Medical Coverage Policy

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Temporomandibular Joint (TMJ) Disorder Surgery

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Coverage Policy

Coverage for the treatment of temporomandibular joint (TMJ) disorder varies across plans. Refer to the customer's benefit plan document for coverage details.

Many medical plans do not cover orthodontic treatment provided as an adjunct to temporomandibular joint (TMJ) disorder surgery, because such treatment is considered dental in nature and, therefore, not covered under the medical benefit.

A letter of medical necessity is required for all requests for TMJ surgery and should include a detailed history of the condition, diagnostic imaging results and documentation of prior medical and surgical treatment.

Arthrocentesis
Arthrocentesis for temporomandibular joint (TMJ) disorder is considered medically necessary when EITHER of the following criteria is met:

- Pain persists despite at least six months of noninvasive therapies such as pharmacologic pain control, physical therapy and the use of intra-oral appliances.
- Clinical examination and/or diagnostic imaging indicate the presence of hypomobility of the temporomandibular joint and symptoms persist despite at least six months of noninvasive therapy such as physical therapy and the use of intra-oral appliances.
**Arthroscopy**

Arthroscopy for TMJ disorder is considered medically necessary when BOTH of the following criteria are met:

- Pain or significant hypomobility persists despite at least six months of scientifically recognized noninvasive therapies such as pharmacologic pain control, physical therapy and the use of intra-oral appliances.
- Clinical examination and diagnostic imaging indicate the presence of joint pathology that requires internal structural modification.

**Arthrotomy**

Arthrotomy for TMJ disorder is considered medically necessary when the criteria for arthroscopy listed above are met but arthroscopy is not technically feasible, appropriate, or has previously failed to resolve the problem being treated.

Arthrotomy with total prosthetic joint replacement is considered medically necessary using The TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis for TMJ disorder when ANY of the following criteria are met, and the indication for surgery is confirmed by magnetic resonance imaging (MRI), computed tomography (CT) or corrected tomogram:

- inflammatory arthritis involving the TMJ 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
- loss of vertical mandibular condylar height due to bone resorption, trauma, developmental abnormality or pathologic lesion

Arthrotomy with total prosthetic joint replacement with either of the following prostheses is considered experimental, investigational or unproven:

- TMJ Fossa Eminence/Condylar Prosthesis System™
- Total Temporomandibular Joint (TMJ) Replacement System

Arthrotomy with partial joint replacement with the TMJ Fossa Eminence Prosthesis™ is considered experimental, investigational or unproven.

Arthrocentesis, arthroscopy, arthrotomy, or arthrotomy with total joint replacement for any other indication as part of the evaluation or treatment of temporomandibular joint (TMJ) disorder is considered experimental, investigational, or unproven.

**Overview**

This Coverage Policy addresses surgical procedures for temporomandibular joint (TMJ) disorder. This Coverage Policy is not intended to address procedures performed on the temporomandibular joint for indications other than TMJ disorder.

**General Background**

The temporomandibular joint (TMJ) consists of two bilateral synovial joints formed by the mandibular condyles that fit into the glenoid fossa of the temporal bones. The function of the TMJ is unique in that two joints act as a single unit. An articular disc, or meniscus, composed of dense fibrous tissue, separates the condyle from the fossa and is connected by collateral ligaments to the condyle. The collateral ligaments allow rotational movement of the disc on the condyle during opening and closing of the jaw. Six principal skeletal masticatory muscles control TMJ movement and stabilization.
Temporomandibular Disease (TMD) is a collective term, which describes clinical problems that involve the function of the masticatory muscles and the jaw joint. TMD has been used to refer to a group of conditions that are often called “TMJ syndrome” by physicians and dentists to describe the pain associated with the head, neck, and jaw. This has resulted in confusion regarding diagnostic and treatment options.

There are two distinct categories: masticatory muscle disorders and temporomandibular joint disorders.

- Masticatory muscle problems may result from abnormal parafunctional habits such as bruxism and clenching of teeth in response to stress, referred pain patterns of the cervical spine, and systemic muscle disorders (e.g., dyskinesia, fibromyalgia, myositis). If the abnormal habits exceed the functional capacity of the jaw joint, temporomandibular joint pathology may occur.
- Temporomandibular joint disorders (e.g., internal derangement, degenerative joint disease, rheumatoid arthritis, mandibular dislocation, ankylosis, hyper- or hypoplasia, condylar osteolysis, fractures) may also occur from varied etiologies.

Typically, the initial presentation can be confusing as both a masticatory element and a joint disorder can coexist (American Association of Oral and Maxillofacial Surgeons, 2013).

**Diagnosis**

There is no widely accepted standard test to diagnose TMD. In the majority of cases, the patient’s history, signs and symptoms, combined with a physical examination of the face and jaw, provide sufficient information to diagnose these disorders. Routine x-rays may be used to identify underlying osteoarthritis or other bony abnormalities of the TMJ. Arthrography, magnetic resonance imaging (MRI) and computed tomography (CT) are generally not indicated, although selected studies may be appropriate for persistent TMD when clinical examination indicates the presence of internal derangement and surgery is being considered.

**Treatment**

Noninvasive, reversible therapies are used in the initial treatment of symptomatic TMD. In many cases, TMD is self-limiting and often responds to simple measures such as eating soft foods, applying heat or ice, and avoiding extreme jaw movements (e.g., wide yawning, gum chewing). Other conservative treatments include:

- Pharmacological pain control: Nonsteroidal anti-inflammatory drugs (NSAIDs), opiates, muscle relaxants and low-dose antidepressants may be useful for symptom management.
- Physical therapy: A variety of modalities may be employed, including active or passive jaw movement, application of heat/ice and vapocoolant spray followed by gentle stretching.
- Intra-oral appliances: The two most common intra-oral appliances are stabilization splints and anterior positioning appliances. Stabilization splints may be used to provide joint stabilization, reduction of pressure within the joint and relaxation of elevator muscles. These appliances should not create major alteration in occlusion, since these changes may be irreversible and lead to other problems. Anterior positioning appliances, also called orthopedic repositioning appliances, are used for acute joint pain, painful crepitus and symptoms associated with acute limitation of motion caused by an anterior displaced disc without reduction (closed lock).

Trigger-point injections may be used when the above noninvasive treatments do not provide adequate symptom relief, or may be used as part of a physical therapy program.

Surgical intervention may be considered when conservative, nonsurgical therapies are unsuccessful in patients with defined intra-articular disorders and a high degree of pain and dysfunction. Controlled trials that compare surgery for TMD with medical treatment are lacking, making it difficult to determine if surgical treatment is effective for these disorders. In addition, the rate of spontaneous recovery in patients who do not receive surgery is unknown (Reston, 2003).

Scriveri and Mehta (UpToDate, 2016) recommend surgery (Grade 2C [weak recommendation, low quality evidence]) for the management of refractory TMD in patients with persistent pain or functional limitations who have structural pathology causing symptoms that do not respond to more than three to six months of initial management. Surgical procedures include arthrocentesis, arthroscopy, open arthrotomy, and combined joint and reconstructive jaw procedures.
Arthrocentesis: Arthrocentesis is the simplest and least invasive surgical treatment of TMD. It is often used to treat closed lock. The procedure may also be used for chronic closed lock and hypomobility caused by condylar restriction in the upper jaw space. The procedure is intended to increase range of motion and function and reduce pain. Arthrocentesis of the TMJ consists of puncturing, irrigating and aspirating the joint, followed by manipulation. Arthrocentesis is performed on an outpatient basis under local anesthesia. Two 20-gauge needles are inserted into the superior joint space, and Ringer’s lactate solution is injected through one needle. The second needle acts as an outlet valve. The outlet needle is blocked briefly to cause distention within the joint space in order to achieve lysis of adhesions. Steroids may be injected as an anti-inflammatory measure. Following the procedure, the mandible is manipulated to release adhesions and free the disc (Frost, 1999; Reston, 2003).

Vos et al. (2014) conducted a randomized controlled trial, including 80 patients with arthralgia of the TMJ. One group received arthrocentesis as initial treatment (n = 40), the other group received conventional treatment including soft diet, physical treatment and occlusal splint therapy (n = 40). Follow-up was after 3, 12 and 26 weeks post treatment. Primary outcome variables were pain in the TMJ, at rest and during movement, and the mandibular range of motion. After 26 weeks, the TMJ pain had comparably declined in both groups and maximum mouth opening (MMO) had slightly improved. Generalized estimated equations (GEE) models showed significant differences between arthrocentesis as initial treatment and conservative treatment, indicating that the arthrocentesis group improved more rapidly with regard to TMJ pain and MMO compared to care as usual. The authors concluded that progression of the primary outcome variables seems to be most pronounced relatively soon after arthrocentesis as initial treatment, whereas progression after conservative treatment seems to occur more gradually. However, over time, both treatment modalities appear to achieve comparable outcomes.

Arthroscopy: Arthroscopy of the TMJ is a surgical procedure that provides direct visualization of joint function and allows confirmation of intra-articular pathology that cannot be confirmed by other means of evaluation. It is intended to reduce pain and increase mandibular range of motion. It may be indicated when joint pathology is refractory to medical treatment and requires internal structural modifications. Arthroscopy may be used to treat internal derangement, hypomobility secondary to intra-joint adhesions, synovitis, degenerative joint disease and hypermobility causing painful subluxation or dislocation. Arthroscopy is performed under general anesthesia and in many cases can be performed on an outpatient basis. The procedure may include lavage, lysis of adhesions, instillation of medication, debridement and/or anterolateral capsular release. Arthroscopy is less invasive than arthrotomy, but there are limitations to the procedure, since only the superior joint space can be manipulated. Arthroscopy is not generally performed on patients with advanced TMD.

A Cochrane systematic review evaluating arthroscopy for temporomandibular disorders concluded that arthroscopy and nonsurgical treatments reduced pain after six months. Open surgery was more effective than arthroscopy in reducing pain after twelve months, but there were no differences in mandibular functionality or other clinical evaluation outcomes. Arthroscopy led to greater improvements than arthrocentesis in maximum interincisal opening after twelve months, but there was no difference in pain (Rigon et al., 2011).

Al-Moraissi et al. (2015) conducted a systematic review and meta-analysis to assess whether arthroscopy or arthrocentesis is most effective and feasible in the management of internal derangement of the TMJ, specifically in relation to joint movement and pain. After applying inclusion and exclusion criteria, a total of six publications were included in the review. Exclusion criteria consisted of case reports, technical reports, and animal or in vitro studies, review papers, and uncontrolled studies. Results demonstrated the improvement in maximal inter-incisal opening (MIO) after arthroscopy was better than the improvement obtained after arthrocentesis. There was a statistically significant difference between the two groups (p=0.0006). There was a statistically significant difference in pain reduction in favor of arthroscopy between arthroscopy and arthrocentesis patients (p=0.00001). There was no statistically significant difference between the two groups with regard to the incidence of postoperative complications (p=0.84). The author concluded the results revealed arthroscopy to have superior efficacy to arthrocentesis in increasing joint movement and decreasing pain. Both arthroscopy and arthrocentesis had comparable postoperative complication rates. However, the current meta-analysis was incomplete due to the paucity of good quality studies in the high-impact, peer-reviewed literature; therefore, further better-designed studies are required to address this important question before final conclusions can be drawn as to the true comparative outcomes of TMJ arthrocentesis versus TMJ arthroscopy.
**Arthrotomy:** Arthrotomy is the most invasive surgical technique used to treat TMD. Arthrotomy is performed under general anesthesia, usually on an inpatient basis. The following surgical procedures are carried out through arthrotomy:

- disc plication
- discectomy (meniscectomy) with or without tissue replacement
- arthroplasty, including high condylectomy with or without prosthesis insertion
- total/partial joint reconstruction with prosthetic implants (see below)

There is inadequate guidance in the published medical literature regarding patient-selection criteria for these procedures. Invasive surgical treatment to treat TMD should only be considered when all appropriate conservative treatment has failed and minimally invasive surgery such as arthrocentesis or arthroscopy is not indicated.

**Prosthetic Joint Replacement**

The U.S. Food and Drug Administration (FDA) began regulating new medical devices entering the market with the 1976 Medical Device Amendments. TMJ implants marketed prior to 1976 (i.e., pre-amendment devices) were allowed to remain on the market without the requirement to demonstrate safety and effectiveness. In 1993, TMJ implants were reclassified by the Dental Products Advisory Panel as Class III Devices. Manufacturers were required at that time to submit a Premarket Approval Application (PMA) for any TMJ prosthetic implants currently on the market.

There are three major prosthetic temporomandibular joint replacement (TJR) systems approved by the FDA: Biomet, TMJ Concepts, Biomet and Nexus. The TMJ Concepts system is a patient-specific custom TJR prosthesis with computer-aided design (CAD) and computer-aided manufacture (CAM). The Biomet and Nexus systems include stock and custom devices. All these systems have similar components.

**TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis (TMJ Concepts, Ventura, CA):** This device is a total (vs. partial jaw) device that is custom-fitted for each patient. The TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis received PMA approval by the FDA on July 2, 1999, for any of the following indications:

- inflammatory arthritis involving the TMJ 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
- loss of vertical mandibular height and/or occlusal relationship due to bone resorption, trauma, developmental abnormality or pathologic lesion

According to the FDA Summary of Safety and Effectiveness, the TMJ Concepts prosthesis is contraindicated in patients with active or suspected infections in or about the implantation site, uncontrollable masticatory muscle hyperfunction (clenching or grinding) which may lead to overload and loosening of screws, and known allergy to any of the component materials.

The Summary of Clinical Studies submitted as part of the PMA application consisted of a case series of 215 patients and a follow-up study that evaluated a subset of 111 patients from the previous study for whom detailed information was available at two or more years. Statistical analysis of patients with complete data showed significant decrease in pain, increase in function, decease in diet restrictions and increase in maximum interincisal opening.

Wolford et al. (2003) conducted a prospective case series to evaluate the first 42 patients to receive TMJ reconstruction provided by one surgeon using the TMJ Concepts prosthesis. All patients had end stage TMJ pathology. Data was included for 38 of the 42 patients. Patients were divided into three groups based on the number of previous TMJ surgeries and previous use of Proplast-Teflon or Silastic (PTS) implants. Group 1 (n=6)
included patients with 0–1 prior TMJ surgeries and no previous alloplastic implants; group 2 (n=6) included patients with two or more previous TMJ surgeries and no previous alloplastic implants; and group 3 (n=26) included patients with one or more previous TMJ surgeries with PTS implants. Clinical evaluation was performed by a single investigator preoperatively and postoperatively at three, six, 12, 24, 36 months, and at the longest follow-up beyond five years. The average follow-up was 6.2 years. Measures included maximum incisal opening, maximum lateral excursions, and occlusal stability. In addition, the Visual Analog Scale (VAS) was used to subjectively analyze pain levels and jaw function. Because of the small sample size of groups 1 and 2, all three groups were combined for statistical analysis. The authors reported statistically significant improvement in all groups in incisal opening, jaw function and pain level and a significant decrease in lateral excursion movements. Better outcomes were seen in patients with fewer previous TMJ surgeries and without exposure to PTS implants. Complications occurred in six patients; five patients had heterotopic bone formation and required reoperation to remove the bone. This study was small and uncontrolled but included objectively measured long-term outcome data suggesting this implant may be a viable alternative for selected patients.

The above prospective study was extended (Wolford, et al., 2015) to include longer-term data on patients treated by 2 of the surgeons who were involved in the original study. Follow up contact was attempted to the first 111 consecutive patients operated on. Of the 111 patients, 56 (50.5%) could be contacted and had adequate records for inclusion. The median follow-up was 21 years (13 patients had 19-year follow-ups, 43 patients had 20- to 24-year follow-ups). Long term results show: the mean preoperative maximum incisal opening (MIO) was 25.8 mm and at longest follow-up was 36.2 mm, indicating a statistically significant improvement (p< .001); the median preoperative TMJ pain score was 8 and the median postoperative TMJ pain score was 3, indicating a statistically significant decrease in pain (p<.001); and the median jaw function (JawFn) score improved from 7.5 preoperatively to 3.0 postoperatively (p< .001), as did diet (median score, from 7 to 3; p< .001). At longest follow-up, 48 patients (85.7%) reported their QoL was improved, six patients (10.7%) reported that it remained the same, and two patients (3.6%) reported that their QoL was worse. The authors stated that although only approximately half the original patients could participate in this final analysis, despite repeated attempts to locate and contact all of them using several methods, none of the 56 patients who completed the study had failure of the prostheses, signifying great durability.

Gruber et al. (2015) prospectively followed a total of 58 patients (84 joints) were followed up for three years and 26 (42 joints) for five years. Inclusion criteria for this surgical cohort included degenerative disease, multiple previous operations, injury, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ankylosis. Patients were fitted with custom-made TMJ Concepts prostheses, either unilaterally or bilaterally. Disease was diagnosed on CT and confirmed histopathologically. Results showed significant improvements in pain scores (7.4 reduced to 0.6 at 3 years and 0.8 at 5 years), and maximum mouth opening (21.0-35.5mm at 3 years and 23.8-33.7mm at 5 years). Revision operations were required in two patients.

In a retrospective study, Wolford et al. (2003) compared outcomes of patients treated with total joint replacement using either the TMJ Implants prosthesis (TMJ Fossa-Eminence) or the TMJ Concepts prosthesis. The TMJ Fossa-Eminence group included 23 patients and 40 prostheses. The TMJ Concepts prosthesis group included 22 patients and 38 prostheses. The average number of previous operations was 3.9 in the TMJ Fossa-Eminence group and 2.6 in the TMJ Concepts group, and the average follow-up in the two groups was 20.8 and 33 months, respectively. Preoperative and longest follow-up evaluations were conducted by one physician using the VAS scale for subjective evaluation of pain and diet, and objective evaluation of maximal incisal opening, and skeletal and occlusive stability. At the final follow-up, patients who received the TMJ Concepts prosthesis had greater improvements in all outcome measures, and these differences between groups were statistically significant (p<0.05). The average maximum incisal opening increased 9.9 mm with the TMJ Concepts prosthesis compared to 6.7 mm with the TMJ Fossa-Eminence prosthesis (p=.008). Average pain on a 0–10 point scale decreased from 7.2 to 4.1 points with the TMJ Concepts prosthesis compared to a decrease from 7.8 to 6 points with the TMJ Fossa-Eminence prosthesis (p=.042). Average jaw function improved three points with the TMJ Concepts prosthesis compared to 1.2 points with the TMJ Fossa-Eminence prosthesis (p=.008). The difference between the two groups in terms of average change in dietary restrictions was smaller: 2.0 points with the TMJ Concepts prosthesis compared to 1.8 points with the TMJ Fossa-Eminence prosthesis (p=.021).

Summary for TMJ Concepts: Although robust studies of TMJ prostheses are lacking including comparative studies across device manufacturers, there is adequate evidence from small long term (6 – 21 years median
follow-up) studies to demonstrate that total joint replacement with the TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis may be a reasonable alternative for selected patients with end-stage TMD when no other medical or surgical options are available. Given the expected lifetime of a joint replacement should be at least 20 years, this long term data is necessary.

**Total Mandibular Joint Replacement System (Zimmer Biomet, Warsaw, Indiana [formerly Walter Lorenz Surgical, Inc.]):** The TMJ replacement system was used clinically under an investigational device exemption from 1995-2005, at which point it received FDA approval under a PMA for commercial use on September 21, 2005. According to the FDA summary of safety and effectiveness, the system is indicated for patients who require reconstruction of the TMJ due to one of the following diagnoses:

- arthritic conditions: osteoarthritis, traumatic arthritis, rheumatoid arthritis
- ankylosis including, but not limited to, recurrent ankylosis with excessive heterotopic bone formation
- revision procedures where other treatments have failed (e.g., alloplastic reconstruction, autogenous grafts)
- avascular necrosis
- multiply operated joints
- fracture
- functional deformity
- benign neoplasms
- malignancy (e.g., post-tumor excision)
- degenerated or resorbed joints with severe anatomic discrepancies
- developmental abnormality

FDA approval was based on a prospective multicenter study designed to compare baseline and postoperative clinical and radiographic assessments in 224 patients (329 joints). The mean duration of symptoms prior to implantation was 11 years (range 0.1–40 years), and the mean number of prior surgeries was 4.8 (range 0–29). Patients were evaluated at six months, one year, 1.5 years, and three years. For the 85 patients who completed the three-year follow-up, the replacement system provided statistically significant levels of reduced jaw pain, reduced interference with eating and increased maximal incisal opening. Although not statistically significant, similar trends were observed in the entire patient population.

In a prospective trial, Gonzalez-Perez et al. (2016a = two year follow-up; 2016b = three year follow-up) evaluated the outcomes achieved with a stock prosthetic system (Biomet Microfixation TMJ Replacement System®) in the management of end-stage TMJ disorders. Patients had a history of persistent and significant pain in the TMJ area accompanied by functional impairment after failure of other non-surgical and surgical therapies, and imaging evidence consistent with advanced TMJ disease of more than 1-year duration. The mean follow-up period from initial TMJ symptoms to TMJ replacement surgery was 5 years. Previous surgical therapies included arthrocentesis, arthroscopic surgery, remodelling of the joint surface, removal of the articular disc, and partial replacement of TMJ components. A total of 52 patients requiring reconstruction (36 unilateral/16 bilateral) were operated on; 68 stock prostheses and 7 custom-made prostheses were implanted. All involved replacing both the skull base component (glenoid fossa) and the mandibular condyle with prostheses. The glenoid fossa and mandibular components were available in three different sizes. The main parameters used to assess the effectiveness of the treatment were (1) pain at rest and upon mastication as measured with the VAS, and (2) range of mandibular movements associated with mouth opening, measured with a Thera-Bite ruler. Gonzalez-Perez et al. (2016a) reported 2 year results showing a reduction in pain intensity from an average pain score of 6.4±1.4 to 1.6±1.2 (p< 0.001), and an improvement in jaw opening from the preoperative average of 2.7±0.9 cm to 4.2±0.7 cm (p< 0.001). No patient had worse symptoms postoperatively. There was a significant reduction in pain for 25 patients with TMJ replacement (48% of the patients studied); these patients reported a pain reduction of over 80% (in comparison with the preoperative pain values). Twelve of these 25 patients (23% of the cases) were in the ‘100%’ pain reduction category. During the study period, three of 68 implants (4%) were explanted and new TMJ replacements fitted. The authors concluded that surgical placement of stock TMJ prostheses provides significant long-term improvements in pain and function, with few complications. The reported outcomes of this study appear to show less than half of the patients experienced significant pain relief.
Gonzalez-Perez et al. (2016b) reported 3 year results, showing a reduction in pain intensity from 6.4±1.4 to 1.6±1.2 (p<0.001), and an improvement in jaw opening from 2.7±0.9 cm to 4.2±0.7 cm (p<0.001). In the custom-made group, results showed a reduction in pain intensity from 6.0±1.6 to 2.2±0.4 (p<0.001), and an improvement in jaw opening from 1.5±0.5 cm to 4.3±0.6 cm (p<0.001). No statistically significant differences between two groups were detected. The longevity of the TMJ replacement remains unknown.

Giannakopoulos et al. (2012) conducted a prospective multicenter study including 256 patients with a mean duration of symptoms 11.4 ± 6.6 years. The mean number of prior surgeries was 4.9 ± 3.9. Patients required total joint reconstruction because of 1) arthritis (osteo-, rheumatoid, traumatic), malignancy, ankylosis, congenital skeletal deformity, avascular necrosis, revision, benign neoplasm, fracture, or a multiply operated-on joint; 2) presence of considerable pain and/or limited function in the joint area; 3) clinical and imaging evidence consistent with anatomic joint pathology; and 4) previous failure of nonsurgical treatment/therapy or a failed implant. At 3 year follow up, the preoperative mean for pain intensity was 8.0; and at 3 years, the postoperative mean was 2.6, demonstrating a statistically significant decrease in pain (p< .0001). The preoperative mean for interference with eating was 8.2; and at 3 years, the postoperative mean was 2.5, demonstrating a statistically significant improvement in jaw function (p< .0001). Maximal incisal opening (MIO) preoperative mean was 20.4 mm; and at 3 years, the postoperative mean was 29.5 mm, showing a statistically significant increase in MIO (p< .0001). It should be noted that of the 288 patients enrolled in the study at baseline, 256 were available for follow-up at 3 years. Of the other 32 patients, there were 8 deaths, 12 with device removals, and 12 who did not respond to follow-up requests. Devices were removed because of heterotopic bone or Infection, not mechanical failure. The authors support the use of the Biomet as a safe and efficacious option when alloplastic reconstruction of the TMJ is indicated.

Leandro et al. (2013) retrospectively reported outcomes after TMJ surgery. The number of patients and years followed postoperatively were as follows: 1 year N=300; 3 years N=212; 5 years N=166; 8 years N=49; 10 years N= 7. After a period of one year, only one patient had an MIO of less than 25 mm. The results of MIO increased significantly at all clinical assessments performed during the 3-year period after surgery, reaching an average of 41.8 mm (SD 4.5), with no significant changes from the fourth year of monitoring onwards. After six months, all initial 300 patients scored no pain at all. no postsurgical infections, surgical interventions for prosthetic system removal, or adjustments for loosened screws or prosthetic components were reported.

Summary for Total TMJ Replacement System: There is insufficient evidence to demonstrate the long term safety and effectiveness of the Biomet Total Temporomandibular Joint Replacement System. Longer term prospective studies, including those comparing outcomes of the various FDA-approved devices and reporting reoperation rates, are needed.

TMJ Fossa-Eminence and Condylar Prosthesis System (NEXUS CMF, LLC., Golden, CO) (formerly TMJ Medical, formerly TMJ Implants, Inc., and commonly referred to as the Christensen device): The FDA issued a Warning letter June 30, 2015 to Nexus CMF citing their failure to comply with a 2011 order to conduct postmarket surveillance on both devices. There are two TMJ prosthetic devices from Nexus CMF:

- **TMJ Fossa-Eminence Prosthesis System (partial) (P000035):** This device is designed to provide a prosthetic covering for the articulating surface of the temporal bone.

- **TMJ Fossa-Eminence and Condylar Prosthesis System (P000023):** This device is designed to replace the articular surface of the mandibular condyle and to be used in conjunction with the partial device above for total joint reconstruction. Both stock and custom-fitted options are manufactured.

The TMJ Fossa-Eminence (Partial) Prosthesis™ received FDA PMA approval on February 27, 2001, for partial joint reconstruction in the treatment of severe temporomandibular joint disease due to any of the following conditions:

- inflammatory arthritis involving the temporomandibular joint
- 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
• internal derangement confirmed to be pathological 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

The FDA summary of safety and effectiveness states that the device is contraindicated in patients with infection or malignancy in the head or neck region, known allergy to any of the components of the system, and in patients with the ability to exert significant postoperative masticatory muscle hyperfunction (clenching or grinding) which may lead to overload and fracture of the device or loosening of the screws.

The Summary of Clinical Studies submitted as part of the PMA application for the Fossa Eminence Prosthesis for partial TMJ joint reconstruction consisted of registry data and a small case series. Registry data, provided for 1358 partial joint recipients representing 1909 devices, reported reduction in pain and improvement in interincisal opening. The case series included 131 patients, with data available for 109 patients. This study reported a reduction in perceived pain, but a decrease in interincisal opening.

Keller et al. (2012) published a prospective study to evaluate the clinical and functional outcomes of a custom temporomandibular hemijoint fossa eminence implant prosthesis in patients with advanced TMJ osteoarthritis as demonstrated on CT scan (n=36). The custom implant was constructed on patient-specific 3D models using CAD/CAM and was designed as a flat non-anatomic implant. Bone removal/reshaping was performed prior to insertion of the implant, and an abdominal autologous fat graft was harvested and placed in the surgical defect. Outcomes (pain, chewing ability, jaw opening, jaw noise and overall satisfaction) were evaluated via a questionnaire at 3, 6, and 13 months after surgery. There were statistically significant improvement between pre- and postoperative measurements for each variable. Kinematic data showed preservation or an increase of bilateral condylar motion, mandibular axis rotation, and mandibular incisor motion. It is not possible to generalize findings from this study due to the small numbers, limited follow-up data and uncontrolled nature of the study, and the use of a custom prosthesis and unique surgical approach.

Park and Keller published a retrospective case series (2004) to evaluate surgical outcome and morbidity of implantation of the TMJ metal fossa-eminence partial prosthesis, and to determine whether future more rigorous clinical trial assessment is warranted. The study evaluated 84 patients who had received 112 prostheses. Information was obtained from patient questionnaires and clinicoradiographic medical chart review. Preoperative and postoperative pain intensity, chewing ability, jaw opening and joint noise were evaluated, and surgical morbidity and implant survival were documented. The authors concluded that surgical placement of the metal fossa-eminence prosthesis provided significant pain relief and reduced TMJ dysfunction secondary to advanced degenerative arthritis. The authors acknowledged that the study was uncontrolled, relied on patient questionnaires and retrospective data based in large part on patient impressions of historical events, including recollection of preoperative pain intensity. The authors cautioned that the results of this study were clearly preliminary, and more vigorous prospective analysis and data collection were required.

Another small case series (McLeod, Hensher, 2001) reported results of implantation of the Fossa Eminence prosthesis in 42 patients with significant symptoms related to internal derangement of the TMJ despite nonsurgical treatment. Follow-up data for six months or more was available for only 34 patients. The authors reported improvement in mean gape, pain and diet measurements. Six of the 34 patients went on to have Fossa Eminence condylar prostheses after failure to show significant improvement postoperatively or for deterioration at a later stage. It is difficult to draw conclusions from this study due to the small numbers, limited long-term follow-up data and the retrospective, uncontrolled, unblinded nature of the study.

A small retrospective case series (Chase, et al., 1995) evaluated the Fossa Eminence prosthesis in the treatment of patients with severe TMJ disorder unresponsive to nonsurgical treatment. Patients who had received the Fossa Eminence prosthesis were classified into three groups: 1) placement of the Fossa Eminence prosthesis with retention of the disc (n=22); 2) placement of the prosthesis without disc retention (n=26); and 3) replacement of the total joint (n=21). Pre- and postoperative measures included pain and function as measured on a VAS, and incisor opening measured with a Therabite scale. The authors reported that all patients in group 1 had a significant decrease in pain, 82% showed significant improvement in the ability to eat, and 77% showed improved incisor opening. In group 2, 25 of 26 patients had a significant decrease in pain, 86% showed
significant improvement in the ability to eat, and 77% showed improved incisor opening. In group 3, 90% of patients had a significant decrease in pain, 86% showed significant improvement in the ability to eat, and 91% showed improved incisor opening. The study reported follow-up between one and 10 years, but does not specify how many patients received long-term follow-up. It is not possible to generalize findings from this study due to the small numbers, limited long-term follow-up data and the retrospective, uncontrolled unblinded nature of the study.

Summary for the TMJ Fossa-Eminence Prosthesis (Partial/hemijoint): There is insufficient evidence from well-designed studies to demonstrate the safety and efficacy of the TMJ Fossa-Eminence Prosthesis. Available studies include small numbers of patients, a lack of objectively measured outcomes, and limited long-term outcome data.

The TMJ Fossa-Eminence/Condylar Prosthesis System received FDA PMA approval on January 5, 2001, for patients with any of the following indications:

- 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 bone resorption, trauma, developmental abnormality or pathologic lesion

The FDA summary of safety and effectiveness states that the device is contraindicated in patients with head and neck infection or malignancy, known allergy to any of the system components, or inability to control muscle exertion, such as clenching or grinding of the teeth, that may overload and fracture the device.

The Summary of Clinical Studies submitted as part of the PMA application consisted of registry data and one small case series. Fossa-Eminence (TMJ Implants, Inc) registry data, provided for 425 total joint recipients representing 1309 devices, reported reduction in perceived pain and a significant improvement in interincisal opening. Interim results of a case series of 43 patients also reported pain reduction and improvement in interincisal opening.

There are few studies of the TMJ Fossa-Eminence/Condylar Prosthesis System in the published medical literature. Speculand et al. (2000) published a small case series reporting on experience treating 62 patients between 1988 and 1997 with the Vitek VKII (n=27) and Fossa Eminence (n=59) systems. The authors reported an overall success rate of 94%, with a lower success rate of 82% for the Vitek device. The Vitek system is no longer marketed. Follow-up ranged from one month to ten years, with a mean of 14.5 months. It is difficult to draw conclusions from this study based on its retrospective, uncontrolled, nonrandomized design, small numbers, and lack of long-term follow-up data.

Saeed et al. (2001) published a small case series reporting results of TMJ replacement using the TMJ Fossa-Eminence system in seven patients with rheumatoid-induced disease. Assessment was performed by measuring the interincisal distance preoperatively and at each follow-up visit. Subjective assessment was performed using VAS for pain and dietary interference. The follow-up period ranged from eight to 50 months with a mean of 30 months. The interincisal opening improved in five patients and decreased in two patients. Six of seven patients reported no pain or dietary interference at follow-up. One patient continued to have moderate pain on one side as well as continued dietary restrictions. The authors acknowledged that the follow-up period of this study was relatively short and that clearly long-term follow-up is needed.

Kanatas et al. published a prospective study in 2011 and also in 2012. There appears to be overlap in the patient population studied. In Kanatas et al. (2011), 46 patients had either a partial or total, stock or patient-specific, Christensen implant. The study did not aim to compare the outcomes and complications between the various types of implant. In 2012, Kanatas et al. (2012) reported on 31 patients who were given custom-made joint prostheses using the Christensen implant system (18 were unilateral and 13 bilateral). The author stated “Our previous practice had entailed use of the Christensen stock system, and although it satisfied all necessary
requirements it had several disadvantages, which have been well-documented”. Joint replacement was indicated for serious joint disease caused by osteoarthritis, ankylosis, and other causes. There was a significant overall improvement between preoperative and postoperative pain, with the mean (SD) pain score falling from 7.4 to 1.6 after one year. For both the osteoarthritis and “other” groups there was a significant improvement in pain at 12 months compared with preoperatively, but this was not the case for patients with ankyloses. For maximal mouth opening (MMO), there was significant improvement was at 12 months for the whole group; the preoperative mean (SD) was 19.7, and this improved to 28.2 at one year. A limitation of this study is the short one year follow up. The authors noted large multicenter trial would be of value to add to the evidence for total joint replacement.

Summary for TMJ Fossa-Eminence/Condylar Prosthesis System: The safety, efficacy and long-term outcomes including reoperation rates of the TMJ Fossa-Eminence/Condylar Prosthesis System have not been demonstrated in the published medical literature. Available studies include small numbers of patients, a lack of objectively measured outcomes, and limited long-term outcome data.

Meta-analysis
A meta-analysis comparing several FDA-approved devices was conducted by Johnson et al. (2017). Inclusion criteria encompassed studies that described one of the three current temporomandibular joint replacement (TMJR) systems and that had pre- and postoperative data on at least two of the following TMJR indications: pain, diet, function, and maximum inter-incisal opening (MIO). Sixteen papers were included in the systematic review, reporting 10 retrospective studies and six prospective studies (no randomized controlled or case-controlled trials). A total 312 patients with 505 TMJ Concepts prostheses, 728 patients with 1048 Biomet prostheses, and 125 patients with 196 Nexus prostheses were included in the analysis. Overall, the pooled estimates for VAS pain and diet, as well as MIO, were similar for the three prostheses. There was a reduction in the pain score of -5.16 for Concepts, -3.21 for Biomet, and -5.05 for Nexus. For diet there was a reduction in diet restriction of -4.26 for Concepts and -5.51 for Biomet. Function scores for Concepts were reduced by -3.50 trending towards normal function. Function scores were only pooled for Concepts, as only two Biomet and two Nexus papers presented data for function. When analyzing the postoperative MIO alone, Concepts (34.55 mm) and Biomet (38.33 mm) were similar, with Nexus being less (27.57 mm). The only long-term follow-up studies reported to date have been for the Concepts system, with the longest average follow-up being 21 years. The authors concluded that further research is required to define the long term success of the prostheses, including prosthesis failure, by investigators independent from the manufacturers and with open reporting of all outcomes.

Zou et al. (2017) conducted a systematic review and meta-analysis to evaluate the effectiveness of different TJR systems. Any follow-up study of at least one of the three TJR systems with more than 10 cases, a follow-up period of at least 12 months, and pre- and postoperative data for at least one TJR outcome (pain score, function score, diet score, and maximum incisal opening [MIO]) were included. No randomized controlled or case-and-control trial was identified, and all included studies were retrospective or prospective cohort studies. A total 20 studies with 1,262 patients and sufficient data were included in this meta-analysis. Results showed that meta-stock and patient-specific TJRs provide similar outcomes for decreased pain and improvements in function, diet, and maximal incisal opening (MIO).

Professional Societies/Organizations
American Association of Oral and Maxillofacial Surgeons (AAOMS): The AAOMS Clinical Condition Statements on Temporomandibular Disorders was updated in 2017. The statement lists the following:

- Non-surgical management:
  - Medication (e.g., NSAIDs)
  - Orthotic appliance
  - Physical therapy
- Surgical treatment:
  - Manipulation under anesthesia (e.g., brisement)
  - Arthrocentesis
  - Non-arthroscopic lysis and lavage and manipulation
  - Arthroscopic surgery
  - Diagnostic
- Operative
- Open arthroplasty with or without autograft
- Open arthroplasty with alloplast
- Disc repair or removal, with or without replacement
- Coronoidectomy
- Condylectomy
- Mandibular Condylotomy
- Myotomy
- Orthognathic Surgery
- Partial or total joint reconstruction (e.g., autogenous graft, allogeneic graft and alloplastic implant)

* Favorable therapeutic outcomes:
  - Level of pain that is of little or no concern to the patient
  - Improved jaw function
  - Improved ability to masticate food
  - Functional and stable occlusion
  - In a growing child, continued symmetrical growth of the mandible in proper relationship to the midface
  - Limited period of disability
  - Acceptable clinical appearance
  - Absence of recurrent jaw locking or dislocation
  - Limited progression of the disease

The AAOMS Parameters of Care: Clinical Practice Guidelines for Oral and Maxillofacial Surgery (Koslin, et al., 2012) state that temporomandibular joint (TMJ) surgery is indicated for the treatment of a wide range of pathologic conditions. The guideline details indications for therapy, therapeutic goals, and specific factors affecting risk, therapeutic parameters, and outcome assessment indices for multiple conditions. The authors’ state that surgical intervention for internal derangement arthritic conditions, degenerative joint disease infectious arthritis and ankylosis/restricted jaw motion is indicated only when nonsurgical therapy has been ineffective and pain and/or dysfunction are moderate to severe.

**American Society of Temporomandibular Joint Surgeons (ASTMJS):** Guidelines for diagnosis and management of disorders involving the temporomandibular joint and related musculoskeletal structures approved by the American Society of Temporomandibular Joint Surgeons (ASTMJS) were published in 2001. The guideline includes arthrotomy in a list of accepted and effective methods of surgical procedures for joints with internal derangement/osteoarthritis and states that FDA-approved alloplastic implants are not generally indicated for initial surgical treatment. Prosthetic joint replacement may be indicated in selected patients with severe joint degeneration, destruction or ankylosis. According to the organization’s website, ASTMJS professional guidelines are currently being revised.

**The American Board of Internal Medicine’s (ABIM) Foundation Choosing Wisely® Initiative**
American Dental Association (Released June 27, 2016): Avoid routinely using irreversible surgical procedures such as braces, occlusal equilibration and restorations as the first treatment of choice in the management of temporomandibular joint disorders. There is a lack of evidence that temporomandibular joint disorders (TMD) (defined as musculo-skeletal disorders, not the lesion of traumatic occlusion) are always progressive, and evidence exists that in many instances, patients with TMD have spontaneous remissions without treatment. Therefore, management is generally conservative and includes reversible strategies such as patient education, medications, physical therapy and/or the use of occlusal appliances that do not alter the shape or position of the teeth or the alignment of the jaws.

**Use Outside the U.S.**
**National Institute for Health and Clinical Excellence (NICE) (United Kingdom):** Interventional procedure guidance issued by NICE in August 2014 states that “Current evidence on the efficacy and safety of total prosthetic replacement of the temporomandibular joint is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.”
**Coding/Billing Information**

**Note:** 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20605</td>
<td>Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow, or ankle, olecranon bursa); without ultrasound guidance</td>
</tr>
<tr>
<td>20606</td>
<td>Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow, or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting</td>
</tr>
<tr>
<td>21010</td>
<td>Arthrotomy, temporomandibular joint</td>
</tr>
<tr>
<td>21050</td>
<td>Condylectomy, temporomandibular joint (separate procedure)</td>
</tr>
<tr>
<td>21060</td>
<td>Meniscectomy, partial or complete, temporomandibular joint (separate procedure)</td>
</tr>
<tr>
<td>21240</td>
<td>Arthroplasty, temporomandibular joint, with or without autograft (includes obtaining graft)</td>
</tr>
<tr>
<td>21242</td>
<td>Arthroplasty, temporomandibular joint, with allograft</td>
</tr>
<tr>
<td>21243†</td>
<td>Arthroplasty, temporomandibular joint, with prosthetic joint replacement</td>
</tr>
<tr>
<td>21247</td>
<td>Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (eg, for hemifacial microsomia)</td>
</tr>
<tr>
<td>29800</td>
<td>Arthroscopy, temporomandibular joint, diagnostic, with or without synovial biopsy (separate procedure)</td>
</tr>
<tr>
<td>29804</td>
<td>Arthroscopy, temporomandibular joint, surgical</td>
</tr>
</tbody>
</table>

†Note: Considered medically necessary when used to report an arthrotomy with total prosthetic joint replacement using the TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis for TMJ disorder.

Experimental, investigational, unproven when used to report an arthrotomy with a) total prosthetic joint replacement with the TMJ Fossa Eminence/Condylar Prosthesis System™; b) total prosthetic joint replacement with the Total Temporomandibular Joint (TMJ) Replacement System; or c) partial joint replacement with the TMJ Fossa Eminence Prosthesis™.


**References**


http://www.accessdata.fda.gov/cdrh_docs/pdf/P000023B.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf/P000035b.pdf


