

TEMPOROMANDIBULAR JOINT DISORDERS

Policy Number: 2014T0079N

Effective Date: April 1, 2014

Table of Contents	Page	Related Medical Policies:
BENEFIT CONSIDERATIONS	1	<ul style="list-style-type: none"> • Manipulative Therapy • Manipulation Under Anesthesia • Sodium Hyaluronate
COVERAGE RATIONALE	3	
APPLICABLE CODES	4	
DESCRIPTION OF SERVICES	5	Related Drug Policy: <ul style="list-style-type: none"> • Botulinum Toxins A and B
CLINICAL EVIDENCE	5	
U.S. FOOD AND DRUG ADMINISTRATION	14	Related Coverage Determination Guideline: <ul style="list-style-type: none"> • Orthognathic and Jaw Surgery
CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)	15	
REFERENCES	15	
POLICY HISTORY/REVISION INFORMATION	19	

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, 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 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.

BENEFIT CONSIDERATIONS

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

Many Certificates of Coverage and many Summary Plan Descriptions 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 benefit document. In all cases, state mandates and the enrollee-specific

benefit document must be reviewed in order to determine enrollee-specific benefit coverage for treatment of TMJ disorders.

Indications for Coverage

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

1. Evaluations, consultations (including pain management consultations), office visits, and examinations
2. Diagnostic testing (e.g., panoramic x-ray, arthrography) *[Note that advanced imaging (MRI, CT scan, etc.) is subject to current utilization review guidelines and the applicable notification process]*
3. Arthrocentesis, TMJ
4. Arthroplasty, TMJ
5. Arthroscopy, TMJ
6. Arthrotomy, TMJ
7. TMJ splints / biteplates (includes dental casts*)
8. Trigger point injections
9. Sodium hyaluronate for TMJ (*Refer to the medical policy titled [Sodium Hyaluronate](#)*)
10. Injections of corticosteroids (See [Coverage Rationale](#) section below)
11. Physical therapy for TMJ
12. FDA approved TMJ implants (*These may be covered when all other treatment has failed; this is subject to clinical review*)

* See the *Supply Reimbursement Policy*.

Coverage Limitations and Exclusions

When a plan excludes coverage for TMJ, all services for TMJ 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 (ie: M.D., D.O., D.C., D.M.D., D.D.S., 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.

1. Unproven services for TMJ
2. Acupuncture for TMJ (See [Additional Information](#) below)
3. Alloplastic implants / TMJ implants
4. Arthrocentesis, TMJ
5. Arthroplasty, TMJ
6. Arthroscopy, TMJ
7. Arthrotomy, TMJ
8. Biofeedback for TMJ (*Not covered even when plan covers TMJ services; also, see [Coverage Rationale](#) section below*)
9. Chiropractic treatment for TMJ (See [Additional Information](#) below)
10. Computerized mandibular scan or jaw tracking for TMJ (*Not covered even when plan covers TMJ services*)
11. Craniosacral therapy/manipulation for TMJ (*Not covered even when plan covers TMJ services; also, see [Coverage Rationale](#) section below*)
12. Dental braces or other orthodontics for TMJ (*Not covered even when plan covers TMJ services*)
13. Dental casts for TMJ
14. Dental restoration work (crowns, bridges) for TMJ (*Not covered even when plan covers TMJ services*)
15. Diagnostic testing (e.g., panoramic x-ray, arthrography) for TMJ

16. Doppler analysis for TMJ (*Not covered even when plan covers TMJ services*)
17. Evaluations (consultations, office visits, examinations) for TMJ
18. Injections of corticosteroids for TMJ
19. Mental health counseling for TMJ (*Not covered even when plan covers TMJ services; see [Additional Information](#) below*)
20. Occlusal adjustment / grinding down teeth for TMJ (*Not covered even when plan covers TMJ services*)
21. Physical therapy for TMJ
22. Surface electromyography for TMJ (*Not covered even when plan covers TMJ services*)
23. TMJ splints / biteplates
24. Trigger point injections for TMJ
25. Sodium hyaluronate for TMJ
26. Vibration analysis for TMJ (*Not covered even when plan covers TMJ services*)

Additional Information

Please note the following clarifications:

1. Acupuncture for TMJ is not covered even if a plan has an acupuncture benefit. Rationale: TMJ exclusion overrides the acupuncture benefit.
2. Manipulative treatment for TMJ (chiropractic or osteopathic) is not covered even if a plan has a manipulative treatment benefit. Rationale: TMJ exclusion overrides the manipulative treatment benefit.
3. 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.
4. For mental health service, please refer to enrollee plan documents for possible mental health benefits.

COVERAGE RATIONALE

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

- Arthrocentesis
- Arthroplasty [See MCG™ Care Guidelines®, 18th edition, 2014, 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 the Dynasplint system discussed below*)

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

Not all services treat all TMJ disorders; specific treatments are based upon the specific diagnosis.

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

- Biofeedback
- Craniosacral manipulation

- Passive rehabilitation therapy
- Low-load prolonged-duration stretch (LLPS) devices such as the Dynasplint system

There are limited studies evaluating biofeedback for the treatment of musculoskeletal pain, including TMJ pain. One small uncontrolled study reported positive effects, while a larger randomized controlled study failed to demonstrate any treatment effect.

Well-designed randomized, blinded and placebo-controlled outcome studies published on craniosacral manipulation for TMJ are not available. For additional information regarding manipulation under anesthesia for TMJ disorders, see the Manipulation Under Anesthesia medical policy.

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 temporomandibular joint (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 codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

Proven/Medically Necessary CPT® Code	Description
20605	Arthrocentesis, aspiration and/or injection; intermediate joint or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa)
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
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
97039	Unlisted modality (specify type and time if constant attendance)

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

Unproven/Not Medically Necessary CPT® Code	Description
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21089	Unlisted maxillofacial prosthetic procedure
90901	Biofeedback training by any modality

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Proven/Medically Necessary HCPCS Code	Description
J0702	Injection, betamethasone acetate 3 mg and betamethasone sodium phosphate 3 mg
J2650	Injection, prednisolone acetate, up to 1 ml
J3303	Injection, triamcinolone hexacetonide, per 5 mg
S8262	Mandibular orthopedic repositioning device, each

Unproven/Not Medically Necessary HCPCS Code	Description
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 set of conditions that affect the temporomandibular joint (TMJ) or the surrounding muscle involved in chewing. Symptoms include pain at rest and/or during jaw function, limited range of mandibular movement and TMJ noises. TMD can be categorized into disorders that affect the masticatory musculature (masticatory muscle disorders) and disorders that directly affect the TMJ itself (TMJ articular disorders). A number of noninvasive and invasive treatment options have been used to treat TMD patients. Since the underlying causes of the various disorders remain unknown, many of these treatments are nonspecific and palliative (ECRI, 2011).

Initial treatment may include conservative measures 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.

Mandibular hypomobility is a condition in which the patient lacks normal range of motion (ROM) in the TMJ. Limited jaw mobility may be related to problems with the jaw joint itself or the surrounding muscles. This condition is also known as trismus. Limited jaw mobility may be idiopathic or due to disease, trauma or radiation for cancer treatment of nearby structures. Loss of mobility in the TMJ may result in pain and/or difficulty eating (ECRI, 2011).

Devices used for passive rehabilitation of the TMJ following surgery or for treatment of mandibular hypomobility include continuous passive motion (CPM) devices. Other types of passive rehabilitation are available, including the Therabite Jaw Motion Rehabilitation System.

CLINICAL EVIDENCE

Temporomandibular Joint Disorders Surgery

A small number of TMJ patients will fail to spontaneously improve or benefit from conservative

therapy. Patients with confirmed intra-articular disorder and intolerable symptoms are candidates for surgical treatment. Surgical treatment can either be done as an open joint or arthroscopic procedure.

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.

Several trials have addressed arthrocentesis. Dolwick et al. (1994) reported on 46 patients who underwent arthrocentesis with lavage, at average follow up of 21 months. The authors reported "encouraging findings" with regard to improved range of motion, function, and reduced pain. Cascone reported findings at average follow up of 24 months, on 10 patients who underwent arthrocentesis (Cascone, 1998). They found that arthrocentesis was a simple intervention which was well-accepted by patients, and resulted in clear improvement in symptoms of pain and impaired function. Goudot et al. (2000) and Sanroman et al. (2004) concluded that arthroscopy and arthrocentesis had good results for functional treatment and pain control.

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.

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.

A study by Goncalves et al. (2008) evaluated 72 patients for the effect of disc displacement and articular disc repositioning on stability after surgical counterclockwise rotation and advancement

of the maxillomandibular complex. The patients were divided into 3 groups. Group 1 (G1; n = 21), with healthy temporomandibular joints (TMJs), underwent double-jaw surgery only. Group 2 (G2; n = 35), with articular disc dislocation, underwent articular disc repositioning using the Mitek anchor technique concomitantly with orthognathic surgery. Group 3 (G3; n = 16), with articular disc dislocation, underwent orthognathic surgery only. Average postsurgical follow-up was 31 months. After surgery, the occlusal plane angle was decreased significantly in all 3 groups: by -6.3 +/- 5.0degrees in G1, by -9.6 +/- 4.8degrees in G2, and by -7.1 +/- 4.8degrees in G3. The maxillomandibular complex was advanced and rotated counterclockwise similarly in all 3 groups, with advancement at the menton of 12.4 +/- 5.5 mm in G1, 13.5 +/- 4.3 mm in G2, and 13.6 +/- 5.0 mm in G3; advancement at the B point of 9.5 +/- 4.9 mm in G1, 10.2 +/- 3.7 mm in G2, and 10.8 +/- 3.7 mm in G3; and advancement at the lower incisor edge of 7.1 +/- 4.6 mm in G1, 6.6 +/- 3.2 mm in G2, and 7.9 +/- 3.0 mm in G3. Postsurgery, the occlusal plane angle increased in G3 (2.6 +/- 3.8degrees; 37% relapse rate) but remained stable in G1 and G2. Postsurgical mandibular changes in the horizontal direction demonstrated a significant relapse in G3 at the menton (-3.8 +/- 4.1 mm; 28%), the B point (-3.0 +/- 3.4 mm; 28%), and the lower incisor edge (-2.3 +/- 2.1 mm; 34%) but remained stable in G1 and G2. The authors concluded that maxillomandibular advancement with counterclockwise rotation of the occlusal plane is a stable procedure for patients with healthy TMJs and for patients undergoing simultaneous TMJ disc repositioning using the Mitek anchor technique. Those patients with preoperative TMJ articular disc displacement who underwent double-jaw surgery and no TMJ intervention experienced significant relapse.

Mehra and Wolford (2001) conducted a study of 105 patients (188 discs) to evaluate treatment outcomes using the Mitek mini anchor for temporomandibular joint (TMJ) articular disc repositioning surgery, with 88 patients having simultaneous orthognathic surgery. Criteria for inclusion into the study were: (1) presurgical TMJ disc displacement with salvageable disc; (2) no prior TMJ surgery; (3) TMJ disc repositioning with the Mitek mini anchor; (4) absence of connective tissue/autoimmune disease; (5) absence of postsurgical trauma; and (6) minimum of 12 months postsurgery follow up. Presurgery (T1), immediately postsurgery (T2), and longest follow up (LFU) clinical and radiographic evaluations were performed. The mean age of the patients was 32.6 years (range 14-57 years), and mean follow-up time was 46.2 months (range 14-84 months). Radiographic evaluation at LFU demonstrated no significant condylar resorption or positional changes of the anchors. At LFU, there was a statistically significant reduction in: TMJ pain, facial pain, headaches, TMJ noises and disability, and improvement in jaw function and diet. Maximum incisal opening improved slightly and lateral excursive movements decreased slightly. The authors concluded that the Mitek mini anchor provides a predictable method for stabilizing the TMJ articular disc to the condyle and a high success rate in decreasing TMJ dysfunction and pain in patients with no previous TMJ surgery.

Holmlund et al. (2001) conducted an RCT comparing arthroscopic lysis and lavage to discectomy in 22 patients with chronic closed lock (disc displacement with reduction). At the one year follow-up, both treatments significantly reduced pain and dysfunction. Miyamoto et al. (1999) conducted a RCT comparing the efficacy of arthroscopic lysis and lavage to lysis and lavage and anterolateral capsular release in a group of patients with various stages of disc displacement without reduction. Both variations of the procedure generated high success rates in terms of reduced pain and increased jaw movement with no significant difference in the success rates for the two treatments. A meta-analysis completed by Reston (2003) supports the effectiveness of arthrocentesis and arthroscopy for patients with disc displacement without reduction. There is insufficient evidence in the peer reviewed literature to establish the efficacy of arthroscopic procedures in the treatment of osteoarthritis, capsulitis and rheumatoid arthritis.

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.

Open joint procedures include discectomy, arthroplasty, disc repositioning, total joint replacement and condylectomy. According to the American Association of Oral and Maxillofacial Surgeons Criteria for Orthognathic Surgery (2008), 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."

Orthognathic surgery is defined by the American Association of Oral and Maxillofacial Surgeons (AAOMS) as surgery performed to correct facial imbalances caused by abnormalities of the jaw bones. It is the surgical correction of abnormalities of the mandible, maxilla or both. The underlying abnormality may be present at birth or may become evident as the patient grows and develops or may be the result of traumatic injuries. TMJ symptoms have been associated with a variety of orthognathic deformities. In some patients, skeletal malocclusion and TMJ disorders may be correlated. Prior to performing an orthognathic procedure on patients with TMJ disorders, non-surgical therapies are usually attempted. Orthognathic surgery is not usually performed solely to correct a TMJ disorder. Published clinical evidence indicates that orthognathic surgery performed to treat a coexisting jaw disorder has resulted in improvement in TMJ function in approximately 80% of patients (AAOMS, 2008). Although sometimes indicated, orthognathic surgery is very rarely recommended for TMJ disorders and it is estimated that fewer than 1% of all patients with symptomatic TMJ disorders require orthognathic surgical intervention (Prater, 1998).

In a nonrandomized retrospective study, Trumpy et al. (1995) reviewed the results of three surgical arthrotomy techniques: discoplasty (n=13), discectomy without replacement n=17), and discectomy with replacement with the Proplast/Teflon implant (n=12). In the discoplasty group, 10/13 reported subjective symptom improvement at average 83 months postoperative. Six patients were experiencing clicking only in the operative joint, and an additional four patients had both clicking and crepitation. MRI demonstrated anterior disc displacement in four patients, and five scans were inconclusive. Osteoarthritic changes were present in eight patients. Six patients demonstrated an increase in maximum interincisal distance. In the discectomy group, 16/17 patients reported subjective symptom improvement at average 69 months postoperative. One patient had clicking only, 11 had crepitation only, and 5 patients had both clicking and crepitation. Osteoarthritic changes were present in 16 patients, and 10 patients had an increase in mouth opening. In the patients who underwent discectomy with Proplast/Teflon implant, at an average interval of 64 months, 10 patients reported subjective symptom improvement. Four patients had clicking only, one had crepitation only, and two had both clicking and crepitation. Osteoarthritic changes were observed in all 12 patients, and 7 patients achieved increased maximum mouth opening.

None of the observed differences among these groups were statistically significant. The authors concluded that discectomy was the preferred procedure, basing their conclusions on 1) greater relapse rate observed in the discoplasty group, and 2) structural failure in the Proplast/Teflon implant appeared to increase the rate of osteoarthritic degeneration. (The FDA subsequently recalled the device).

In a similar study, Holmlund et al. (1993) evaluated the results at five years, of discectomy on 13 patients available (of 72 patients who were operated on). No patients reported joint pain, but all

patients (13) reported crepitation. Holmlund's conclusions were in agreement with Trumpy's that discectomy was an acceptable procedure that might benefit patients with internal derangements, degenerative joint disease and rheumatoid arthritis.

Sato et al. (2003) concluded that the clinical outcomes of arthroscopic eminoplasty procedures are as effective as those obtained with conventional open eminectomy.

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.

Surgical replacement of jaw joints with artificial implants may cause severe pain and permanent jaw damage. Some of these devices may fail to function properly or may break apart in the jaw over time (National Institutes of Health, 2010).

Current evidence on the efficacy of total prosthetic replacement of the temporomandibular joint (TMJ) in the short and medium term is adequate, but the quantity of evidence on long-term efficacy and on safety is inadequate. Patient selection should be carried out in specialist units by a team with regular practice and specialist expertise in the conservative and surgical management of TMJ problems, and should include consideration of all relevant surgical and medical options. The procedure should be carried out only by surgeons with specific training and experience in total prosthetic replacement of the TMJ (NICE, 2009).

One hundred ninety-eight patients underwent total TMJ reconstruction with a TMJ Concepts prosthesis. Patients were divided into 4 groups based on prior exposure to failed implants: group I, Proplast-Teflon (82 patients, 135 joints); group II, Silastic (28 patients, 46 joints); group III, both Proplast-Teflon and Silastic (25 patients, 46 joints); and group IV, no prior exposure to Proplast-Teflon or Silastic (63 patients, 105 joints). Follow-up ranged from 2 to 120 months. The authors found that multiply operated patients previously exposed to failed Proplast-Teflon alone or both failed Proplast-Teflon and Silastic implants have poorer reported long-term outcomes with alloplastic joint reconstruction (Mercuri, 2004).

Wolford et al. (2003) conducted a prospective study evaluating TMJ reconstruction using the TMJ Concepts/Techmedica custom made total joint prosthesis. Thirty-eight of 42 patients (90%) with 69 TMJs reconstructed were included in the study. The average follow-up was 73.5 months. Patients were divided into three groups according to the number of previous TMJ surgeries and previous use of Proplast or Silastic implants. Due to the small sample size, no valid statistical comparison could be used on groups one and two; therefore, all three groups were combined into one for statistical analysis. Patients were objectively evaluated for incisal opening, lateral excursions and occlusal stability, while subjectively assessed for pain and jaw function. For the group of 38 patients, there was statistically significant improvement in incisal opening ($P=0.001$), jaw function ($P=0.001$) and pain level ($P=0.0001$). Lateral excursion movements significantly decreased ($P=0.04$). The occlusion remained stable in all cases. Five patients required additional surgery. Comparison analysis of the three groups demonstrated significantly better outcomes for patients with fewer previous TMJ surgeries and without exposure to Proplast or Silastic implants. This study is limited by small sample size and lack of randomization and control.

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.

A 2013 statement by the American Association of Oral and Maxillofacial Surgeons lists partial or total joint reconstruction (e.g. autogenous graft, allogeneic graft and alloplastic implant) as an

indicated therapy for temporomandibular disorders, but does not specify under what circumstances this procedure is appropriate.

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 limitation of this study is small sample size.

AAOMS Parameters of Care (2012) lists total alloplastic or autogenous joint replacement as a treatment option for degenerative joint disease, rheumatoid arthritis, infections arthritis, recurrent or persistent mandibular dislocation, and ankylosis and restricted jaw motion.

Injections

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

In patients with rheumatoid arthritis of the TMJ, corticosteroid injections resulted in pain reduction in 75.6% of patients as compared to the hyaluronic acid group (19.6%) and the placebo group (17.8%) (Kopp, 1991).

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.

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.

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, to keep the jaw in a more relaxed position or provide some other function. Stabilization splints are believed to function by stabilizing the intra-capsular structure of the TMJ. Repositioning splints alter joint loading and create a change of mandibular position allowing the disc tissue to heal and the condyle to return to its original position (Attanasio, 1997; Dimitroulis, 1995).

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.

A review of the literature for splint therapy is hampered by the overall lack of studies concerning this treatment modality and the lack of identification of the type of splint used and the type of disc displacement treated. For example, Tecco et al. (2004) concluded in their study of 40 patients that the repositioning splint was effective with a decrease in pain 8 months after treatment in 20 patients. However, this study did not identify the type of internal derangement present. Splint therapy appears to be beneficial for individuals with disc displacement with reduction and capsulitis. A meta-analysis of documentation from 1985-1996 was completed by Santacatterina et al. (1998) concluded that the statistical comparison between the horizontal splint and repositioning splint used in treatment for disc dislocation with reduction, demonstrated that the repositioning splint was more effective in the resolution of the articular click and pain. A study using MRI confirmation of anterior disc displacement with reduction found that both types of splints were useful in eliminating pain and clicking, but the stabilization splint was superior to the repositioning splint (Ekberg, 1998). One well designed RCT concludes that stabilization splints resulted in 76% improvement in the treatment of patients with capsulitis/synovitis as compared to the controlled group receiving a sham appliance (Ekberg, 1998).

An 18 year follow-up study was conducted by Capurso and Marini (2007) in which 68 patients treated with occlusal orthodontic therapy were evaluated. At the end of treatment there was a significant improvement of the mandibular function. In the course of the 18-year period subsequent to the treatment only minor relapse of symptoms/signs was noted; spontaneous pain was present in 13 patients, with a pain intensity of TMJ level significantly lower than at baseline ($p < 0.001$). Clicking was present systematically in 3 patients and only occasionally in 19 patients ($p < 0.001$). A relapse of condylar dislocation was found only in 11 cases at the X-ray examination. The authors therefore concluded that patients would benefit from permanent occlusal orthodontic treatment if pain from disc displacement is present, particularly if patients need that for malocclusion and if orthopaedic joint instability is present after a change in the mandibular positioning with a stabilization splint.

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.

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.

The clinical evidence was reviewed on September 23, 2013 with no additional information identified that would change the unproven conclusion.

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).

Clinical evidence does not support the use of craniosacral therapy as randomized, blinded and placebo controlled outcome studies have not been published to establish its efficacy. According to the British Columbia Office of Health Technology Assessment and other authors, the theory is invalid and practitioners cannot reliably measure the claimed outcomes. There is no evidence to substantiate that the bones of the head can be manipulated and that this manipulation will treat, alter, or cure a disorder of any nature (Hartman, 2002; Kazanjian, 1999).

The clinical evidence was reviewed on September 23, 2013 with no additional information identified that would change the unproven conclusion.

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, 2013).

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 website).

TMJ Association

Replacement of the temporomandibular joint with an artificial implant should be considered a last resort. When used in patients who have had multiple prior jaw surgeries it may improve function, but studies have shown that it generally does not significantly reduce pain. Before undergoing such surgery on the jaw joint, it is extremely important to get other independent opinions and to fully understand the benefits and risks (TMJ Association website, 2012).

Mandibular Hypomobility

Passive Rehabilitation

Limited published studies are available on the use of passive rehabilitation for the treatment of jaw hypomobility.

One small randomized controlled study (Kuwahara, 1996) and one very small case series report (Sebastian, 1989) evaluated the effects of passive rehabilitation on clinical outcomes, including

chewing pattern and maximal incisal opening, after temporomandibular joint (TMJ) surgery. They reported significant increase in maximal incisal opening and restoration of normal chewing motion. A third study, also a small case series by Lemke (1993), reported electromyographic confirmation of muscle passivity during jaw continuous passive motion (CPM). Two other studies, both small randomized trials, compared the effect of passive jaw movement with that of active exercise on jaw mobility, as indicated by maximal incisal opening, in patients who had undergone radiation therapy following surgery for cancer of the head or neck (Buchbinder, 1993), or who had TMJ disease (Maloney, 2002). Both of these studies demonstrated significantly greater increase in maximal interincisal opening distance for patients using the Therabite device compared with standard passive jaw rehabilitation therapy modalities. Duration of treatment varied among the studies, with follow-up ranging from 4 to 10 weeks.

McNeely et al. (2006) conducted a qualitative review that included two studies that examined the use of therapeutic exercise interventions (i.e. TheraBite) in patients with myogenous TMD. Both studies found that a reduction in pain and increase in range of motion were achieved with the device. However, how the results achieved using the device compare to those achieved with the standard of care (i.e. control) is unclear. The authors of the review state that interpretation of the studies' results warrant caution, as "most of the studies included in this review were of very poor methodological quality."

Dijkstra et al. (2006) conducted a retrospective study evaluating the effects of exercise therapy on trismus. Twenty-seven patients with trismus related to head and neck cancer and eight patients with trismus not related to cancer underwent exercise therapy with active range of motion exercises, hold relax techniques, manual stretching, and joint distraction. Mouth opening increased significantly after exercise therapy. The increase in mouth opening was significantly higher for patients with trismus not related to cancer.

Cohen et al. (2005) conducted an uncontrolled study of 7 patients who received a Therabite jaw mobilization device after surgery for oropharyngeal carcinoma. Six of these patients also underwent preoperative or postoperative radiation therapy. Average gain in maximal interincisor opening was 10 mm. Two patients could not be located for follow-up.

Dijkstra et al. (2004) evaluated the use of device-assisted stretching for mandibular hypomobility after head or neck radiation therapy. Twelve studies were reviewed, and the authors concluded that Therabite devices or tongue blades significantly increase mouth openings; however, the results achieved with Therabite as compared to standard stacked tongue depressors were not indicated. The quality of the 12 studies was rated as moderate to poor.

The clinical evidence was reviewed on September 23, 2013 with no additional information identified that would change the unproven conclusion.

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.

Shulman et al. (2008) retrospectively evaluated the effect of the Dynasplint Trismus System in 48 patients diagnosed with trismus following radiation therapy, dental treatment, oral surgery or stroke. The cohort case series showed that there was a statistically significant difference in maximal interincisal distance (MID) for all patient groups, but no significant difference was observed between groups. This study is limited by small sample size, lack of a control group and a lack of randomization.

The clinical evidence was reviewed on September 23, 2013 with no additional information identified that would change the unproven conclusion.

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/cfPMA/pma.cfm>. Accessed September 23, 2013.

TMJ Concepts total TMJ Prosthesis received premarket approval (P980052) on July 2, 1999. The device is indicated for reconstruction of the temporomandibular joint for use in patients with one or more of the following conditions: inflammatory arthritis involving the temporomandibular joint not responsive to other modalities of treatment; recurrent fibrous and/or bony ankylosis not responsive to other modalities of treatment; failed tissue graft; failed alloplastic joint reconstruction; and loss of vertical mandibular height and/or occlusal relationship due to bone resorption, trauma, developmental abnormality, or pathologic lesion. See the following website for further information.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpm/pma.cfm?id=8444> Accessed September 23, 2013.

TMJ Fossa-Eminence/Condylar Prosthesis received premarket approval (P000023) on January 5, 2001. The device is indicated for reconstruction of the natural temporomandibular joint (TMJ). The device is indicated if patients have one of more of the following conditions: inflammatory arthritis involving the temporomandibular joint not responsive to other modalities of treatment; recurrent fibrous and/or bony ankylosis not responsive to other modalities of treatment; failed tissue graft; failed alloplastic joint reconstruction; loss of vertical mandibular height and/or occlusal relationship due to resorption, trauma, developmental relationship due to bone resorption, trauma, developmental abnormality, or pathologic lesion. See the following website for further information.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpm/pma.cfm?id=8186> Accessed September 23, 2013

TMJ Fossa-Eminence Prosthesis received premarket approval (P000035) on February 27, 2001. The device is indicated for partial joint reconstruction for use in treatment of severe temporomandibular joint disease due to: inflammatory arthritis involving the temporomandibular joint not responsive to other modalities of treatment; recurrent fibrosis and/or bony ankylosis not responsive to other modalities of treatment; failed tissue graft; failed alloplastic joint reconstruction; and internal derangement confirmed to be pathologic in origin by both clinical observation and radiographic findings, where the patient has moderate to severe pain and/or disabling dysfunction and has not responded to less invasive conventional therapy. See the following website for further information.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpm/pma.cfm?id=8187> Accessed September 23, 2013.

Biomet (formerly Walter Lorenz) total TMJ Replacement System received premarket approval (P020016) on September 21, 2005. The device is indicated for reconstruction of the temporomandibular joint when the reconstruction is necessary due to one of the following diagnoses: 1) arthritic conditions: osteoarthritis, traumatic arthritis, rheumatoid arthritis, 2) ankylosis including but not limited to recurrent ankylosis with excessive heterotopic bone formation, 3) revision procedures where other treatments have failed (e.g., alloplastic reconstruction, autogenous grafts), 4) avascular necrosis, 5) multiple operated joints, 6) fracture, 7) functional deformity, 8) benign neoplasms, 9) malignancy (e.g., post-tumor excision), 10) degenerated or resorbed joints with severe anatomic discrepancies, and 11) developmental abnormality. See the following website for further information.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=21134>. Accessed September 23, 2013.

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. The OIC model J4 TMJ CPM unit (August 5, 1992) and FMA Translator (August 7, 1991) have received 510(k) approval for treatment of the jaw. Additional information, under product code BXB, is available at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. Accessed September 23, 2013

In March 1996, the FDA determined that the Therabite Jaw Motion Rehabilitation System was non-measuring exercise equipment and therefore a class I device, exempt from all but general recording and complaint files regulations. Additional information, under product code ION, is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. Accessed September 23, 2013.

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/pmnm.cfm>. Accessed September 23, 2013.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) specific for the treatment of temporomandibular joint (TMJ) syndrome. Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for [Arthrocentesis](#), [Oral Maxillofacial Prosthesis](#) and [Surgical Treatment of Obstructive Sleep Apnea \(OSA\)](#).

Medicare covers the manipulation of the occipitocervical or temporomandibular regions of the head when indicated for conditions affecting those portions of the head and neck. Refer to the NCD for [Manipulation \(150.1\)](#). LCDs do exist; refer to the LCDs for [Noncovered Services](#)

Medicare does not have a NCD for passive rehabilitation therapy for mandibular hypomobility. Local Coverage Determinations (LCDs) do not exist at this time.

Medicare does not have a NCD for Jaw Motion Rehabilitation Systems. Local Coverage Determinations (LCDs) do not exist at this time. Refer to the DMERC Jurisdiction List for DME POS HCPCS Codes for TMJ devices and supplies at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2637CP.pdf>.

Refer to the Medicare Benefit Policy Manual (Pub 110-2) Chapter 15, §150.1 – Treatment of Temporomandibular Joint Syndrome and §50 - Drugs and Biologicals at <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf> for additional information. (Accessed September 13, 2013)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
04/01/2014	<ul style="list-style-type: none">• Replaced references to “MCG™ Care Guidelines, 17th edition, 2013” with “MCG™ Care Guidelines, 18th edition, 2014” (effective 04/01/14)• Archived previous policy version 2014T0079M