Clinical Policy Bulletin: Temporomandibular Disorders

Revised February 2015

Number: 0028

Policy

Notes: Most Aetna HMO plans exclude coverage for treatment of temporomandibular disorders (TMD) and temporomandibular joint (TMJ) dysfunction, and may also exclude coverage for other services described in this bulletin (e.g., non-surgical management) The plan determines the scope of coverage. Please check benefit plan descriptions for details.

For plans that cover treatment of TMD and TMJ dysfunction, requests for TMJ surgery require review by Aetna's Oral and Maxillofacial Surgery patient management unit. Reviews must include submission of a problem-specific history (i.e., Aetna Temporomandibular Disorder Questionnaire) and physical examination, TMJ radiographs/diagnostic imaging reports, patient records reflecting a complete history of 3 to 6 months of non-surgical management (describing the nature of the non-surgical treatment, the results, and the specific findings associated with that treatment), and the proposed treatment plan. The provider will be notified of the coverage decision after review of all pertinent data.

I. Non-Surgical Management

Comprehensive non-surgical management of TMJ/TMD includes all of the following, unless contraindicated:

A. Reversible Intra-Oral Appliances: (i.e., occlusal orthopedic appliances-orthotics, occlusal splints, bite appliances/planes/splints, mandibular occlusal repositioning appliances [MORAs])

Reversible intra-oral appliances may be considered medically necessary in selected cases only when there is evidence of clinically significant masticatory impairment with documented pain and/or loss of function. Prolonged (greater than 6 months) application of TMD/J intra-oral appliances is not considered medically necessary unless, upon individual case review, documentation is provided that supports prolonged intra-oral appliance use. Note: Appliances for
bruxism are typically excluded under Aetna medical plans (please check benefit plan descriptions), but may be covered under dental plans. Only 1 oral splint or appliance is considered medically necessary for TMD/TMJ therapy.

For plans that cover intra-oral appliances, adjustments of intra-oral appliances performed within 6 months of initial appliance therapy are considered medically necessary; while adjustments performed after 6 months are subject to review to determine necessity and appropriateness. More than 4 adjustments or adjustments that are done more than 1 year after placement of the initial appliance are subject to review. Note: Replacement of a lost, missing or stolen intra-oral appliance is not covered; while replacement (for other reasons) or repair is subject to review to determine necessity and appropriateness.

Note: Intra-oral appliances for the treatment of headaches or trigeminal neuralgia are considered experimental and investigational, as there is insufficient data on the effectiveness of this therapy. See CPB 0688 -- Intra-oral Appliances for Headaches and Trigeminal Neuralgia.

B. Physical Therapy:

Aetna considers physical therapy to be a medically necessary conservative method of TMD/TMJ treatment. Therapy may include repetitive active or passive jaw exercises, thermal modalities, manipulation, vapor coolant spray-and-stretch technique, and electro-galvanic stimulation. For manipulation under anesthesia for TMD/TMJ, see CPB 0204 - Manipulation Under General Anesthesia.

C. Pharmacological Management:

Non-opiate analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) are considered medically necessary for mild-to-moderate inflammatory conditions and pain. Low-dosage tricyclic antidepressants (e.g., amitriptyline) are considered medically necessary for treatment of chronic pain, sleep disturbance and nocturnal bruxism. Adjuvant pharmacologic therapies, including anticonvulsants, membrane stabilizers, and sympatholytic agents, are considered medically necessary for unremitting TMJ pain. Opiate analgesics, corticosteroids, anxiolytics, and muscle relaxants are considered medically necessary in refractory pain.

D. Relaxation Therapy and Cognitive Behavioral Therapy (CBT):

Aetna considers relaxation therapy, electromyographic biofeedback and cognitive behavioral therapy medically necessary for treatment of TMJ/TMD.

Relaxation therapy, electromyographic biofeedback, and cognitive behavioral therapy are considered medically necessary in chronic
headaches and insomnia, which are frequently associated with TMD/TMJ conditions. The above therapies may be considered medically necessary in treating these conditions as well. Treatment in multi-disciplinary pain centers may be considered medically necessary in those few individuals who have been unresponsive to less comprehensive interventions. See CPB 0237 - Chronic Pain Programs.

E. **Acupuncture and Trigger Point Injections:** (Note: some plans limit coverage of acupuncture only when used in lieu of surgical anesthesia. Please check plan benefit descriptions for details. See CPB 0135 - Acupuncture). Aetna considers acupuncture and trigger point injections medically necessary for persons with temporomandibular pain. For acute pain, generally 2 visits per week for 2 weeks are considered medically necessary. Additional treatment is considered medically necessary when pain persists and further improvement is expected.

F. **Manipulation for reduction of fracture or dislocation of the TMJ** is considered medically necessary.

II. Surgical Procedures:

Surgical procedures include therapeutic arthroscopy, arthrocentesis, condylotomy/eminectomy, modified condylotomy, arthroplasty, and joint reconstruction using autogenous or alloplastic materials. In general, the least invasive appropriate surgical treatments should be attempted prior to progression to more complicated surgeries. **Note:** All TMJ surgical precertification requests or claims are reviewed by Aetna's Oral and Maxillofacial Surgery (OMS) Patient Management Unit.

TMJ surgery may be considered medically necessary in cases where there is conclusive evidence that severe pain or functional disability is produced by an intra-capsular condition, confirmed by magnetic resonance imaging (MRI), computed tomography or other imaging, that has not responded to nonsurgical management, and surgery is considered to be the only remaining option. Nonsurgical management include three or more months of the following, where appropriate: professional physical therapy, pharmacological therapy, behavioral therapy (such as cognitive behavioral therapy or relaxation therapy), manipulation (for reduction of dislocation or fracture of the TMJ) and reversible intra-oral appliances (unless the member is unable to open mouth wide enough). In certain cases (e.g., bony ankylosis and failed TMJ total joint prosthetic implants) that require immediate surgical intervention, surgery may be considered medically necessary without prior non-surgical management. **Note:** All requests for surgery must include documentation that all medically appropriate non-surgical therapies noted above have been exhausted. Patients with chronic head and neck pain may be candidates for chronic pain assessment.

A. **Arthrocentesis with insufflation, lysis, and lavage** is considered medically necessary when imaging and clinical examination reveal
anchored disc phenomenon, anterior disc displacement without reduction and without effusion, osteoarthritis without fibrosis or loose bone particles, open lock, or hemarthrosis. Note: For purposes of this policy, arthrocentesis for TMJ internal derangement is defined as the insertion of two separate single-needle portals or a single double-needle portal for input and output of fluids. The process includes insufflation of the joint space, lavage, manipulation of the mandible for the purpose of lysis of adhesions, and the elective infusion of steroids.

B. Therapeutic arthroscopy is considered medically necessary when MRI or other imaging confirms the presence of adhesions, fibrosis, degenerative joint disease, or internal derangement of the disc that requires internal modification.

C. Open surgical procedures including, but not limited to meniscus or disc repositioning or plication, disc repair, and disc removal with or without replacement are considered medically necessary when TMJ dysfunction is the result of congenital anomalies, trauma, or disease in patients who have failed nonsurgical management.

D. Arthroplasty or arthrotomy includes: a) disk repair procedures; b) diskectomy with or without replacement; and c) articular surface recontouring (condylectomy and eminectomy or eminoplasty). Arthroplasty or arthrotomy is considered medically necessary when MRI or other imaging confirms the presence of any of the following:

1. Osteoarthritis or osteoarthrosis; or
2. Severe disc displacement associated with degenerative changes or perforation; or
3. Scarring that is severe and often the result of old injury or prior procedure

E. Aetna considers joint replacement with an FDA-approved prosthesis (including the TMJ Concepts prosthesis, the Christensen TMJ Fossa-Eminence Prosthesis System (partial TMJ prosthesis), the Christensen TMJ Fossa-Eminence/Condylar Prosthesis System (Christensen total joint prosthesis), or the W. Lorenz TMJ prosthesis) medically necessary when used as a “salvage device” for treatment of end-stage TMJ disease, when conservative management and other surgical treatment has been unsuccessful, and MRI or other imaging documents one or more of the following:

1. Temporal bone that no longer provides a smooth articular fossa; or
2. Damaged condyles that are no longer ball-shaped; or
3. Persistent, stable inflammatory arthritis that is not responsive to other modalities of treatment; or
4. Recurrent fibrous or bony ankylosis that is not responsive to other modalities of treatment; or
5. Loss of mandibular condylar height and/or occlusal relationship due to trauma, resorption, pathological lesion or congenital anomaly; or
6. Failed autologous bone graft or alloplastic reconstruction effort.

F. Autogenous grafts (e.g., costochondral, cartilage, dermal, fat, fascial and other autogenous graft materials) may be considered medically necessary upon individual case review. Autologous costochondral grafts are considered medically necessary when criteria for joint replacement (II.D.) are met or when there is congenital absence or deformity of the joint or for surgical reconstruction post head and neck tumor resection.

III. Aetna considers the following experimental and investigational for diagnosis and treatment of TMJ disorders:

A. Diagnostic procedures

1. Cephalometric or lateral skull x-rays
2. Computerized mandibular scan/kinesiography/electrogathograph/jaw tracking
3. Diagnostic study models
4. Electromyography (EMG), surface EMG (see CPB 0112 - Surface Scanning and Macro Electromyography)
5. Electronic registration (Myomonitor)
6. Joint vibration analysis
7. Muscle testing/range of motion measurements (incidental to examination)
8. Neuromuscular junction testing, somatosensory testing
9. Sonogram (ultrasonic Doppler auscultation)
10. Standard dental radiographic procedures
11. Thermography (see CPB 0029 - Thermography)

B. Non-surgical treatments

1. Botulinum toxin (type A or type B) (however, botulinum toxin type A is considered medically necessary for jaw-closing oromandibular dystonia -- see CPB 0113 - Botulinum Toxin)
2. Continuous passive motion (see CPB 0010 - Continuous Passive Motion (CPM) Machines)
3. Cranial (craniosacral) manipulation (see CPB 0388 - Complementary and Alternative Medicine)
4. Dental restorations/prostheses (see CPB 0082 - Dental Services and Oral and Maxillofacial Surgery: Coverage Under Medical Plans)
5. Diathermy, infrared, and ultrasound treatments
6. Dry needling
7. Hydrotherapy (immersion therapy, whirlpool baths)
8. Iontophoresis (see CPB 0229 - Iontophoresis)
9. Intra-articular injection of hyaluronic acid (viscosupplementation)
10. Intra-articular injection of platelet-rich plasma
11. Intraoral appliances for headache or trigeminal neuralgia (see CPB 0688 - Intra-oral Appliances for Headache and Trigeminal Neuralgia)

12. Irreversible occlusion therapy aimed at modification of the occlusion itself through alteration of the tooth structure or jaw position

13. Ketamine (local/intra-articular administration)

14. Low level (cold) laser (see CPB 0363 - Cold Laser and High-Power Laser Therapies)

15. Myofunctional therapy

16. Myomonitor treatment (J-4, BNS-40, Bio-TENS)

17. Neuromuscular re-education

18. Orthodontic/bite adjustment services and orthodontic fixed appliances (see CPB 0095 - Orthognathic Surgery; and CPB 0082 - Dental Services and Oral and Maxillofacial Surgery: Coverage Under Medical Plans)

19. Prophylactic management of TMJ disorder, including occlusal adjustment

20. Radiofrequency generator thermolysis (see also CPB 0400 - Ernest or Eagle's Syndrome (Stylomandibular Ligament Pain): Treatment with Radiofrequency Thermoneurolysis)

21. Therabite Jaw Motion Rehabilitation System (see CPB 0412 - Therabite Jaw Motion Rehabilitation System)

22. Transcutaneous electrical nerve stimulation (TENS) (see CPB 0011 - Electrical Stimulation for Pain)

C. Surgical treatments

1. Orthognathic surgery (see CPB 0095 - Orthognathic Surgery)

2. Treatment of alveolar cavitational osteopathosis (see CPB 0642 - Neuralgia Inducing Cavitational Osteonecrosis (NICO) and Ultrasonograph Bone Densitometer to Detect NICO)

Background

Although the precise etiology of temporomandibular joint (TMJ) syndrome and temporomandibular joint disorder (TMD) has not yet been identified, these conditions are believed to be the result of either "macro" or "micro" trauma affecting the joint and/or the associated facial musculature. Macro-trauma is usually historically obvious (e.g., acute joint overload), and there is generally a documented history of direct trauma to the TMJ. Micro-trauma is a chronic and insidious process, multi-factorial in presentation, and commonly associated with para-functional habits, stress and anxiety, sleep disorders, dysfunctional occlusion, and various myofascial conditions (e.g., fibromyalgia).

The etiology of temporomandibular disorders are intracapsular or extracapsular. Intracapsular abnormalities consist of internal derangements, including anterior disc displacement with or without reduction, disc perforation or fragmentation leading to degenerative joint disease, rheumatoid arthritis, synovitis, and
neoplasia. Extracapsular abnormalities consist of myalgia or myospasm which may be related to trauma or parafunctional habits such as bruxism, tooth pain, or postural abnormalities.

The diagnosis of TMD is largely based upon the symptoms of pain and signs of TMD (e.g., joint sounds, variations from ideal disc position, clicking). These signs may also be found in large segments of the general population without evidence of impairment or dysfunction. According to available literature, specialized radiological studies (e.g., cephalometric x-rays, tomograms, submental vertex radiographs) are not medically necessary in evaluating persons with TMD unless surgery is being considered.

The extent of internal derangements is often determined by magnetic resonance imaging (MRI). MRI is useful for assessing disc morphology, disc fragmentation, and the disc-condylar relationship, especially where the patient is in a closed lock with a limited oral opening. Limchaichana et al (2006) assessed the evidence for the effectiveness of MRI in the diagnosis of disk position and configuration, disk perforation, joint effusion, and osseous and bone marrow changes in the TMJ. Two reviewers evaluated the level of evidence of relevant publications as high, moderate, or low. Based on this, the evidence grade for diagnostic efficacy was rated as strong, moderately strong, limited, or insufficient. The literature search yielded 494 titles, of which 22 were relevant. No publication had a high level of evidence, and 12 had moderate and 10 low levels of evidence. The evidence grade for diagnostic efficacy expressed as sensitivity, specificity, and predictive values was insufficient. The authors concluded that evidence for the effectiveness of MRI is insufficient; and it emphasizes the need for high-quality studies on the diagnostic efficacy of MRI, incorporating accepted methodological criteria.

Therapy of TMD varies considerably according to the particular training, discipline and experience of the clinician. This variation in clinical practice is due, in part, to a paucity of evidence-based outcome research and lack of consensus on the appropriate management of TMD. Scientifically valid clinical trials are lacking for the vast majority of therapies that are currently employed. There are also no objective, generally accepted, diagnostic standards to correctly identify when a TMD is present.

The appropriate diagnosis and treatment of TMD is complicated by a high incidence of TMD/TMJ signs and symptoms that are associated with systemic disorders. These usually represent local or regional manifestations of chronic, global, musculoskeletal pain conditions, such as fibromyalgia, systemic myofascial pain and chronic fatigue syndrome. While an association with headaches has been identified, a causal relationship between TMD/TMJ and headaches has not been established. These conditions occur coincidentally and may be produced by etiologic factors that are common to both.

The National Institutes of Health emphasizes the importance of 2 key words in therapy: CONSERVATIVE and REVERSIBLE. A growing body of literature supports non-surgical intervention for this condition. Similar to other musculoskeletal/joint conditions, treatment is directed towards unloading the affected structures and managing the attendant discomfort. Non-surgical therapy customarily includes occlusal appliance therapy, physical therapy, medical management, and relaxation/cognitive-behavioral therapy. Prudence usually
dictates that non-surgical therapy first be exhausted prior to any invasive therapies. Patients with a long history of head and neck pain may be candidates for a chronic pain assessment.

The American Academy of Oral and Maxillofacial Surgeons Parameters of Care (2012) states: “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.”

Appliance (splint) therapy has been shown to be beneficial for TMD. These devices represent the most common and effective TMD/TMJ therapy that is routinely provided by dentists, even though the physiologic mechanism of the treatment response is not completely understood. Splint design and usage are different depending upon whether the etiology is intracapsular or extracapsular. For extracapsular problems, a night guard or bite plain appliance worn at night may help. For intracapsular problems, the appliance needs to be worn through the entire day and night, except at meal times for a trial period of at least 2 to 3 months. Appliance therapy would not be indicated for patients who are unable to open their mouth wide enough to obtain the impressions of dental arches that are necessary for making a dental model for a custom made appliance.

Physical therapy is an established conservative method of TMD/TMJ treatment. As is the case with physical therapy for most other medical conditions, scientific evidence of therapeutic benefit from physical therapy in TMJ/TMD is limited. Therapy may include repetitive active or passive jaw exercises, thermal modalities, manipulation, vapor coolant spray-and-stretch technique, and electro-galvanic stimulation.

Initial medical management of TMD/TMJ conditions may include pharmaceutical therapy, similar to other acute and chronic orthopedic and musculoskeletal conditions. Non-opiate analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) have been shown to be effective for mild-to-moderate inflammatory conditions and pain. Low-dosage tricyclic anti-depressants (e.g., amitriptyline) are have been used successfully in the treatment of chronic pain, sleep disturbance and nocturnal bruxism. Adjuvant pharmacologic therapies, including anticonvulsants, membrane stabilizers, and sympatholytic agents, may be useful for unremitting TMJ pain. Opiate analgesics, corticosteroids, anxiolytics, and muscle relaxants are also used in refractory pain.

There is strong evidence of effectiveness for the relaxation class of techniques in reducing chronic pain associated with a variety of medical conditions. See CPB 132 - Biofeedback. The effectiveness of EMG biofeedback in the treatment of TMD has been evaluated in a meta-analysis of 13 studies. Approximately 70% of patients required no further treatment, were symptom free, or were substantially improved following EMG biofeedback therapy, compared with approximately 35% of patients who received placebo treatments. A synergistic response has been demonstrated when intra-oral appliance therapy is combined with biofeedback and stress management. These results demonstrate the importance of using both dental and psychological treatments for successful intervention. Cognitive-
behavioral therapy (CBT) also has been demonstrated to improve long-term outcomes for TMD patients, as has been the case with other chronic pain disorders. Behavior modification interventions and relaxation techniques are frequently included as a behavioral component of CBT.

Acupuncture and trigger-point injections may be used for TMD pain. A systematic review found substantial evidence of the effectiveness of acupuncture for treatment of TMD pain. While relatively fewer controlled studies on trigger-point injection have been conducted, trigger-point injection and dry needling of trigger points have become widely accepted. While dry needling and trigger point injections of anesthetic appear to be equally effective, post-injection soreness from dry needling has been found to be more intense and of longer duration than experienced by patients injected with local anesthetic.

In cases involving chronic intractable pain and/or prior (including multiple) TMJ surgical procedures, caution is recommended due to the significant morbidity that may be experienced with TMJ surgical interventions. The long-term prognosis of this therapy for intractable pain may be unfavorable, due to the neurophysiology of chronic pain disorders. There is also evidence that the prognosis for success decreases with each additional (repeat) TMJ surgical intervention. In such cases, the literature indicates that the most promising treatment may be admission into a multidisciplinary chronic pain treatment program.

In a review on TMD, Laudenbach and Stoopler (2003) noted that when patients do not respond to non-invasive TMD therapy, surgical procedures are considered. Initial closed-approach, surgical options include arthrocentesis and arthroscopy of the TMJs. These are the simplest and least invasive of all the surgical techniques. More advanced, open-approach TMJ surgeries include disk re-positioning, diskectomy, and modified condylotomy. Indeed, guidelines for the diagnosis and management of disorders involving the TMJ and related musculoskeletal structures that are approved by the American Society of Temporomandibular Joint Surgeons (2001) listed condylotomy (including modified condylotomy) as one of the surgical options.

In a prospective, controlled study, Hall et al (2005) compared the outcomes of 4 operations (arthroscopy, condylotomy, discectomy, and disc repositioning) used for the treatment of painful TMJ with an internal derangement. Studies were conducted at 3 sites, and all sites used the same inclusion and exclusion criteria. Trained, independent examiners assessed pain, diet, and range of motion before operation and 1 month and 1 year after operation. There were statistically significant reductions in the amount of pain (p < 0.001) and daily time in pain (p < 0.001) that were similar for all 4 operations 1 month and 1 year after the procedures. The degrees of change after each of the 4 procedures were not statistically different from each other (amount: p = 0.453 and time: p = 0.416). Ability to chew, as measured by diet visual analog scale, was substantially improved 1 year after operation (p < 0.001). The degrees of change for diet at 1 year also were not different from each other (p = 0.314). There were, however, statistically significant differences (p < 0.05) in range of motion that varied with procedure. The authors concluded that all 4 operations were followed by marked improvements in pain and diet. The amounts of improvement varied slightly by
operation, but these differences were not statistically significant. There were small but statistically significant differences between procedures for range of motion.

McKenna (2006) stated that the therapeutic objective of modified condylotomy is to increase joint space, providing immediate joint load reduction and reducing if not abolishing condylar interference. The technical aspects of modified condylotomy are simple and familiar to surgeons comfortable with intraoral vertical ramus osteotomy. Satisfactory pain relief following modified condylotomy for non-reducing disc displacement (NRDD) demonstrate that disc reduction is not a prerequisite. However, when disc reduction is possible, as it often is in reducing disc displacement joints or joints that have recently progressed to NRDD, the odds of pain relief, especially moderate to severe pain, are improved and lower the risk for re-operation. Furthermore, modified condylotomy seems to favorably change the natural course of internal derangement/osteoarthrosis.

A partial TMJ prosthesis consists of a meniscectomy and placement of a metallic glenoid fossa metal prosthesis (Christensen fossa-eminence prosthesis, TMJ, Inc., Golden, CO) in place of the meniscus, such that a natural condyle articulates with a metal fossa prosthesis. The U.S. Food and Drug Administration (FDA) Dental Products Advisory Panel reviewed clinical studies of the Christensen fossa prosthesis, and advised the FDA to approve the total prosthesis, but to not approve the partial joint prosthesis because of a lack of clinical data on its safety and effectiveness. The information originally submitted to the FDA on the safety and effectiveness of the partial TMJ prosthesis was limited and had not been published in a peer-reviewed journal. In an editorial, Laskin (2001), former editor-in-chief of the Journal of Oral and Maxillofacial Surgery, the official journal of the American Association of Oral and Maxillofacial Surgeons, commented on the data on the partial TMJ prosthesis presented to the FDA Dental Products Advisory Panel: “At that meeting [of the FDA Dental Products Advisory Panel where the partial TMJ prosthesis was considered] the FDA staff presentation expressed concern regarding the lack of data on the effect of the natural condyle articulating against a metal fossa, the limited number of patients with long-term follow-up, and the broad diagnosis of internal derangement as an indication for its use. The panel expressed similar concerns about these issues, as well as the fact that the registry data provided in support of the product did not include all the patients treated and the sample size was insufficient for each of the individual indications. They recommended clarification of the patient inclusion criteria in the clinical study, evaluation of failures and additional patient follow-up, more clearly defined indications for use of the device, and that a power analysis of the clinical data be done to place the pre-market approval in an approvable form. However, despite these criticisms, and the panel’s opinion that adequate safety and effectiveness data for the given surgical indications were lacking, the device was approved by the FDA for distribution in February 2001”.

Laskin (2001) concluded that “there are insufficient data” to answer questions about the safety and effectiveness of the partial TMJ prosthesis. “For example, how reliable are clinical data based on a registry that did not include all patients treated with the device, in which there was a very small number of total patients with serial data and even smaller numbers in each diagnostic subcategory, and where in 1 group of 97 patients with a diagnosis of internal derangement and/or inflammatory arthritis, only 30% (12 subjects) had a follow-up of 3 or more years
and 70 % were either lost to follow-up, withdrawn, or potentially lost to follow-up. How can one make an informed decision with such information?"

The manufacturer subsequently submitted a post-approval study to the FDA on the long-term follow-up of patients with a variety of TMJ conditions treated with the partial TMJ prosthesis (Christensen, 2008). A total of 145 subjects (228 joints) were evaluated immediately before surgery and at regular intervals after surgery for up to 3 years. Success was measured as improvement of function and decrease in pain as measured on a visual analog scale (VAS), as well as improved incisor opening as measured with a Therabite Scale. Subjects showed a 4.9-cm reduction of pain on a 10-cm VAS scale and a 5.0-cm reduction in diet restriction at 36 months. Subjects who were admitted with an inter-incisal opening of less than or equal to 15 mm showed a 19.4 mm average improvement at 18 months and 17.4 mm average improvement at 36 months. The manufacturer reported that 4.1 % (6 subjects) of partial joint replacement subjects experienced device-related events, a percentage that was not significantly different than the percentage of device-related events reported with total joint replacement subjects (11.5 %). Limitations of the post-approval study were similar to those of the initial study submitted for FDA approval. In particular, less than half (44 %) of the 145 subjects enrolled in the study had pain, diet restriction, and incisal opening data through three years (36 months).

The manufacturer also submitted a post-approval study to the FDA on the long-term followup of patients with a variety of TMJ conditions who were treated with the total TMJ prosthesis (Christensen, 2008). A total of 78 subjects (127 joints) were evaluated immediately before surgery and at regular intervals after surgery for up to 3 years. Subjects showed a 4.9 cm reduction of pain and a 5.9 cm diet restriction at 36 months. Subjects who were admitted with an interincisal opening of less than or equal to 15 mm showed a 16.8 mm average improvement at 18 months and 18.0 mm average improvement at 36 months. Nine subjects (11.5 %) of total joint replacement subjects experienced device-related events. Follow-up was incomplete, as just over half (54 %) of subjects had pain data and diet restriction data (54 % and 57 %, respectively) at 36 months, and half (50 %) of subjects with reduced inter-incisal openings had incisal opening data at 36 months.

An evaluation study has reported better post-surgical outcomes with the TMJ Concepts total joint prosthesis than the Christensen total joint prosthesis. Wolford et al (2003) reported the results of a study comparing the Christensen total joint prosthesis (TMJ Inc., Golden, CO) with the TMJ Concepts total joint prosthesis (TMJ Concepts Inc, Camarillo, CA) in 45 patients, 23 of whom were treated with the Christensen prosthesis, and 22 of whom were treated with the TMJ Concepts Prosthesis. The investigators reported that, although subjects treated with either total joint prosthesis showed good skeletal and occlusal stability, the subjects treated with the TMJ Concepts Prosthesis had statistically significant improved outcomes compared to subjects treated with the Christensen prosthesis with respect to post-surgical incisal opening (37.3 mm versus 30.1 mm, p = 0.008), pain (decrease of 3.1 versus 1.8 on 10 point VAS score, p = 0.042), jaw function (improvement of 3.0 versus 1.2 on a 10 point scale, p = 0.008), and diet (2.0 versus 1.8 on a 10-point scale, p = 0.021). The investigators concluded "[a]s a result of our study, it appears that [TMJ Concepts Prosthesis] provides a more
biologically accepted and functional prosthesis than the [Christensen prosthesis] for the complex TMJ patient.”

In a study that examined factors to consider in joint prosthesis systems, Wolford (2006) stated that metal-on-ultra-high-molecular-weight polyethylene (UMWPE) has shown negligible wear debris histologically in the TMJ, whereas the Christensen prosthesis often demonstrates visible and histological evidence of metallosis from wear debris. Furthermore, the author stated that to appropriately evaluate the success of the Christensen products, independent researchers (not affiliated with TMJ Implants Inc.) must perform prospective studies, because the research data provided by the company are highly suspect.

The W. Lorenz total TMJ replacement system (Walter Lorenz Surgical, Inc., Jacksonville, FL) was approved by the FDA on September 21, 2005 for the functional reconstruction of diseased and/or damaged jaw joints. Its 2 components (mandibular condyle and glenoid fossa) are available in multiple sizes as left- and right-side specific designs. Approved indications for the W. Lorenz TMJ replacement system include arthritic conditions such as osteoarthritis, traumatic arthritis, or rheumatoid arthritis; ankylosis including but not limited to recurrent ankylosis with excessive heterotopic bone formation; and revision procedures in which other treatments have failed (e.g., alloplastic reconstruction, autogenous grafts). The approval was based on data from a 6-year case series study of 224 patients (329 joints), showing that patients receiving the implant reported reduced pain, improved function, an increase in maximal incisal opening, as well as satisfaction with the outcome.

The device is not intended for partial TMJ reconstruction or for use in patients susceptible to infection or having active/chronic infection, insufficient bone to support the device, an immature skeleton, or hyper-functional habits such as clenching/grinding of teeth. An evaluation of the W. Lorenz total TMJ replacement system by the Australian Department of Health and Aging (2006) stated that the only available study on this prosthesis was the case series included in the FDA safety and effectiveness summary. The Australian Department of Health and Aging recommended monitoring of the continual development of this technology.

Certain other total joint prostheses, such as the Vitek-Kent total joint prosthesis (Vitek Inc, Houston, TX) and silastic implants, are not considered medically necessary as they have been removed from the market due to poor biocompatibility, increased wear, fragmentation, and foreign body giant cell reaction.

For persons who already have had implant or other invasive surgery, additional surgical interventions (with the possible exception of implant removal) should be considered only with great caution, since the evidence indicates that the probability of success decreases with each additional surgical intervention. For these persons, available evidence indicates that the most promising immediately available treatment may be a patient-centered, multidisciplinary, palliative approach.

In a pilot study, Adiels and colleagues (2005) assessed if fibromyalgia syndrome (FMS) patients with signs and symptoms of TMD refractory to conservative TMD treatment would respond positively to tactile stimulation in respect of local and/or
general symptoms. A total of 10 female patients fulfilling the inclusion criteria received such treatment once-weekly during a 10-week period. At the end of treatment, a positive effect on both clinical signs and subjective symptoms of TMD, as well as on general body pain, was registered. Eight out of 10 patients also perceived an improved quality of their sleep. At follow-ups after 3 and 6 months, some relapse of both signs and symptoms could be seen, but there was still an improvement compared to the initial degree of local and general complaints. At the 6-month follow-up, half of the patients also reported a lasting improvement of their sleep quality. One hypothetical explanation to the positive treatment effect experienced by the tactile stimulation might be the resulting improvement of the patients' quality of sleep leading to increased serotonin levels. The authors concluded that "the results of the present pilot study are so encouraging that they warrant an extended, controlled study".

There is insufficient evidence in the literature to support the hypothesis that orthognathic surgical correction for TMJ abnormalities such as condylar hypertrophy, status post condylar fracture, ankylosis, etc., will predictably prevent or improve a temporomandibular dysfunction. There is no body of evidence in the peer reviewed literature to suggest that orthognathic surgery is a curative modality for internal joint derangements of the temporomandibular joints.

A systemic review on malocclusions and orthodontic treatment by the Swedish Council on Technology Assessment in Health Care (SBU, 2005) concluded that the appearance of the teeth is the patients' most important reason for seeking orthodontic treatment. In addition, scientific evidence is insufficient for conclusions on patient satisfaction in the long-term (at least 5 years) after the conclusion of orthodontic treatment. Furthermore, the assessment stated that scientific evidence is insufficient for conclusions on a correlation between specific untreated malocclusions and symptomatic TMJ disorders.

In a Cochrane review on orthodontics for treating TMD, Luther et al (2010) examined the effectiveness of orthodontic intervention in reducing symptoms in patients with TMD (compared with any control group receiving no treatment, placebo treatment or reassurance) and whether active orthodontic intervention leads to TMD. The Cochrane Oral Health Group's Trials Register, CENTRAL, MEDLINE and EMBASE were searched. Hand-searching of orthodontic journals and other related journals was undertaken in keeping with the Cochrane Collaboration hand-searching program. No language restrictions were applied. Authors of any studies were identified, as were experts offering legal advice, and contacted to identify unpublished trials. Most recent search was April 13, 2010. All randomized controlled trials (RCTs) including quasi-randomized trials assessing orthodontic treatment for TMD were included. Studies with adults aged equal to or above 18 years old with clinically diagnosed TMD were included. There were no age restrictions for prevention trials provided the follow-up period extended into adulthood. The inclusion criteria required reports to state their diagnostic criteria for TMD at the start of treatment and for participants to exhibit 2 or more of the signs and/or symptoms. The treatment group included treatment with appliances that could induce stable orthodontic tooth movement. Patients receiving splints for 8 to 12 weeks and studies involving surgical intervention (direct exploration/surgery of the joint and/or orthognathic surgery to correct an abnormality of the underlying skeletal pattern) were excluded. Main outcome
measures were how well the symptoms were reduced, adverse effects on oral health and quality of life. Screening of eligible studies, assessment of the methodological quality of the trials and data extraction were conducted in triplicate and independently by 3 review authors. As no 2 studies compared the same treatment strategies (interventions) it was not possible to combine the results of any studies. The searches identified 284 records from all databases. Initial screening of the abstracts and titles by all review authors identified 55 articles that related to orthodontic treatment and TMD. The full articles were then retrieved and of these articles only 4 demonstrated any data that might be of value with respect to TMD and orthodontics. After further analysis of the full texts of the 4 studies identified, none of the retrieved studies met the inclusion criteria and all were excluded from this review. The authors concluded that there are insufficient research data on which to base their clinical practice on the relationship of active orthodontic intervention and TMD. There is an urgent need for high quality RCTs in this area of orthodontic practice. When considering consent for patients it is essential to reflect the seemingly random development/alleviation of TMD signs and symptoms.

da Cunha et al (2008) assessed the effectiveness of low-level laser therapy (LLLT) in patients presenting with TMD. A total of 40 patients were randomized into an experimental group (G1) or a placebo group (G2). The treatment was carried out with an infrared laser (830 nm, 500 mW, 20s, 4J/point) at the painful points, once-weekly for 4 consecutive weeks. Patients were evaluated before and after the treatment through a VAS and the cranio-mandibular index (CMI). The baseline and post-therapy values of VAS and CMI were compared by the paired t-test, separately for the placebo and laser groups. A significant difference was observed between initial and final values (p < 0.05) in both groups. Baseline and post-therapy values of pain and CMI were compared in the therapy groups by the 2-sample t-test, yet no significant differences were observed regarding VAS and CMI (p > 0.05). The authors concluded that after either placebo or laser therapy, pain and temporomandibular symptoms were significantly lower, although there was no significant difference between groups. The LLLT was ineffective for the treatment of TMD, when compared to the placebo. This is in agreement with the findings of Emshoff et al (2008) who reported that LLLT is not better than placebo in reducing TMJ pain during function (n = 52).

In a randomized, double-blinded, placebo-controlled study, Castrillon et al (2008) examined the effect of peripheral N-methyl-D-aspartate (NMDA) receptor blockade with ketamine on chronic myofascial pain in patients with TMD. A total of 14 patients (10 women and 4 men) were recruited. The subjects completed 2 sessions in a double-blinded randomized and placebo-controlled trial. They received a single injection of 0.2 ml ketamine or placebo (buffered isotonic saline, 155 mmol/l) into the most painful part of the masseter muscle. The primary outcome parameters were spontaneous pain assessed on an electronic VAS and numeric rating scale. In addition, numeric rating scale of unpleasantness, numeric rating scale of pain relief, pressure pain threshold, pressure pain tolerance, completion of a McGill Pain Questionnaire and pain drawing areas, maximum voluntary bite force and maximum voluntary jaw opening were obtained. Paired t-tests and analysis of variance were performed to compare the data. There were no main effects of the treatment on the outcome parameters except for a significant effect of time for maximum voluntary bite force (analysis of variance
[ANOVA; p = 0.030) and effects of treatment, time, and interactions between
treatment and time for maximum voluntary jaw opening (ANOVA; p < 0.047). The
authors concluded that these findings suggest that peripheral NMDA receptors do
not play a major role in the pathophysiology of chronic myofascial TMD pain.
Although there was a minor effect of ketamine on maximum voluntary jaw opening,
local administration may not be promising treatment for these patients.

In a cross-over, double-blinded, placebo-controlled manner, Ayesh and associates
(2008) studied the effect of intra-articular ketamine on TMJ pain and
somatosensory function. Spontaneous pain and pain on jaw function was scored
by patients on 0 to 10 cm VAS for up to 24 hours. Quantitative sensory tests:
tactile, pin-prick, pressure pain threshold and pressure pain tolerance were used
for assessment of somatosensory function at baseline and up to 15 mins after
injections. There were no significant effects of intra-articular ketamine over time
on spontaneous VAS pain measures (ANOVA: p = 0.532), pain on jaw opening
(ANOVA: p = 0.384), or any of the somatosensory measures (ANOVA: p > 0.188).
The poor effect of ketamine could be due to involvement of non-NMDA receptors
in the pain mechanism and/or ongoing pain and central sensitization independent
of peripheral nociceptive input. The authors concluded that there appears to be no
rationale to use intra-articular ketamine injections in TMJ arthralgia patients, and
peripheral NMDA receptors may play a minor role in the pathophysiology of this
disorder.

In a systematic review, Manfredini and colleagues (2010) examined the clinical
studies on the use of hyaluronic acid (HA) injections to treat TMJ disorders
performed over the last decade. The selected papers were assessed according to
a structured reading of articles format, which provided that the study design was
methodologically evaluated in relation to 4 main issues: (i) population, (ii)
intervention, (iii) comparison, and (iv) outcome. A total of 19 papers were selected
for inclusion in the review, 12 dealt with the use of HA in TMJ disk displacements
and 7 dealt with inflammatory-degenerative disorders. Only 9 groups of
researchers were involved in the studies, and less than 50 % of the studies (8/19)
were randomized and controlled trials. All studies reported a decrease in pain
levels independently by the patients’ disorder and by the adopted injection
protocol. Positive outcomes were maintained over the follow-up period, which
ranged between 15 days and 24 months. The superiority of HA injections was
shown only against placebo saline injections, but outcomes are comparable with
those achieved with corticosteroid injections or oral appliances. The available
literature seems to be inconclusive as to the effectiveness of HA injections with
respect to other therapeutic modalities in treating TMJ disorders. The authors
concluded that studies with a better methodological design are needed to gain
better insight into this issue and to draw clinically useful information on the most
suitable protocols for each different TMJ disorder.

Al-Saleh et al (2012) noted that although electromyography (EMG) has been used
extensively in dentistry to assess masticatory muscle impairments in several
conditions, especially TMD, many investigators have questioned its psychometric
properties and accuracy in diagnosing TMD. These investigators performed a
systematic review to analyze the literature critically and determine the accuracy of
EMG in diagnosing TMDs. They conducted an electronic search of Medline,
Embase, all Evidence-Based Medicine Reviews, Allied and Complementary
Medicine, Ovid HealthSTAR and SciVerse Scopus. They selected abstracts that fulfilled the inclusion criteria, retrieved the original articles, verified the inclusion criteria and hand searched the articles’ references. They used a methodological tool (Quality Assessment of Diagnostic Accuracy Studies [QUADAS]) to evaluate the quality of the selected articles. The electronic database search resulted in a total of 130 articles. The authors selected 8 articles as potentially meeting eligibility for the review. Of these 8 articles, only 2 fulfilled the study inclusion criteria, and the authors analyzed them. Investigators in both studies reported low sensitivity (values ranged from 0.15 to 0.40 in 1 study and a mean of 0.69 in the second study). In addition, investigators in the 2 studies reported contradictory levels of specificity (values ranged from 0.95 to 0.98 in 1 study, and the mean value in the 2nd study was 0.67). The likelihood ratios and predictive values were not helpful in diagnosing TMD by means of EMG. The quality of the 2 studies was poor on the basis of the QUADAS checklist. The authors concluded that this systematic review found no evidence to support the use of EMG for the diagnosis of TMD.

Sharma et al (2013) conducted a systematic review of papers reporting the reliability and diagnostic validity of the joint vibration analysis (JVA) for diagnosis of TMD. A search of PubMed identified English-language publications of the reliability and diagnostic validity of the JVA. Guidelines were adapted from applied STAndards for the Reporting of Diagnostic accuracy studies (STARD) to evaluate the publications. A total of 15 publications were included in this review, each of which presented methodological limitations. The authors concluded that this literature review was unable to provide evidence to support the reliability and diagnostic validity of the JVA for diagnosis of TMD.

Pihut et al (2014) evaluated the regression of temporo-mandibular pain as a result of intra-articular injections of platelet-rich plasma (PRP) to patients with TMJ dysfunction previously subjected to prosthetic treatment. The baseline study material consisted of 10 patients, aged 28 to 53 years, previously treated due to painful TMJ dysfunction using occlusal splints. All patients underwent a specialist functional assessment of the dysfunction using the Polish version of the RDC/TMD questionnaire axis I and II. The injection sites were determined by the method used during arthroscopic surgical procedures. Following aspiration, 0.5 ml of PRP was injected into each TMJ. The comparison of the intensity of pain during all examinations suggested a beneficial effect of the procedure being performed as the mean VAS score was 6.5 at examination I, 2.8 at examination II, and 0.6 at examination III. The authors concluded that the application of the intra-articular injections of PRP into the TMJs has a positive impact on the reduction of the intensity of pain experienced by patients treated for TMJ dysfunction. These preliminary findings need to be validated by well-designed studies.

CPT Codes / HCPCS Codes / ICD-9 Codes

**CPT codes covered if selection criteria are met:**

20552
CPT codes not covered for indications listed in the CPB:

20605

21120 - 21123

21125 - 21127

21141 - 21147

21150 - 21151
97036
97532
97750

**Other CPT codes related to the CPB:**

70328
70330
70332
70336
70486
70540
70542
70543

**HCPCS codes covered if selection criteria are met:**

D0320  Temporomandibular joint arthrogram, including injection
D0321  Other temporomandibular joint films, by report
D0322  Tomographic survey
D0340  Cephalometric film
D5931 - D5933, D5936  Obturator prostheses
D5934  Mandibular resection prosthesis with guide flange
D5982  Surgical stent
D5988  Surgical splint
D7630  Mandible, open reduction (teeth immobilized, if present)
D7640  Mandible, closed reduction (teeth immobilized, if present)
D7730  Mandible, open reduction
D7740  Mandible, closed reduction
D7810 - D7880  Reduction of dislocation and management of other temporomandibular joint dysfunctions
E0746  Electromyography (EMG), biofeedback device
HCPCS codes not covered for indications listed in the CPB:

A4556  Electrodes (e.g., apnea monitor), per pair
A4557  Lead wires (e.g., apnea monitor), per pair
A4558  Conductive gel or paste, for use with electrical device (e.g., TENS, NMES), per oz.
A4595  Electrical stimulator supplies, 2 lead, per month, (e.g., TENS, NMES)
D0350  Oral/facial photographic images
D5110 - D5899 Prosthodontics (removable)
D6210 - D6999 Prosthodontics (fixed)
D7899 Unspecified TMD therapy, by report
D7940 Osteoplasty, for orthognathic deformities
D7941 Osteotomy - mandibular rami
D7943 Osteotomy - mandibular rami with bone graft; includes obtaining the graft
D7944 Osteotomy - segmented or subapical
D7945 Osteotomy, body of mandible
D7946 Lefort I (maxilla, total)
D7947 Lefort I (maxilla, segmented)
D7948 Lefort II or Lefort III (osteoplasty of facial bones for midface hypoplasia or retrusion), without bone graft
D7949 Lefort II or Lefort III, with bone graft
D7950 Osseous, osteoperiosteal, or cartilage graft of the mandible or maxilla, autogenous or nonautogenous, by report
D7951 Sinus augmentation with bone or bone substitutes
D7953 Bone replacement graft for ridge preservation - per site
D7955 Repair of maxillofacial soft and/or hard tissue defect
D9940 Occlusal guards, by report
D9951 Occlusal adjustment, limited

S8262  Mandibular orthopedic repositioning device, each
D9952 Occlusal adjustment, complete

E0720 Transcutaneous electrical nerve stimulation (TENS) device, 2 lead, localized stimulation

E0730 Transcutaneous electrical nerve stimulation (TENS) device, 4 or more leads, for multiple nerve stimulation

E0745 Neuromuscular stimulator, electronic shock unit

J7321 Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose [knee only - see selection criteria]

J7323 Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose [knee only - see selection criteria]

J7324 Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose [knee only - see selection criteria]

J7325 Hyaluronan or derivative, Synvisc, or Synvisc-One for intra-articular injection, per dose [knee only - see selection criteria]

ICD-9 codes covered if selection criteria are met:

524.60 - 524.69 Temporomandibular joint disorders

802.20 - 802.5 Fracture of mandible, closed or open, or malar and maxillary bones closed or open

830.0 - 830.1 Dislocation of jaw, closed or open

Other ICD-9 codes related to the CPB:

306.8 Other specified psychophysiological malfunction

327.00 - 327.8 Organic sleep disorders

346.00 - 346.93 Migraine

352.1 Glossopharyngeal neuralgia

715.1 Osteoarthritis, localized, primary [temporomandibular joint]

715.28 Osteoarthritis, localized, secondary [temporomandibular joint]

715.38 Osteoarthritis, localized, not specified whether primary or secondary [temporomandibular joint]

718.18 Loose body in joint, other specified sites [temporomandibular joint]
718.28 Pathological dislocation, other specified sites [temporomandibular joint] 
718.38 Recurrent dislocation of joint, other specified sites [temporomandibular joint] 
719.18 Hemarthrosis, other specified sites [temporomandibular joint] 
729.1 Myalgia and myositis, unspecified 
733.40 Aseptic necrosis of bone, site unspecified 
733.49 Aseptic necrosis of bone, other 
780.50 - 780.59 Sleep disturbances 
780.71 Chronic fatigue syndrome 
784.0 Headache 
908.6 Late effect of certain complications of trauma [scarring of temporomandibular joint that is severe and the result of old injury or prior procedure] 
909.3 Late effect of complications of surgical and medical care [scarring of temporomandibular joint that is severe and the result of old injury or prior procedure] 
959.09 Injury of face and neck [temporomandibular joint] 
996.77 - 996.78 Other complications due to internal joint prosthesis and other internal orthopedic device, implant, and graft 
V45.89 Other postprocedural states [head and neck tumor resection]

The above policy is based on the following references:

23. De Boever JA, Carlsson GE, Klineberg IJ. Need for occlusal therapy and prosthodontic treatment in the management of temporomandibular


