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.

### 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

### Populations

<table>
<thead>
<tr>
<th>Individuals with:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Suspected temporomandibular joint disorder</td>
</tr>
<tr>
<td>• Confirmed diagnosis of temporomandibular joint disorder</td>
</tr>
</tbody>
</table>

<table>
<thead>
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</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>

### Interventions

<table>
<thead>
<tr>
<th>Interventions of interest are:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ultrasound</td>
</tr>
<tr>
<td>• Surface electromyography</td>
</tr>
<tr>
<td>• Joint vibration analysis</td>
</tr>
<tr>
<td>• Intraoral devices or appliances</td>
</tr>
<tr>
<td>• Pharmacologic treatment</td>
</tr>
<tr>
<td>• Acupuncture</td>
</tr>
<tr>
<td>• Biofeedback</td>
</tr>
<tr>
<td>• Transcutaneous electrical nerve stimulation</td>
</tr>
<tr>
<td>• Orthodontic services</td>
</tr>
<tr>
<td>• Hyaluronic acid</td>
</tr>
<tr>
<td>• Arthrocentesis</td>
</tr>
<tr>
<td>• Arthroscopy</td>
</tr>
</tbody>
</table>

### Comparators

<table>
<thead>
<tr>
<th>Comparators of interest are:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Comprehensive history and physical exam</td>
</tr>
<tr>
<td>• Alternative diagnostic test</td>
</tr>
<tr>
<td>• Alternative nonsurgical intervention</td>
</tr>
<tr>
<td>• Nonsurgical intervention</td>
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</tbody>
</table>

### Outcomes

<table>
<thead>
<tr>
<th>Relevant outcomes include:</th>
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</thead>
<tbody>
<tr>
<td>• Test validity</td>
</tr>
<tr>
<td>• Other test performance measures</td>
</tr>
<tr>
<td>• Symptoms</td>
</tr>
<tr>
<td>• Functional outcomes</td>
</tr>
<tr>
<td>• Quality of life</td>
</tr>
<tr>
<td>• Treatment-related morbidity</td>
</tr>
<tr>
<td>• Symptoms</td>
</tr>
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<td>• Treatment-related morbidity</td>
</tr>
</tbody>
</table>
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 with 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 that the technology results in an improvement in the net health outcome.

For individuals with 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 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. Several studies, meta-analyses, and systematic reviews exploring the effectiveness of stabilization splints on TMJD pain revealed conflicting results. Overall, the evidence shows that stabilizing splints may improve pain and positively impact depressive and anxiety symptoms. The evidence related to pharmacologic treatment varies because studies, systematic reviews, and meta-analyses lack consistency in evaluating specific agents. Some systematic reviews have found a significant benefit of several pharmacologic treatments (e.g., analgesics, muscle relaxants, and anti-inflammatory medications [vs. placebo]), but other studies showed a lack of benefit with agents such as methylprednisolone and botulinum toxin type A. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with a confirmed diagnosis of TMJD who receive acupuncture, biofeedback, transcutaneous electrical nerve stimulation, orthodontic services, hyaluronic acid, platelet concentrates, or dextrose prolotherapy, 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 that the technology results in an improvement in the net health outcome.

For individuals with a confirmed diagnosis of TMJD who receive arthrocentesis or arthroscopy, the evidence includes RCTs, systematic reviews of RCTs, and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One review, which included 3 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. A network meta-analysis, which included 36 RCTs, revealed that arthroscopy and arthrocentesis improve pain control and maximum mouth opening. The evidence is sufficient to determine that the technology results in an 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;
• Platelet concentrates;
• Dextrose prolotherapy.

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.\(^1,2,3\)

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).
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 K7x Evaluation 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.

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

<table>
<thead>
<tr>
<th>Devices</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>K6-I Diagnostic System</td>
<td>Myotronics, Inc</td>
<td>Jun 1994</td>
<td>K922456</td>
<td>Electromyography</td>
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<tr>
<td>GrindCare Measure</td>
<td>Medotech A/S</td>
<td>Apr 2012</td>
<td>K113677</td>
<td>Electromyography, Nocturnal Bruxism</td>
</tr>
<tr>
<td>M-Scan™</td>
<td>Bio-Research Associates</td>
<td>Jul 2013</td>
<td>K130158</td>
<td>Electromyography</td>
</tr>
<tr>
<td>TEETHAN 2.0</td>
<td>BTS S.P.A.</td>
<td>Dec 2016</td>
<td>K161716</td>
<td>Electromyography</td>
</tr>
<tr>
<td>GrindCare System</td>
<td>Sunstar Suisse S.A.</td>
<td>Sep 2017</td>
<td>K163448</td>
<td>Electromyography, Sleep Bruxism</td>
</tr>
</tbody>
</table>

FDA product code: KZM.

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.


46. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Manipulation (150.1), Effective Date of this Version, this is a longstanding national coverage determination. The effective date of this version has not been posted.
47. Noridian Healthcare Solutions, LLC, (Jurisdiction A - New York - Entire State, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania) Local Coverage Determination (LCD): Cervical Traction Devices (L33823), Revision Effective Date For services performed on or after 01/01/2020.