

(20121)

Medical Benefit		Effective Date: 01/01/17	Next Review Date: 05/21
Preauthorization	No	Review Dates: 09/07, 09/08, 09/09, 09/10, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 05/17, 05/18, 05/19, 05/20	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals with: <ul style="list-style-type: none"> • Suspected temporomandibular joint disorder 	Interventions of interest are: <ul style="list-style-type: none"> • Ultrasound • Surface electromyography • Joint vibration analysis 	Comparators of interest are: <ul style="list-style-type: none"> • Comprehensive history and physical exam • Alternative diagnostic test 	Relevant outcomes include: <ul style="list-style-type: none"> • Test validity • Other test performance measures
Individuals with: <ul style="list-style-type: none"> • Confirmed diagnosis of temporomandibular joint disorder 	Interventions of interest are: <ul style="list-style-type: none"> • Intraoral devices or appliances • Pharmacologic treatment 	Comparators of interest are: <ul style="list-style-type: none"> • Alternative nonsurgical intervention 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals with: <ul style="list-style-type: none"> • Confirmed diagnosis of temporomandibular joint disorder 	Interventions of interest are: <ul style="list-style-type: none"> • Acupuncture • Biofeedback • Transcutaneous electrical nerve stimulation • Orthodontic services • Hyaluronic acid 	Comparators of interest are: <ul style="list-style-type: none"> • Alternative nonsurgical intervention 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals with: <ul style="list-style-type: none"> • Confirmed diagnosis of temporomandibular joint disorder 	Interventions of interest are: <ul style="list-style-type: none"> • Arthrocentesis • Arthroscopy 	Comparators of interest are: <ul style="list-style-type: none"> • Nonsurgical intervention 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

DESCRIPTION

Temporomandibular joint disorder (TMJD) refers to a group of disorders characterized by pain in the temporomandibular joint and surrounding tissues. Initial conservative therapy is generally recommended; there are also a variety of nonsurgical and surgical treatment possibilities for patients whose symptoms persist.

SUMMARY OF EVIDENCE

For individuals who have suspected TMJD who receive ultrasound, surface electromyography, or joint vibration

analysis, the evidence includes systematic reviews of diagnostic test studies. Relevant outcomes are test validity and other performance measures. None of the systematic reviews found that these diagnostic techniques accurately identified patients with TMJD, and many of the studies had methodologic limitations. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a confirmed diagnosis of TMJD who receive intraoral devices or appliances or pharmacologic treatment, the evidence includes randomized controlled trials (RCTs) and systematic reviews of the RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A systematic review of intraoral appliances (44 studies) and meta-analyses of subsets of these studies found a significant benefit of intraoral appliances compared with control interventions. Other systematic reviews have found a significant benefit of several pharmacologic treatments (e.g., analgesics, muscle relaxants, and anti-inflammatory medications [vs. placebo]). One RCT found little benefit and higher adverse events for methylprednisolone versus saline injection. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a confirmed diagnosis of TMJD who receive acupuncture, biofeedback, transcutaneous electrical nerve stimulation, orthodontic services, or hyaluronic acid, the evidence includes RCTs, systematic reviews of these RCTs, and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic reviews did not find that these technologies reduced pain or improved functional outcomes significantly more than control treatments. Moreover, many individual studies were small and/or had methodologic limitations. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a confirmed diagnosis of TMJD who receive arthrocentesis or arthroscopy, the evidence includes RCTs, systematic reviews of the RCTs, and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Only one review, which included three RCTs, compared arthrocentesis or arthroscopy with nonsurgical interventions for TMJD. Pooled analyses of the RCTs found that arthrocentesis and arthroscopy resulted in superior pain reduction compared with control interventions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

POLICY

DIAGNOSTIC PROCEDURES

The following diagnostic procedures may be considered **medically necessary** in the diagnosis of temporomandibular joint disorder (TMJD):

- Diagnostic X-ray, tomograms, and arthrograms;
- Computed tomography (CT) scan or magnetic resonance imaging (MRI) (in general, CT scans and MRIs are reserved for presurgical evaluations);
- Cephalograms (X-rays of jaws and skull);
- Pantograms (X-rays of maxilla and mandible).

(Cephalograms and pantograms should be reviewed on an individual basis.)

The following diagnostic procedures are considered **investigational** in the diagnosis of TMJD:

- Electromyography (EMG), including surface EMG;
- Kinesiography;

- Thermography;
- Neuromuscular junction testing;
- Somatosensory testing;
- Transcranial or lateral skull X-rays; Intra-oral tracing or gnathic arch tracing (intended to demonstrate deviations in the positioning of the jaws that are associated with TMJD);
- Muscle testing;
- Standard dental radiographic procedures;
- Range of motion measurements;
- Computerized mandibular scan (measures and records muscle activity related to movement and positioning of the mandible and is intended to detect deviations in occlusion and muscle spasms related to TMJD);
- Ultrasound imaging/sonogram;
- Arthroscopy of the temporomandibular joint for purely diagnostic purposes;
- Joint vibration analysis.

NONSURGICAL TREATMENTS

The following nonsurgical treatments may be considered **medically necessary** in the treatment of TMJD:

- Acupuncture;
- Intra-oral removable prosthetic devices/appliances (encompassing fabrication, insertion, and adjustment);
- Pharmacological treatment (e.g., anti-inflammatory, muscle relaxing, and analgesic medications).

Note: Refer to Pharmacy Drug Guidelines.

The following non-surgical treatments are considered **investigational** in the treatment of TMJD:

- Electrogalvanic stimulation;
- Iontophoresis;
- Biofeedback;
- Ultrasound;
- Devices promoted to maintain joint range of motion and to develop muscles involved in jaw function;
- Orthodontic services;
- Dental restorations/prostheses;
- Transcutaneous electrical nerve stimulation;
- Percutaneous electrical nerve stimulation;
- Hyaluronic acid.

SURGICAL TREATMENTS

The following surgical treatments may be considered **medically necessary** in the treatment of TMJD:

- Arthrocentesis;
- Manipulation for reduction of fracture or dislocation of the TMJ;

- Arthroscopic surgery in patients with objectively demonstrated (by physical examination or imaging) internal derangements (displaced discs) or degenerative joint disease who have failed conservative treatment;
- Open surgical procedures (when TMJD is the result of congenital anomalies, trauma, or disease in patients who have failed conservative treatment) including, but not limited to, arthroplasties; condylectomies; meniscus or disc plication and disc removal.

MEDICARE ADVANTAGE

The above applies with the following exception:

Cervical traction (pneumatic, not for mandible) may be considered **medically necessary** for TMJ dysfunction if the member has tried other treatment first and is able to tolerate and understands this treatment.

BACKGROUND

DIAGNOSIS OF TEMPOROMANDIBULAR JOINT DISORDER

In the clinical setting, Temporomandibular Joint Disorder (TMJD) is often a diagnosis of exclusion and involves physical examination, patient interview, and a review of dental records. Diagnostic testing and radiologic imaging are generally only recommended for patients with severe and chronic symptoms. Diagnostic criteria for TMJD have been developed and validated for use in both clinical and research settings.¹⁻³

Symptoms attributed to TMJD vary and include, but are not limited to, clicking sounds in the jaw; headaches; closing or locking of the jaw due to muscle spasms (trismus) or displaced disc; pain in the ears, neck, arms, and spine; tinnitus; and bruxism (clenching or grinding of the teeth).

Treatment

For many patients, symptoms of TMJD are short-term and self-limiting. Conservative treatments (e.g., eating soft foods, rest, heat, ice, avoiding extreme jaw movements) and anti-inflammatory medication are recommended before considering more invasive and/or permanent therapies (e.g., surgery).

Note that low-level laser therapy for TMJD is addressed in the Low-Level Laser Therapy Protocol.

REGULATORY STATUS

Since 1981, several muscle-monitoring devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Some examples are the K6-I Diagnostic System (Myotronics), the BioEMG III™ (Bio-Research Associates), M-Scan™ (Bio-Research Associates), and the GrindCare Measure (Medotech A/S). These devices aid clinicians in the analysis of joint sound, vibrations, and muscle contractions when diagnosing and evaluating TMJD. FDA product code: KZM.

Table 1. Muscle-Monitoring Devices Cleared by the U.S. Food and Drug Administration

Devices	Manufacturer	Date Cleared	510(k) No.	Indication
K6-I Diagnostic System	Myotronics, Inc	Jun 1994	K922456	Electromyography
BioEMG IIITM	Bio-Research Associates, Inc	Feb 2009	K082927	Electromyography, Joint Vibration Recording
GrindCare Measure	Medotech A/S	Apr 2012	K113677	Electromyography, Nocturnal Bruxism
M-Scan™	Bio-Research Associates	Jul 2013	K130158	Electromyography
TEETHAN 2.0	BTS S.P.A.	Dec 2016	K161716	Electromyography

Devices	Manufacturer	Date Cleared	510(k) No.	Indication
GrindCare System	Sunstar Suisse S.A.	Sep 2017	K163448	Electromyography, Sleep Bruxism

FDA product code: KZM.

RELATED PROTOCOLS

Biofeedback as a Treatment of Chronic Pain

Intra-articular Hyaluronan Injections for Osteoarthritis

Low Level Laser Therapy

Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

Transcutaneous Electrical Nerve Stimulation

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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