in patients with myogenous TMD.

Physical therapy (PT) modalities such as active and passive jaw movement exercises, correction of body posture and relaxation techniques can be effective in reducing the symptoms of TMJ disorders. Nicolakis et al. (2001) found that 6 months after physical therapy, pain, perceived impairment and mouth opening had all significant improvements in the treatment group. Oh et al. (2002) documents that patients completing PT following TMJ surgery, also had significantly less pain and increased function as compared to the non-treatment group.

Calixtre et al. (2015) conducted a systematic review to analyze the evidence regarding the isolated effect of manual therapy (MT) on improving signs and symptoms in temporomandibular disorder (TMD) patients. Randomized Controlled Trials (RCTs) comparing a manual therapy physical therapy intervention to a reference group (placebo intervention, controlled comparison intervention, standard treatment or other treatment) were utilized. Eight studies were included. The number of patients in the studies ranged from 30-93. Seven out of the eight studies presented high methodological quality. Treatment effect size was calculated for pain, maximum mouth opening (MMO) and pressure pain threshold (PPT). There was moderate and low evidence that myofascial release and massage techniques are more effective than placebo or no intervention for MMO and pain outcomes respectively. There was also moderate

evidence that no significant difference exists between myofascial release and toxin botulinum for improvement on the same outcomes. Overall there was moderate-to-high evidence that MT techniques protocols are effective. The authors concluded that there is widely varying evidence that MT improves pain, MMO and PPT in patients with TMD, depending on the technique. They stated that further studies using standardized evaluations and better study designs are needed to strengthen clinical relevance.

Splints

Splints (also referred to as night guards, occlusal guards or appliances) have been used to treat bruxism and TMJ disorders. Splint therapy consists of either a stabilization splint or a repositioning splint. All of the splints attempt to reduce or eliminate clenching or bruxism, to keep or reposition the jaw into a more relaxed position

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.

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

A Cochrane review by Al-Ani et al. (2009) of randomized or quasi-randomized controlled trials (RCTs), in which splint therapy was compared concurrently to no treatment, other occlusal appliances, or any other active intervention concluded there is insufficient evidence either for or against the use of stabilization splint therapy for the treatment of temporomandibular pain dysfunction syndrome. This review suggests the need for further, long term, well conducted RCTs that pay attention to method of allocation, outcome assessment and are of sufficient sample size.

Biofeedback

Biofeedback is a behavioral training program that teaches the control of certain autonomic reactions. Its goal is to reduce or eliminate pain through learned control of physiological responses of the body.

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

that the fact that BFB-CBT resulted in larger improvements in pain coping skills, and was well accepted by the patients, underlines the importance and feasibility of psychological treatments in the clinical management of TMD. Further research with randomized controlled trials is needed to validate these findings.

Biofeedback has been found to be useful for management of episodic or recurrent migraine or tension type headaches in pediatric patients. Turk et al. (1993) found that biofeedback provided sustained TMJ pain control, but the study protocol also included stress management techniques making it difficult to evaluate the weight of the contribution of biofeedback to the reduced pain levels. Ryan et al. (2004) demonstrated that biofeedback based interventions were effective for reduction of pain symptoms due to functional disorders, but TMJ diagnoses were not included in the study group. Due to the lack of randomized controlled trials (RCT), there is insufficient evidence to support the use of biofeedback for TMJ related symptoms.

Craniosacral Manipulation

Craniosacral therapy is the application of light pressure to the head allegedly completed to release restrictions in the craniosacral system. It is used for a variety of conditions especially for TMJ disorder. It is done by some osteopaths, massage therapist, chiropractors, dentists and physical therapists. The other terms used for this form of treatment are cranial osteopathy, cranial therapy, bio-cranial therapy, craniopathy and sacro-occipital technique (SOT).

Jäkel et al (2012) conducted a systematic review to identify and critically evaluate the available literature regarding craniosacral therapy (CST) and to determine the clinical benefit in the treatment of patients with a variety of clinical conditions. Electronic databases were searched through April 2009, and studies describing observational or randomised controlled trials (RCTs) in which CST as the only treatment method was used, and studies published in the English language were selected. Seven studies met the inclusion criteria, of which three studies were RCTs and four were of observational study design. Positive clinical outcomes were reported for pain reduction and improvement in general well-being of patients. The authors concluded that this review revealed the paucity of CST research in patients with different clinical pathologies. CST assessment is feasible in RCTs and has the potential of providing valuable outcomes to further support clinical decision making. However, due to the current moderate methodological quality of the included studies, further research is needed.

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

Mandibular Hypomobility

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

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

Grondin et al. (2017) conducted a study to investigate the influence of isolated temporomandibular joint (TMJ) manual therapy on pain and range of motion (ROM) of the TMJ and cervical spine including flexion-rotation test (FRT) in people suffering chronic pain arising from chronic arthralgic temporomandibular disorder (TMD). An experienced clinician managed a case series of 12 patients with TMD (mean duration 28.6 months +/- 26.9). The intervention comprised four-weekly sessions of transverse medial accessory TMJ mobilization and advice. Patients were examined prior to and one-week following the intervention period. Outcome measures included jaw disability, jaw pain measured by Visual Analogue Scale (VAS), maximal mouth opening ROM, cervical ROM including FRT, and pain during cervical movement. A paired t-test revealed significant improvement following the intervention in disability, VAS pain score at rest and at maximum mouth opening, jaw opening ROM, FRT ROM to the left and right. In contrast, no significant change was identified for total cervical ROM ($p = 0.905$). After the intervention, five patients (41.66%) had no pain at rest or at maximal mouth opening, and all had a negative FRT. The effect sizes indicate a moderate to

strong, clinically significant effect for all variables apart from total cervical ROM. The authors concluded that while a case series cannot identify a cause and effect relationship, these results provide preliminary evidence for the influence of TMJ manual therapy on measures of TMD including pain, as well as upper but not whole cervical movement and associated pain in patients with a diagnosis of TMJ arthralgia. Further research with larger patient samples and randomized controlled trials are needed to validate these findings. The significance of this study is also limited by a short follow-up period.

Low-Load Prolonged-Duration Stretch (LLPS) Devices

In a retrospective cohort study of twenty patients, Stubblefield et al. (2010) evaluated the effectiveness of a dynamic jaw opening device for treating trismus in patients with head and neck cancer. The use of the Dynasplint Trismus System (DTS) as part of multimodal therapy including physical therapy, pain medications and botulinum toxin injections resulted in an overall improvement of the maximal interincisal distance (MID). Further prospective controlled clinical trials that directly compare DTS to other treatment modalities are needed.

A Hayes 2016 report focused on the use of the Jaw Dynasplint System for treatment of mandibular hypomobility found there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management.

Professional Societies

American Association for Dental Research (AADR)

Based on clinical evidence, 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).

According to the American Association of Oral and Maxillofacial Surgeons Criteria for Orthognathic Surgery (2017), subsection on Facial Skeletal Discrepancies Associated with Documented Temporomandibular Joint Pathology. "It is evident that, 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."

American Society of Temporomandibular Joint Surgeons (ASTJS)

Alloplastic implants are not generally indicated for initial surgical treatment of joints with internal derangement/osteoarthritis. Prosthetic joint replacement may be indicated in selected patients with severe joint degeneration, destruction or ankylosis (ASTJS, 2001).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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/cfPMN/pmn.cfm>. (Accessed October 10, 2017)

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 October 10, 2017)

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/pmnmn.cfm>. (Accessed October 10, 2017)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2017T0079W]

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
04/01/2018	<ul style="list-style-type: none"> Revised coverage rationale; replaced reference to "MCG™ Care Guidelines, 21st edition, 2017" with "MCG™ Care Guidelines, 22nd edition, 2018" Archived previous policy version DENTAL 008.17 T2