For Sierra Health-Care Options products, please review plan documents prior to issuing a determination.

Description	After evaluating relevant benefit document language (exclusions or limitations), refer to Coverage sections of this document to determine coverage.
This policy describes the medical and surgical treatment of temporomandibular joint disorders.	

Coverage	All reviewers must first identify member eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this policy.

Commercial Coverage Rationale:

- The following services are **medically necessary** for treating disorders of the temporomandibular joint (TMJ):
  - Arthrocentesis
  - Arthroplasty
  - Arthroscopy
  - Arthrotomy/open joint surgery
  - Intra-articular injections of sodium hyaluronate for disc displacement or osteoarthritis of the TMJ
  - Injections of corticosteroids for rheumatoid arthritis-related TMJ disorders
  - Physical therapy
  - Stabilization and repositioning splint therapy

****Limitations vary by plan, refer to plan documents.**

- The following services are **not medically necessary** for treating disorders of the temporomandibular joint (TMJ):
  - Alloplastic implants to replace the temporomandibular joint
  - Bioelectronic devices such as transcutaneous electrical nerve stimulation (TENS), electrogalvanic
  - stimulation and iontophoresis
  - Biofeedback
  - Botulinum toxin A or B
  - Craniosacral manipulation

- Charges for dental services in connection with temporomandibular joint dysfunction are also not covered unless they are determined to be Medically Necessary.

Medicare Coverage Rationale:

- National Coverage:
  - Manipulation of the Head
    - Manipulation of the occipitocervical or temporomandibular regions of the head when indicated for conditions affecting those portions of the head and neck is a covered service.
- Local Coverage:
  - Temporomandibular Joint Disorder (TMJ) splint fabrication and fitting:
    - TMJ services can only be covered if the TMJ is directly attributable to a medical condition (e.g., direct result of arthritis) or accidental injury.
    - CPT Code 21089 (unlisted maxillofacial prosthetic procedure) is the appropriate code for billing this service.
    - A description of the service is required in Item 19 on the CMS 1500 claim form or the electronic equivalent.
    - Covered diagnoses are:
      524.60,524.69 Temporomandibular joint disorders
      715.98 Osteoarthritis, other unspecified sites
      830.0-830.1 Dislocation of jaw, closed or open
    - In addition, all other conditions of medical necessity must be met and supported by the medical record.

Medicaid Coverage Rationale:

- Dental Exclusions Ages 21 and older
  - TMJ Services (Medicaid Services Manual Chapter 1000)
- Dental Benefit Ages 0-20
  - Maxillofacial Surgery
    - TMJ services for member under age 21 (Medicaid Services Manual Chapter 1000)

For Medicare and Medicaid Service Determinations Related to States Outside of Nevada:
Please review Local Coverage Determinations that apply to other states outside of Nevada.
http://www.cms.hhs.gov/mcd/search

Regulatory Requirements

U.S. Food and Drug Administration (FDA): The FDA regulates total temporomandibular joint prostheses as Class III devices which require premarket approval (PMA). The devices, indicated for reconstruction of the temporomandibular joint, are a ball and socket joint with one side mounted to the jaw and the other side mounted to the head right in front of the ear. See the following web site for more information (use product code LZD). Available at

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed January 16, 2009.

Research Evidence

Published studies have not demonstrated convincingly that alloplastic implants for treating TMJ disorders improve long-term outcomes relative to pain, dysfunction and impairment.

Well-designed randomized, controlled trials on the use of bioelectronic devices and treatments, including mandibular kinesiography (MKG-monitor), ultrasound, doppler ultrasound, iontophoresis, phonophoresis, TENS, electromyography, biofeedback, thermography, and electromyographic feedback in the treatment of temporomandibular joint disorder are not available.

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

Well-designed randomized, controlled trials on the use of botulinum toxin in the treatment of TMJ disorders are not available. Further research, using larger sample sizes and longer term studies evaluating the safety and duration of benefits, is needed.

Well-designed randomized, blinded and placebo-controlled outcome studies published on craniosacral manipulation for TMJ are not available.

Although results of nonrandomized and uncontrolled studies are promising, further research from controlled studies comparing artificial implants with open TMJ reconstruction using tissue grafts is needed.

The temporomandibular joint (TMJ) is a small joint in front of each ear and consists of the temporal bone (side and base of the skull) and the mandible (lower jaw). The joint has a disc between the articulating surfaces which cushions the load and provides a stable platform for the rotational and gliding movements of the joint. It is susceptible to all conditions that affect other joints in the body including ankylosis, arthritis, trauma, dislocations, developmental anomalies and neoplasms.

TMJ disorders include those conditions with true pathology of the TMJ and those with involvement of the masticatory (chewing) muscles. According to information on the TMJ Association website, there are at least five conditions - disc displacement with and without reduction, osteoarthritis, capsulitis and rheumatoid arthritis - which can be the cause of TMJ dysfunction.

Symptoms may include pain in or around the ear, facial or jaw pain, facial swelling, restricted maximum mouth opening or jaw locking, clicking or popping sounds emanating from the joint, bite that feels uncomfortable, "off" or as if it is changing and headaches, neck, shoulder and/or back pain. Initial treatment may include conservative measures such as non-steroidal anti-inflammatory drugs (NSAIDs), soft diet, jaw rest, moist heat, steroids, physical therapy, splints, muscle relaxants and/or antidepressants. Failure of conservative methods may require the addition of injection therapy or

surgery.

Research
There is little published clinical evidence to guide specific treatment of TMJ disorders. Scientific research is still in its infancy with no coherent body of knowledge on the etiology and pathogenesis of TMJ disorders (TMJ Association website).

Surgery

A small number of TMJ patients will fail to spontaneously improve or benefit from conservative therapy. Patients with confirmed intra-articular disorder and intolerable symptoms are candidates for surgical treatment. Surgical treatment can either be done as an open joint or arthroscopic procedure. Arthrocentesis, puncture of a joint space with a needle to remove accumulated fluid, may also include irrigating the temporomandibular joint. This is the simplest and least involved of the invasive surgical options. It is performed under local anesthesia using two needles placed into the joint spaces to inject and withdraw Ringer's lactate solution. Increased pressure within the joint may be used in an attempt to lyse adhesions. Steroids or hyaluronic acid (HA) may be injected to prevent inflammation or lubricate the joint. The mandible may also be manipulated to complete the process of freeing the disc.

Several trials have addressed arthrocentesis. Dolwick et al reported on 46 patients who underwent arthrocentesis with lavage, at average follow up of 21 months (Dolwick, 1994). The authors reported "encouraging findings" with regard to improved range of motion, function, and reduced pain. Cascone reported findings at average follow up of 24 months, on 10 patients who underwent arthrocentesis (Cascone, 1998). They found that arthrocentesis was a simple intervention which was well-accepted by patients, and resulted in clear improvement in symptoms of pain and impaired function. Sato reported on 26 patients who had nonreducing disc displacement; the superior joint space was rinsed with 1% xylocaine followed by sodium hyaluronate injection (Sato, 1997). A control group (n=50) received no treatment. At 6 months, patients receiving the intervention demonstrated improvement in 73% of cases, whereas the control group showed improvement only 36% of the time. Goudot et al. and Sanroman et al. concluded that arthroscopy and arthrocentesis had good results for functional treatment and pain control (Goudot, 2000; Sanroman, 2004).

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

Open surgery techniques such as arthrotomy (cutting into a joint) are more invasive, and are performed under general anesthesia. A preauricular incision is usually used, and then an incision in the temporal fascia exposes articular capsule and superior joint space, or an incision in the collateral

ligament allows access to the inferior joint space. Prophylactic antibiotics and/or steroids may be administered. Arthrotomy may include meniscoplasty, meniscectomy, or condylectomy with or without total joint replacement or tissue grafting.

Orthognathic surgery is defined by the American Dental Association as surgery performed to correct facial imbalances caused by abnormalities of the jaw bones. It is the surgical correction of abnormalities of the mandible, maxilla or both. The underlying abnormality may be present at birth or may become evident as the patient grows and develops or may be the result of traumatic injuries. TMJ symptoms have been associated with a variety of orthognathic deformities. In some patients, skeletal malocclusion and TMJ disorders may be correlated. Prior to performing an orthognathic procedure on patients with TMJ disorders, non-surgical therapies are usually attempted.

Orthognathic surgery is not usually performed solely to correct a TMJ disorder. Published clinical evidence indicates that orthognathic surgery performed to treat a coexisting jaw disorder has resulted in improvement in TMJ function in approximately 80% of patients (AAOMS). Although sometimes indicated, orthognathic surgery is very rarely recommended for TMJ disorders and it is estimated that fewer than 1% of all patients with symptomatic TMJ disorders require orthognathic surgical intervention (Prater, 1998).

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

Open joint procedures include discectomy, arthroplasty, disc repositioning, total joint replacement and condylotomy. According to the American Association of Oral and Maxillofacial Surgeons Criteria for Orthognathic Surgery, subsection on Facial Skeletal Discrepancies Associated with Documented Temporomandibular Joint Pathology "It is evident that, in some patients, skeletal malocclusion and TMJ dysfunction may be correlated. While some types of malocclusion have been more commonly implicated, a variety of deformities have been reported to be associated with TMJ symptoms. The rationale for proceeding with surgery to correct skeletal-dental deformities is based on common reports of significant improvement in joint and muscle symptoms after a variety of orthognathic procedures. The literature reports that approximately 80% of patients show improvement of pre-operative symptoms after orthognathic surgery. Prior to performing an orthognathic procedure on such patients, non-surgical therapies should be attempted, including those procedures and treatments that mimic the effects of occlusal alteration" (AAOMS).

Of the four surgical procedures, discectomy is more effective in the treatment of disc displacement disorders and osteoarthritis related TMJ dysfunction. In a nonrandomized retrospective study, Trumpy et al. reviewed the results of three surgical arthrotomy techniques: discoplasty (n=13), discectomy without replacement n=17), and discectomy with replacement with the Proplast/Teflon implant (n=12) (Trumpy, 1995). In the discoplasty group, 10/13 reported subjective symptom improvement at average 83 months postoperative. Six patients were experiencing clicking only in the operative joint, and an additional four patients had both clicking and crepitation. MRI demonstrated anterior disc displacement in four patients, and five scans were inconclusive.

Osteoarthritic changes were present in eight patients. Six patients demonstrated an increase in maximum interincisal distance. In the discectomy group, 16/17 patients reported subjective symptom improvement at average 69 months postoperative. One patient had clicking only, 11 had crepitation only, and 5 patients had both clicking and crepitation. Osteoarthritic changes were present in 16 patients, and 10 patients had an increase in mouth opening. In the patients who underwent discectomy with Proplast/Teflon implant, at an average interval of 64 months, 10 patients reported subjective symptom improvement. Four patients had clicking only, one had crepitation only, and two had both clicking and crepitation. Osteoarthritic changes were observed in all 12 patients, and 7 patients achieved increased maximum mouth opening.

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

In a similar study, Holmlund et al. evaluated the results at five years, of discectomy on 13 patients available (of 72 patients who were operated on) (Holmlund, 1993). No patients reported joint pain, but all patients (13) reported crepitation. Holmlund's conclusions were in agreement with Trumpy's that discectomy was an acceptable procedure that might benefit patients with internal derangements, degenerative joint disease and rheumatoid arthritis.

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

Injections
Injection of lubricating agents (sodium hyaluronate) or anti-inflammatory agents (corticosteroids) into the TMJ joint spaces is a minimally invasive therapy for TMJ disorders. Patients receive one to five injections over a period of weeks. The injection of lubricating agents is sometimes referred to as viscosupplementation therapy.

There is evidence from a number of randomized, double-blind, placebo-controlled clinical trials that intra-articular hyaluronic acid (HA) can relieve pain and allow increased activity in patients with disc disorders and osteoarthritis of the TMJ who have failed or cannot tolerate conservative therapy. The treatment effect is similar in magnitude to that provided by corticosteroids, suggesting that use

of HA should be reserved for patients who have failed steroid therapy or in whom steroid therapy might be contraindicated. While the evidence supporting the beneficial effect of a single course of treatment with HA is strong, there is presently limited information regarding the long-term benefits or adverse effects of repeated treatments, and there is only preliminary evidence suggesting that HA may also have disease-modifying effects (Hayes, 2004).

Intra-articular injections of sodium hyaluronate (hyaluronic acid or HA) have been demonstrated to be beneficial in patients with osteoarthritis or disc disorders of the temporomandibular joint. Sato et al found that in a study of 121 patients with disc displacement without reduction who received injections of HA, had significantly improved outcomes as compared to the control group at the one and two year follow-up (Sato, 2001). Hepguler et al. found that the use of HA in patients with disc displacement with reduction was an effective treatment for reducing pain, joint sounds and signs of clinical dysfunction (Hepguler, 2002). In patients with degenerative TMJ pain unresponsive to analgesics, physical therapy, and occlusal adjustment, sodium hyaluronate has been shown to reduce pain and increase range of motion in the joint. This effect can be sustained for several years and appears to be equivalent to corticosteroids without the potential adverse effects associated with chronic steroid use (Gray, 1996; Bertolami, 1993).

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

Physical therapy
Physical therapy modalities such as exercises, heat, jaw mobilization, ultrasound etc. have been used to treat the muscular component of myofascial pain of the masticatory muscles and TMJ disorders. Physical therapy (PT) modalities such as active and passive jaw movement exercises, correction of body posture and relaxation techniques can be effective in reducing the symptoms of TMJ disorders.

Nicolakis et al. found that 6 months after physical therapy, pain, perceived impairment and mouth opening had all significant improvements in the treatment group (Nicolakis, 2001). Oh et al. documents that patients completing PT following TMJ surgery also had significantly less pain and increased function as compared to the non treatment group (Oh, 2002).

Splints
Splints (also referred to as night guards, occlusal guards or appliances) have been used for nearly 70 years to treat bruxism and TMJ disorders. Splint therapy consists of either a stabilization splint or a repositioning splint. All of the splints attempt to reduce or eliminate clenching, to keep the jaw in a more relaxed position or provide some other function. Stabilization splints are believed to function by stabilizing the intra-capsular structure of the TMJ. Repositioning splints alter joint loading and create a change of mandibular position allowing the disc tissue to heal and the condyle to return to it original position (Attanasio, 1997; Dimitroulis, 1995).

A review of the literature for splint therapy is hampered by the overall lack of studies concerning this treatment modality and the lack of identification of the type of splint used and the type of disc

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

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

Implants
Arthroplasty procedures with alloplastic (artificial) implants do not appear to be effective for the treatment of TMJ disorders. Fricton et al. completed a cross-sectional study of 466 patients who received treatment for unilateral or bilateral TMJ disc displacement. The non-surgical group (n=159) and the group having TMJ surgery without implants (n=149) had statistically better results than the group who underwent surgery with a Proplast implant (n=94), and either a temporary or permanent Silastic implants (n=31 and 33 respectively). They concluded that the use of interpositional disc implants in TMJ surgery did not improve the long-term outcome relative to pain, dysfunction and impairment as compared with non-implant surgery or nonsurgical rehabilitation (Fricton, 2002).

Bioelectronic devices
There are no published studies of randomized controlled trials to evaluate the effectiveness of bioelectronic devices and treatments, including mandibular kinesiography (MKG-monitor), ultrasound, doppler ultrasound, iontophoresis, phonophoresis, TENS, electromyography, biofeedback, thermography, and electromyographic feedback in the treatment of temporomandibular joint disorder.

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

Botulinum toxin
Botulinum toxin (Botox) type A and B are neurotoxins produced by the bacterium *Clostridium (C.) botulinum*, which block the release of the neurotransmitter acethylcholine at the neuromuscular junction, thereby interfering with nerve transmission and blocking subsequent muscle contraction. Botox is used to reduce excessive muscle contraction or spasm associated with a variety of movement disorders. It is being studied for a variety of indications, including temporomandibular joint disorder; however, there is a need for further research using larger sample sizes and longer term studies evaluating the safety and duration of benefits.

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

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

Additional product information
Euflexxa (formerly known as Nuflexxa), HA, Hyalgan, Orthovisc, Synvisc

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Resources
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History/Updates Approval

01/29/09	Medical Technology Assessment Committee
06/26/09	Corporate Medical Affairs Committee

Coding

The Current Procedural Terminology (CPT) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document.

CPT Codes:

20605	Arthrocentesis, aspiration and/or injection; intermediate joint or bursa (eg, emporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa)
21010	Arthrotomy, temporomandibular joint
21050	Condylectomy, temporomandibular joint (separate procedure)
21060	Meniscectomy, partial or complete, temporomandibular joint (separate procedure)
21085	Impression and custom preparation; oral surgical splint
21089	Unlisted maxillofacial prosthetic procedure
21110	Application of interdental fixation device for conditions other than fracture or dislocation, includes removal
21240	Arthroplasty, temporomandibular joint, with or without autograft (includes obtaining graft)
21242	Arthroplasty, temporomandibular joint, with allograft
21243	Arthroplasty, temporomandibular joint, with prosthetic joint replacement
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (eg, for hemifacial microsomia)
29800	Arthroscopy, temporomandibular joint, diagnostic, with or without synovial biopsy (separate procedure)
29804	Arthroscopy, temporomandibular joint, surgical

90901	Biofeedback training by any modality
97039	Unlisted modality (specify type and time if constant attendance)
HCPCS codes:	
E1700	Jaw motion rehabilitation system
S8262	Mandibular orthopedic repositioning device, each
ICD 9 Diagnosis Codes:	
524.60	Unspecified temporomandibular joint disorders
524.61	Adhesions and ankylosis (bony or fibrous) of temporomandibular joint
524.62	Arthralgia of temporomandibular joint
524.63	Articular disc disorder (reducing or non-reducing) of temporomandibular joint
524.64	Temporomandibular joint sounds on opening and/or closing the jaw
524.69	Other specified temporomandibular joint disorders
ICD-9 Procedure Codes:	
76.19	Other diagnostic procedures on facial bones and joints
81.91	Arthrocentesis
81.92	Injection of therapeutic substance into joint or ligament
87.13	Temporomandibular contrast arthrogram