



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Temporomandibular Joint (TMJ) Disorder Surgery

Effective Date 8/15/2011
Next Review Date 8/15/2012
Coverage Policy Number 0156

Table of Contents

Coverage Policy	1
General Background	2
Coding/Billing Information	9
References	10
Policy History	12

Hyperlink to Related Coverage Policies

Acupuncture
 Continuous Passive Motion (CPM) Devices
 Stretch Devices for Joint Stiffness and Contracture

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

Treatment of temporomandibular joint (TMJ) disorder is specifically excluded under some benefit plans, and coverage may be governed by state mandates. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.

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.

Unless excluded from the benefit plan, the service is covered when the medical necessity criteria for the specific procedure are met.

CIGNA covers arthrocentesis for temporomandibular joint (TMJ) disorder as 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.

CIGNA covers arthroscopy for TMJ disorder as 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.

CIGNA covers arthrotomy for TMJ disorder as 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.

CIGNA covers arthrotomy with total prosthetic joint replacement as 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

CIGNA does not cover arthrotomy with total prosthetic joint replacement with either of the following prostheses because they are considered experimental, investigational or unproven:

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

CIGNA does not cover arthrotomy with partial joint replacement with the TMJ Fossa Eminence Prosthesis™ because it is considered experimental, investigational or unproven.

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 disorder (TMD) is a collective term used to describe medical and dental conditions affecting the TMJ and/or the muscles of mastication. The term TMD has come to characterize a broad range of conditions with various symptoms. The most common symptom consists of TMJ sounds (e.g., clicking, popping, crepitus) that occur with jaw movement. Treatment may not be needed if this is the only symptom. Pain in the TMJ or muscles of mastication is the most common complaint of patients who seek treatment. Difficulty in opening or closing the jaw is also common in patients with TMD. This restricted range of motion may be due to pain, articular defects, or both.

The two major TMD categories are TMJ articular disorders and masticatory muscle disorders. TMJ articular disorders affect the TMJ directly, while masticatory muscle disorders affect the surrounding musculature. TMJ articular disorders include disc derangement disorders, inflammatory disorders, osteoarthritis, TMJ dislocation,

ankylosis, condylar process fracture, and congenital or developmental disorders. Although various masticatory muscle disorders with differing etiologies may be associated with TMD, these disorders are usually described in general terms, such as myofascial pain dysfunction syndrome or myogenic pain (ECRI, 2001).

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). The following surgical procedures may be used to treat TMD.

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).

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).

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.

ECRI

An ECRI technology assessment evaluated the effectiveness of various nonsurgical and surgical treatments for patients with TMJ articular disorders, particularly disc (or internal) derangements and inflammatory and noninflammatory arthritic disorders (ECRI, 2001). The assessment provides recommendations for patients with disc displacement with or without reduction. Disc displacement with reduction is defined as an alteration or interference with the disc-condyle structural relationship during mouth opening and closing. From the closed mouth position, the disc reduces or improves its relation with the condyle with mouth opening. This is usually accompanied by clicking or popping. In disc displacement without reduction, also referred to as closed lock, the misaligned disc does not reduce and is permanently displaced.

The ECRI assessment provided the following conclusions regarding the surgical interventions discussed above:

- In general, patients with disc displacement with reduction might benefit from arthroscopy.
- There is insufficient information to determine whether patients with disc displacement with reduction will benefit from disc repair/repositioning procedures
- In general, patients with disc displacement without reduction benefit from arthroscopy and will benefit from arthrocentesis
- In general, patients with disc displacement without reduction might benefit from disc repair/repositioning procedures
- There is insufficient information to determine whether patients with disc displacement without reduction benefit from modified condylotomy
- In general, patients with internal derangements (mixed populations of disc displacement with and without reduction) benefit from discectomy
- In general, patients with degenerative joint disease (with or without disc displacement with reduction) might benefit from discectomy
- There is insufficient evidence to determine whether patients with generalized osteoarthritis benefit from arthroscopy
- There is insufficient evidence to determine whether patients with rheumatoid arthritis benefit from arthroscopy or discectomy
- Although certain patients with disc derangements or arthritides may not obtain relief without open joint procedures, the available evidence is not strong enough to determine whether these procedures are necessary for specific patients

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.

TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis (TMJ Concepts, Camarillo, CA): 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, decrease 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. 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 73.5 months. 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. 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.

In a retrospective case series, Wolford et al. (2003) compared outcomes of patients treated with total joint replacement using either the TMJ Implants prosthesis (discussed below) or the TMJ Concepts prosthesis. The TMJ Implants 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 Implants 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 occlusal 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 Implants 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 Implants prosthesis ($p=.042$). Average jaw function improved three points with the TMJ Concepts prosthesis compared to 1.2 points with the TMJ Implants 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 Implants prosthesis ($p=.021$).

Although robust studies of TMJ prostheses are lacking, there is adequate evidence from several small 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.

TMJ Fossa-Eminence/Condylar Prosthesis System™ (TMJ Implants, Inc., Golden, CO): 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. 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 Implants 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.

The safety, efficacy and long-term outcomes 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. There are no published studies that compare this device to the TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis.

Total Temporomandibular Joint (TMJ) Replacement System (Walter Lorenz Surgical, Inc., Jacksonville, FL): The Total Temporomandibular Joint Replacement System received FDA approval through the PMA

process 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.

There is insufficient evidence to demonstrate the safety and effectiveness of the Total Temporomandibular Joint Replacement System or to determine how this system compares to available alternative treatments. No published studies evaluating this device were found in a search of the medical literature.

TMJ Fossa-Eminence Prosthesis™ (TMJ Implants, Inc., Golden, CO): The devices described above are used for total TMJ joint reconstruction. The Fossa-Eminence 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 an/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. TMJ Implants, Inc. 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.

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.

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.

National Institute for Health and Clinical Excellence (NICE) (United Kingdom)

Interventional procedure guidance issued by NICE in 2009 states that current evidence on the efficacy of total prosthetic replacement of the TMJ in the short and medium term is adequate, but the quantity of evidence on long-term efficacy and on safety is inadequate. The procedure should therefore not be done without special arrangements for consent and for audit or research.

Professional Societies/Organizations

Guidelines for practice, monitoring and evaluation of temporomandibular surgery published in 1995 by the American Association of Oral and Maxillofacial Surgeons (AAOMS), list partial or total joint replacement (e.g., autogenous graft, allogeneic graft, alloplastic implant) as a surgical management option for patients with rheumatoid arthritis, condylar hyperplasia or hypoplasia, or idiopathic condylar resorption. No specific patient selection criteria or device recommendations are included (AAOMS Parameters of Care-95).

Guidelines for diagnosis and management of disorders involving the temporomandibular joint and related musculoskeletal structures approved by the American Society of Temporomandibular Joint Surgeons 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.

Summary

Surgical intervention for temporomandibular joint (TMJ) disorder may be considered when conservative, nonsurgical therapies are unsuccessful in treating patients with defined intra-articular disorders and a high

degree of pain and dysfunction. There is general agreement, however, that the greater the number of surgical procedures performed on the temporomandibular joint (TMJ), the less the chance for significant improvement.

Although robust studies of TMJ prostheses are lacking, there is adequate evidence that total joint replacement with the TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis may be a reasonable alternative for selected patients with end-stage temporomandibular disorder (TMD) when no other medical or surgical options are available.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of the TMJ Fossa-Eminence/Condylar Prosthesis System™, the Total Temporomandibular Joint Replacement System for total joint replacement, or the TMJ Fossa-Eminence Prosthesis™ for partial joint replacement. Available studies of the TMJ Fossa-Eminence Prosthesis™ for partial joint replacement and the TMJ Fossa-Eminence/Condylar Prosthesis System™ for total joint replacement include small numbers of patients, a lack of objectively measured outcomes, and limited long-term outcome data. No studies of the Total Temporomandibular Joint Replacement System have been published in the medical literature.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
20605	Arthrocentesis, aspiration and/or injection; intermediate joint or bursa (e.g., temporomandibular, acromioclavicular, wrist, elbow, or ankle, olecranon bursa)
21010	Arthrotomy, temporomandibular joint
21050	Condylectomy, temporomandibular joint (separate procedure)
21060	Meniscectomy, partial or complete, temporomandibular joint (separate procedure)
21240	Arthroplasty, temporomandibular joint, with or without autograft (includes obtaining graft)
21242	Arthroplasty, temporomandibular joint, with allograft
21243†	Arthroplasty, temporomandibular joint, with prosthetic joint replacement
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (e.g., for hemifacial microsomia)
29800	Arthroscopy, temporomandibular joint, diagnostic, with or without synovial biopsy (separate procedure)
29804	Arthroscopy, temporomandibular joint, surgical

†**Note:** Covered when 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 and not covered 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™.

ICD-9-CM Diagnosis Codes	Description
524.60	Temporomandibular joint disorders, unspecified
524.61	Temporomandibular joint disorders, adhesions and ankylosis (bony or fibrous)
524.62	Temporomandibular joint disorders, arthralgia of temporomandibular joint
524.63	Temporomandibular joint disorders, articular disc disorder (reducing or non-reducing)
524.69	Temporomandibular joint disorders, other specified temporomandibular joint

	disorders
714.0	Rheumatoid arthritis
718.58	Ankylosis of joint, other specified site
733.90	Other and unspecified disorders of bone and cartilage
996.41	Mechanical loosening of prosthetic joint
996.42	Dislocation of prosthetic joint
996.43	Broken prosthetic joint implant
996.77	Other complications of internal (biologic) (synthetic) prosthetic device, implant, and graft; due to internal joint prosthesis
V43.69	Organ or tissue replaced by other means, Joint, Other

***Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

References

1. American Association of Oral and Maxillofacial Surgeons. Parameters of care for oral and maxillofacial surgery. A guide for practice, monitoring, and evaluation (AAOMS parameters of care-95). J Oral Maxillofac Surg. 1995 Sept;53(9 Suppl 5):201-234.
2. American Society of Temporomandibular Joint Surgeons. Guidelines for diagnosis and management of disorders involving the temporomandibular joint and related musculoskeletal structures. Revised 2001 Apr. Accessed Jul 7, 2011. Available at URL address: <http://astmjs.org/guidelines.html>
3. Baltali E, Keller EE. Surgical management of advanced osteoarthritis of the temporomandibular joint with metal fossa-eminence hemijoint replacement: 10-year retrospective study. J Oral Maxillofac Surg. 2008 Sep;66(9):1847-55.
4. Britton C, Christensen RW, Curry JT. Use of the Christensen TMJ Fossa-Eminence Prosthesis System: A Retrospective Clinical Study. Surg Technol Int. 2002 Sep;10:273-81.
5. Chase, DC, Hudson, JW, Gerara, MS, Russell, R, Chambers, K, Curry, JR. The Christensen prosthesis. A retrospective clinical study. Oral Surg Oral Med Oral Pathol Oral Radiol Endo. 1995;80:273-8.
6. Christensen RW, Alexander R, Curry JT, Christensen MS, Dollar JV. Hemi and total TMJ reconstruction using the Christensen prostheses: a retrospective and prospective evaluation. Surg Technol Int. 2004;12:292-303.
7. Dimitroulis G. Temporomandibular disorders: a clinical update. BMJ. 1998 Jul 18;317(7152):190-4.
8. Ebrahimi A, Ashford BG. Advances in temporomandibular joint reconstruction. Curr Opin Otolaryngol Head Neck Surg. 2010 Aug;18(4):255-60
9. ECRI Institute. Temporomandibular Articular Disorders: Selected Treatments. Plymouth Meeting (PA): ECRI Institute Health Technology Assessment information Service; 2001 March. Available at URL address: <http://www.ecri.org>
10. Firestein: Kelley's textbook of rheumatology, 8th ed. W.B. Saunders Company; 2008.
11. Frost DE, Kendell BD. The use of arthrocentesis for treatment of temporomandibular joint disorders. J Oral Maxillofac Surg. 1999 May;57(5):583-7.
12. Goroll AH, Mulley AG. Management of temporomandibular joint dysfunction. In: Primary care medicine: office evaluation and management of the adult patient, 6th ed. Philadelphia, PA: Lippincott, Williams and Wilkins; 2009.

13. Guarda-Nardini L, Manfredini D, Ferronato G. Temporomandibular joint total replacement prosthesis: current knowledge and considerations for the future. *Int J Oral Maxillofac Surg.* 2008 Feb;37(2):103-10. Epub 2007 Nov 19.
14. Guo C, Shi Z, Revington P. Arthrocentesis and lavage for treating temporomandibular joint disorders. *Cochrane Database Syst Rev.* 2009 Oct 7;(4):CD004973.
15. Hobeiche J, Salameh Z, Tashkandi E, Almas. Arthroscopy vs. open-joint surgery for the management of internal derangement of the temporomandibular joint: a retrospective study comparing female subjects from two centers. *J Contemp Dent Pract.* 2008 Mar 1;9(3):48-55.
16. Israel HA. The use of arthroscopic surgery for treatment of temporomandibular joint disorders. *J Oral Maxillofac Surg.* 1999 May;57(5):579-82.
17. Koopman WJ, Moreland LW. Temporomandibular disorders. In: *Arthritis & Allied Conditions*, 15th ed. Philadelphia, PA: Lippincott, Williams and Wilkins; 2005.
18. Laskin DM. Temporomandibular disorders: the past, present, and future. *Odontology.* 2007 Jul;95(1):10-5. Epub 2007 Jul 25.
19. Lindenmeyer A, Sutcliffe P, Eghtessad M, Goulden R, Speculand B, Harris M. Oral and maxillofacial surgery and chronic painful temporomandibular disorders--a systematic review. *J Oral Maxillofac Surg.* 2010 Nov;68(11):2755-64. Epub 2010 Sep 6.
20. McLeod NMH, Saeed, NR, Hensher, R. Internal derangement of the temporomandibular joint treated by discectomy and hemi-arthroplasty with a Christensen fossa-eminence prosthesis. *Br J Oral Maxillofac Surg.* 2001 Feb;39(1):63-6.
21. McNeill C. Management of temporomandibular disorders: concepts and controversies. *J Prosthet Dent.* 1997 May;77(5):510-22.
22. Mercuri LG. Considering total temporomandibular joint replacement. *Cranio.* 1999 Jan;17(1):44-8.
23. Mercuri LG, Edibam NR, Giobbie-Hurder A. Fourteen-year follow-up of a patient-fitted total temporomandibular joint reconstruction system. *J Oral Maxillofac Surg.* 2007 Jun;65(6):1140-8.
24. Mercuri LG. Subjective and objective outcomes in patients reconstructed with a custom-fitted alloplastic temporomandibular joint prosthesis. *J Oral Maxillofac Surg.* 1999 Dec;57(12):1427-30.
25. Mercuri, LG, Wolford LM, Sanders, B, White, RD, Long-term follow-up of the CAD/CAM patient fitted total temporomandibular joint reconstruction system. *J Oral Maxillofac Surg.* 2002 60(1):1440-48.
26. Myamoto H, Sakashita H, Miyata M, Goss AN. Arthroscopic surgery of the temporomandibular joint: comparison of two successful techniques. *Br J Oral Maxillofac Surg.* 1999 Oct;37(5):397-400.
27. National Institutes of Health. National Institute of Dental and Craniofacial Research. Temporomandibular joint and muscle disorders. Accessed Jul 7, 2011. Available at URL address: <http://www.nidcr.nih.gov/OralHealth/Topics/TMJ/>
28. Nyberg J, Adell R, Svenson B. Temporomandibular joint discectomy for treatment of unilateral internal derangements: a 5 year follow-up evaluation. *Int J Oral Maxillofac Surg.* 2004 Jan;33(1):8-12.
29. Park J, Keller EE, Reid K. Surgical management of advanced degenerative arthritis of temporomandibular joint with metal fossa-eminence hemijoint replacement prosthesis: an 8-year retrospective pilot study. *J Oral Maxillofac Surg.* 2004 Mar;62(3):320-8.
30. Reston JT, Turkelson CM. Meta-analysis of surgical treatments for temporomandibular articular disorders. *J Oral Maxillofac Surg.* 2003 Jan;61(1):3-10; discussion 10-2.

31. `Rigon M, Pereira LM, Bortoluzzi MC, Loguercio AD, Ramos AL, Cardoso JR. Arthroscopy for temporomandibular disorders. Cochrane Database Syst Rev. 2011 May 11;5:CD006385.
32. Saeed NR, McLeod MH, Hensher, R. Temporomandibular joint replacement in rheumatoid-induced disease. Br J Oral Maxillofac Surg. 2001 Feb;39(1):71-5.
33. Speculand B, Hensher, R, Powell, D. Total prosthetic replacement of the TMJ: experience with two systems 1988-1997.Br J Oral Maxillofac Surg. 2000 Aug;38(4):360-9.
34. U.S. Food and Drug Administration. PMA-Premarket Approval Database. Accessed Jul 15, 2010. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>
35. U.S. Food and Drug Administration. TMJ Implants, Inc. warning letter, 2006 Dec 20. Accessed Jul 7, 2011. Available at URL address: <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076215.htm>
36. Valentini V, Vetrano S, Agrillo A, Torroni A, Fabiani F, Iannetti G. Surgical treatment of TMJ ankylosis: our experience (60 cases). J Craniofac Surg. 2002 Jan;13(1):59-67.
37. Wolford LM. Temporomandibular joint devices: treatment factors and outcomes. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 1997 Jan;83(1):143-9.
38. Wolford LM, Pitta MC, Reiche-Fishel, O. TMJ Concepts/Techmedica custom-made TMJ total joint prosthesis: 5-year follow-up study. Int J Oral Maxillofac Surg. 2003 Jun;32(3):268-74.
39. Wolford LM, Dingwerth DJ, Talwar RM, Pitta MC. Comparison of 2 temporomandibular joint total joint prosthesis systems. J Oral Maxillofac Surg. 2003 Jun;61(6):685-90; discussion 690.
40. Yoon HJ, Baltali E, Zhao KD, Rebellato J, Kademani D, An KN, Keller EE. Kinematic study of the temporomandibular joint in normal subjects and patients following unilateral temporomandibular joint arthrotomy with metal fossa-eminence partial joint replacement. J Oral Maxillofac Surg. 2007 Aug;65(8):1569-76.

Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	08/15/2008	0156	Temporomandibular Joint (TMJ) Surgery

"CIGNA", "CIGNA HealthCare" and the "Tree of Life" logo are registered service marks of CIGNA Intellectual Property, Inc., licensed for use by CIGNA Corporation and its operating subsidiaries. All products and services are provided by such operating subsidiaries and not by CIGNA Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, CIGNA Health and Life Insurance Company, CIGNA Behavioral Health, Inc., CIGNA Health Management, Inc., and HMO or service company subsidiaries of CIGNA Health Corporation and CIGNA Dental Health, Inc. In Arizona, HMO plans are offered by CIGNA HealthCare of Arizona, Inc. In California, HMO plans are offered by CIGNA HealthCare of California, Inc. In Connecticut, HMO plans are offered by CIGNA HealthCare of Connecticut, Inc. In North Carolina, HMO plans are offered by CIGNA HealthCare of North Carolina, Inc. In Virginia, HMO plans are offered by CIGNA HealthCare Mid-Atlantic, Inc. All other medical plans in these states are insured or administered by Connecticut General Life Insurance Company or CIGNA Health and Life Insurance Company.