Title: Temporomandibular Joint Dysfunction (TMJD) Testing and Treatment

Description/Background

Temporomandibular joint disorder 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 non-surgical and surgical treatment possibilities for patients whose symptoms persist.

Background

TEMPOROMANDIBULAR JOINT DISORDER
Temporomandibular joint dysfunction (TMJD) (also known as TMJ syndrome) refers to a cluster of problems associated with the temporomandibular joint and musculoskeletal structures. The etiology of TMJD remains unclear and is believed to be multifactorial. TMJD are often divided into two main categories: articular disorders (e.g., ankylosis, congenital or developmental disorders, disc derangement disorders, fractures, inflammatory disorders, osteoarthritis and joint dislocation) and masticatory muscle disorders (e.g., myofascial pain, myofibrotic contracture, myospasm, and neoplasia).

Diagnosis
In the clinical setting, TMJD is often a diagnosis of exclusion and involves physical examination, patient interview, and dental record review. Diagnostic testing and radiologic imaging is 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 may include 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, such as eating soft foods, rest, heat, ice, avoiding extreme jaw movements, and anti-inflammatory medications are recommended prior to consideration of more invasive and/or permanent therapies (eg. 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 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 TMJ dysfunction. FDA product code: KZM.

<table>
<thead>
<tr>
<th>Devices</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
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<tr>
<td>K6-I Diagnostic System</td>
<td>Myotronics, Inc</td>
<td>Jun 1994</td>
<td>K922456</td>
<td>Electromyography</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>GrindCare Measure</td>
<td>Medotech A/S</td>
<td>Apr 2012</td>
<td>K113677</td>
<td>Electromyography, Nocturnal Bruxism</td>
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**Medical Policy Statement**
Certain tests, non-surgical and surgical procedures are considered safe and effective for the diagnosis and treatment of temporomandibular joint disorders. They may be considered useful therapeutic options when indicated.

**Inclusionary and Exclusionary Guidelines** *(Clinically based guidelines that may support individual consideration and pre-authorization decisions)*

**INCLUSIONS**

**Evaluation:**
- History, physical examination that establishes the diagnosis of temporomandibular joint dysfunction
The patient’s response to a trial of conservative treatment prior to surgery of the temporomandibular joint.

**Diagnostic procedures:**
The following diagnostic procedures are considered safe and effective in the diagnosis of TMJ dysfunction:
- Diagnostic X-ray, tomograms and arthrograms
- CT scan or MRI (generally CT scans and MRIs are reserved for presurgical evaluations)
- Cephalograms (x-rays of jaws and skull)
- Pantograms (panoramic x-rays of maxilla and mandible)

**Non-surgical treatments:**
The following non-surgical treatments are considered safe and effective in the treatment of TMJ dysfunction:
- Intraoral removable prosthetic devices/appliances (encompassing fabrication, insertion, adjustment)
- Pharmacologic treatment (such as anti-inflammatory, muscle relaxing and analgesic medications).

**Surgical treatments:**
The following surgical treatments may be covered in the treatment of TMJ dysfunction:
- Arthrocentesis, with or without ultrasound guidance
- Manipulation for reduction of fracture or dislocation of the TMJ
- Arthroscopic surgery in patients that objectively demonstrate (by physical examination or imaging) internal derangements (displaced discs) or degenerative joint disease who have failed conservative treatment
- Open surgical procedures including, but not limited to, arthroplasties, condylectomies, meniscus or disc plication and disc removal, when TMJ dysfunction is the result of congenital anomalies, trauma or disease in patients who have failed conservative treatment

**EXCLUSIONS**

**Diagnostic procedures:**
The following diagnostic procedures are considered experimental/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 gothic 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 (this 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/sonogram (ultrasonic Doppler auscultation)
• Joint vibration analysis

Non-surgical treatments*:
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/treatment
• Dental restorations/prosthesis/treatment/appliances
• TENS (transcutaneous electrical nerve stimulation)
• PENS (percutaneous electrical nerve stimulation)
• Acupuncture
• Hyaluronic Acid

*Intra-oral reversible orthotic device (also known as occlusal orthotic, occlusal guard or bite splint), including fabrication, insertion and adjustment of the device is a certificate exclusion in most cases. Refer to current certificate.

Surgical treatments:
The following surgical procedure is considered experimental/investigational:
• Arthroscopy of the TMJ for purely diagnostic purposes.

CPT/HCPCS Level II Codes (Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)

Established codes:

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**Rationale**

**Diagnosis of Temporomandibular Disorder**

**Clinical Context and Test Purpose**
The purpose of specific diagnostic tests in patients with suspected TMJD is to provide a treatment option that is an alternative to or an improvement on existing diagnostic approaches, such as a comprehensive history and physical exam and alternative diagnostic tests.

The question addressed in this evidence review is: do specific diagnostic tests improve the net health outcome for individuals with suspected TMJD?

**Patients**
The relevant population of interest is individuals with suspected TMJD.

**Interventions**
The diagnostic tests being considered are ultrasound, surface electromyography, and joint vibration analysis.

**Comparators**
Comparators of interest include comprehensive history and physical exam and alternative diagnostic tests. Alternative diagnostic tests can include routine dental x-rays, panoramic radiographs, computed tomography, magnetic resonance imaging, and scintigraphy.

**Outcomes**
The general outcomes of interest are test accuracy, test validity, and other test performance measures.

**Timing**
The existing literature evaluating ultrasound, surface electromyography, and joint vibration analysis as diagnostic tests for suspected TMJD has varying lengths of follow-up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Therefore, at least one year of follow-up is considered necessary to demonstrate efficacy.
Setting
Patients with suspected TMJD are managed by primary care providers, dentists, and otolaryngologists in an outpatient clinical setting.

Study Selection Criteria
Below are selection criteria for studies to assess whether a test is clinically valid.

a. The study population represents the population of interest. Eligibility and selection are described.
b. The test is compared with a credible reference standard.
c. If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
d. Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (eg, ROC, AUROC, c-statistic, likelihood ratios) may be included but are less informative.
e. Studies should also report reclassification of diagnostic or risk category.

Several systematic reviews of the literature on specific techniques for diagnosing TMJD were identified.

Ultrasound
A 2009 systematic review identified 20 studies evaluating ultrasound for diagnosing TMJD; all studies evaluated disc displacement and several also considered osteoarthrosis and/or joint effusion.(4) The reported sensitivity of ultrasound to detect disc displacement, compared with the reference standard (magnetic resonance imaging [MRI] in most studies), ranged from 31% to 100%, and the specificity ranged from 30% to 100%. Researchers stated that even when changes in ultrasound technology over time were taken into consideration, study findings were contradictory. They noted unexplained differences between studies conducted by the same group of researchers. Researchers concluded that additional advances need to be made in standardizing ultrasound assessment of the TMJD before it can be considered an accurate diagnostic tool.

Surface Electromyography
A 2006 systematic review on surface electromyography found a lack of literature on the accuracy of this method of diagnosis, compared to a criterion standard (i.e., comprehensive clinical examination and history-taking).(5) Reviewers concluded that there is insufficient evidence that electromyography can accurately identify people with facial pain from those without pain but that the technique may be useful in a research setting.

Joint Vibration Analysis
Sharma et al (2013) published a systematic review of literature on joint vibration analysis for diagnosis of TMJD.(6) Reviewers identified 15 studies that evaluated the reliability and/or diagnostic accuracy of joint vibration analysis compared with a reference standard. Methodologic limitations were identified in all studies, and included the absence of well-defined diagnostic criteria, use of a non-validated system for classifying disease progression, variability within studies in the reference standard used, and lack of blinding. In the 14 studies reporting
on diagnostic accuracy, there was a wide range of reported values, with sensitivity ranging from 50% to 100% and specificity ranging from 59% to 100%.

Section Summary: Diagnosis of TMJD
Current evidence is insufficient or imprecise to support the use of ultrasound, surface electromyography or joint vibration analysis to diagnose TMJD.

TREATMENT OF TEMPOROMANDIBULAR DYSFUNCTION

Clinical Context and Therapy Purpose
The purpose of orthotics and pharmacologic treatment in patients with a confirmed diagnosis of TMJD is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as alternative nonsurgical intervention.

The question addressed in this evidence review is: do orthotics and pharmacologic treatment improve the net health outcome for individuals with a confirmed diagnosis of TMJD?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is individuals with confirmed TMJD.

Interventions
The therapies being considered are intraoral devices or appliances and pharmacological treatment.

Intraoral devices and appliances are described in the Regulatory Status section above and can include stabilization splints. Pharmacological treatment can include nonsteroidal anti-inflammatory drugs, opioids, corticosteroids, muscle relaxants, antidepressants, anticonvulsants, and benzodiazepines.

Comparators
The main comparators of interest is alternative nonsurgical intervention, such as medications, physical therapy, and injections. Alternative medicine techniques can also be used, such as acupuncture, relation techniques, TENS, and biofeedback.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Symptoms of TMJD may include, pain, tenderness, or aching in the jaw or one or both of the temporomandibular joints, difficulty or pain while chewing, and locking of the temporomandibular joint.

Timing
The existing literature evaluating intraoral devices or appliances and pharmacologic treatment as a treatment for confirmed TMJD has varying lengths of follow-up, ranging from 6 weeks to 1 year of follow-up While the systematic reviews described below all reported at least one
outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, at least one year of follow-up is considered necessary to demonstrate efficacy.

**Setting**

Patients with confirmed TMJD are actively managed by primary care providers, dentists, and otolaryngologists in an outpatient clinical setting.

**Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

d. Studies with duplicative or overlapping populations were excluded.

**Systematic Reviews**

List and Axelsson (2010) published a review of systematic reviews on treatments for TMJDs published through August 2009.(7) They identified 30 reviews; there were 23 qualitative systematic reviews and 7 meta-analyses. Eighteen of the systematic reviews included only randomized controlled trials (RCTs), 3 included case control studies, and 9 included a mixture of RCTs and case series. TMJD were defined inconsistently in the primary studies and systematic reviews, and several of the reviews addressed the related diagnoses of bruxism, disc replacements, and myofascial pain. Twenty-nine of the systematic reviews had pain intensity or pain reduction as the primary outcome measure, and 25 reported clinical outcome measures such as jaw movement or jaw tenderness on palpation. Reviewers divided the treatments into 5 categories (some studies were included in more than 1 category). These categories and the main findings are listed in Table 2.

<table>
<thead>
<tr>
<th>Categories</th>
<th>No. of Articles</th>
<th>Findings</th>
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<tbody>
<tr>
<td>Occlusal appliances, occlusal adjustment, and orthodontic treatment</td>
<td>10</td>
<td>Six systematic reviews did not find significant benefit vs other treatments, 4 found no benefit vs a placebo device, and 3 found occlusal therapy was better than no treatment</td>
</tr>
<tr>
<td>Physical treatments including acupuncture, TENS, exercise, and mobilization</td>
<td>8</td>
<td>Four reviews found no significant benefit of acupuncture over other treatments, 1 found no difference between acupuncture and placebo treatment, and 3 found acupuncture was better than no treatment. One review found active exercise and postural training were effective for treating TMJD-related pain.</td>
</tr>
<tr>
<td>Pharmacologic treatment</td>
<td>7</td>
<td>Treatments found to be superior to placebo were analgesics (2 reviews), clonazepam or diazepam (3 reviews), antidepressants (4 reviews), and hyaluronate (1 review). One review found effects of hyaluronate and corticosteroids to be similar.</td>
</tr>
<tr>
<td>Maxillofacial surgery</td>
<td>4</td>
<td>Three reviews evaluated surgery for patients with disc displacements and 1 addressed orthognathic surgery in patients with TMJD. Reviews of surgical treatments generally included lower level evidence (eg, case series), and did not always compare surgery with a control condition. One review of patients with disc displacements with reduction reported similar treatment</td>
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effects for arthrocentesis, arthroscopy, and discectomy, and another review in patients in disc displacement without reduction found similar effects of arthrocentesis, arthroscopy, and physical therapy (used as a control intervention). Due to the lack of high quality controlled studies, conclusions could not be drawn about intervention equivalence.

<table>
<thead>
<tr>
<th>Behavioral therapy and multimodal treatments</th>
<th>6</th>
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<td>Two reviews found biofeedback to be better than active control or no treatment, 1 review found a combination of biofeedback and CBT to be better than no treatment, and 2 found a combination of biofeedback and relaxation to be better than no treatment. One review found the effects of biofeedback and relaxation to be similar.</td>
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Adapted from List and Axelsson (2010)

CBT: cognitive-behavioral therapy; TENS: transcutaneous electrical nerve stimulation; TMJD: temporomandibular joint disorders.

Overall, reviewers concluded that there was insufficient evidence that electrophysical modalities and surgery would be effective for treating TMJD. They found some evidence that occlusal appliances, acupuncture, behavioral therapy, jaw exercise, postural training, and some medications could be effective at reducing pain for patients with TMJD. However, reviewers noted that most of the systematic reviews they examined included primary studies with considerable variation in methodologic quality, and thus, it is not possible to make definitive conclusions about the effectiveness of any of the treatments.

Randhawa et al (2016) published a systematic review of noninvasive interventions for TMJDs, which included RCTs with at least 30 individuals per treatment arm, cohort studies with at least 100 patients per exposed group, and case control interventions. (8) Reviewers identified 31 studies for appraisal, of which 7 RCTs described in 8 publications had a low risk of bias and were assessed further. Most RCTs evaluated interventions outside the scope of our review, including cognitive-behavioral therapy and self-care management. Three RCTs evaluated occlusal devices for TMJD of variable duration, and generally reported no significant improvements with occlusal devices in terms of pain, mouth opening, or other outcomes.

ORTHOTICS

Intraoral Devices/Appliances
Friction et al (2010) reported on a systematic review of RCTs on intraoral treatment of TMJD and identified 47 publications on 44 trials. (9) Intraoral appliances included soft and hard stabilization appliances, anterior positioning appliances, anterior bite appliances, and soft resilient appliances. Studies compared 2 types of devices or compared 1 device with a different treatment (eg, acupuncture or biofeedback). None of the studies evaluated use of 1 device during the day and a different device during the night. The primary outcome of the meta-analysis was pain. Pain was measured differently in the studies, and reviewers defined a successful outcome as at least a 50% reduction in pain on a self-report scale or at least an “improved” status when pain was measured by subjective report of status. Ten RCTs were included in 2 meta-analyses; the others were excluded because they did not measure pain, there were not at least 2 studies using similar devices or control groups, or data were not usable in a pooled analysis. A pooled analysis of 7 RCTs (n=385 patients) that evaluated hard stabilization appliances and using palatal non-occluding appliances as a control found a significantly greater reduction in pain with hard appliances (odds ratio [OR], 2.45; 95% confidence interval [CI], 1.56 to 3.86; p<0.001). A pooled analysis of 3 studies (n=216 patients)
did not find a statistically significant effect of hard appliances compared with a no-treatment control group (OR=2.14; 95% CI, 0.80 to 5.75; p=0.12).

Ivorra-Carbonell et al (2016) reported on a systematic review of functional advancement devices for TMJD, which included systematic reviews, meta-analyses, RCTs, case-control studies, and cohort studies.(10) Reviewers included 21 articles evaluating some kind of advancement device, considered of medium or high quality by CONSORT criteria. Results were summarized descriptively; reviewers concluded that after treatment with mandibular advancement the condyle was in “more advanced position.”

**Stabilization Splints**

Ebrahim et al (2012) identified 11 RCTs comparing splint therapy for TMJD with minimal or no therapy.(11) Nine of the 11 studies used stabilization splints, 1 used soft splints and 1 used an anterior repositioning appliance. Reviewers used the GRADE system to rate study quality. Nine studies did not report whether allocation was concealed, and 6 studies did not report masking of outcome assessors. Length of follow-up in the studies ranged from 6 to 52 weeks. A pooled analysis of study findings found that splint therapy was significantly associated with a reduction in reported pain compared with minimal or no intervention (standardized mean difference [SMD], -0.93; 95% CI, -1.33 to -0.53). Using a 100-millimeter visual analog scale (VAS) to measure pain, splint therapy was associated with an 11.5 mm lower mean VAS score (95% CI, -16.5 to -6.6 mm). There were not statistically significant differences between groups in quality of life or depression scores.

Zhang et al (2016) identified 13 publications from 11 studies (n=538 patients) evaluating splint therapy for TMJD.(12) Risk of bias was high for 2 or more domains for all of the studies. Splint therapy group patients had greater improvement in pain control than control patients (mean difference [MD], 2.02; 95% CI, 1.55 to 2.49; \(I^2=0.558\)).

An earlier Cochrane review by Al-Ani et al (2014) identified 12 RCTs that compared stabilization splint therapy for TMJD with a control intervention.(13) (The control group was not limited to minimal or no intervention as in the Ebrahim review.) There was wide variability in the comparison interventions and no standardization of outcomes; thus, study results could not be pooled. This Cochrane review was withdrawn in 2016 for being out of date and not meeting current Cochrane methodologic standards.(14)

**Pharmacologic Treatment**

Häggman-Henrikson et al (2017) published a systematic review that included 41 RCTs assessing various pharmacologic regimens for pain from TMJDs or burning mouth syndrome; of these, 13 were selected for a network meta-analysis.(15) Nine studies evaluated temporomandibular muscular pain, which appeared to decrease more with cyclobenzaprine than with placebo, although no specific statistics were reported. Pain reduction was also favorable for botulinum toxin and Ping-On ointment in the meta-analysis; other descriptive analyses showed a reduction of pain with nonsteroidal anti-inflammatory drugs and melatonin tablets when compared with placebo.
Section Summary: Orthotics and Pharmacologic Treatment
Evidence evaluating the use of orthotics in the treatment of TMJD, while sometimes conflicting and inconclusive, suggests that use of orthotics reduces TMJD pain. A systematic review found that different pharmacologic agents reduced pain in patients with TMJD. 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). The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

OTHER NONSURGICAL THERAPIES

Clinical Context and Therapy Purpose
The purpose of nonsurgical therapies in patients with a confirmed diagnosis of TMJD is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as alternative nonsurgical intervention.

The question addressed in this evidence review is: do nonsurgical therapies improve the net health outcome for individuals with a confirmed diagnosis of TMJD?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is individuals with confirmed TMJD.

Interventions
The nonsurgical therapies being considered are acupuncture, biofeedback, TENS, orthodontic services, and hyaluronic acid.

Comparators
The main comparator of interest is alternative nonsurgical intervention, such as medications.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment related morbidity. Symptoms of TMJD are described in the second PICOTS above.

Timing
The existing literature evaluating nonsurgical therapies as a treatment for confirmed TMJD has varying lengths of follow-up, ranging from 1 week to 6 months of follow-up. While the systematic reviews and RCTs described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, at least one year of follow-up is considered necessary to demonstrate efficacy.

Setting
Patients with confirmed TMJD are actively managed by primary care providers, dentists, and otolaryngologists in an outpatient clinical setting.
Study Selection Criteria
Methodologically credible studies were selected using the following principles:
a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Acupuncture
A 2011 meta-analysis identified 7 sham-controlled RCTs on acupuncture for treating TMJD.(16) The studies included a total of 141 patients. Sample sizes of individual studies ranged from 7 to 28. Four studies used a single acupuncture session, and the other 3 used 6-12 sessions. All 7 studies reported change in pain intensity as assessed by a visual analogue scale (VAS). In 6 of the studies, pain intensity was measured immediately after treatment, the seventh measured pain after 16 weeks. A pooled analysis of findings from 5 studies (n=107) found a statistically significant improvement in pain intensity, as measured by a VAS. The pooled weighted mean difference (WMD) in pain intensity was -13.63 (95% CI: -21.16 to -6.10, p=0.001). A pooled subgroup analysis of 4 studies (n=89) found acupuncture to be superior to a non-penetrating sham acupuncture, WMD: -13.73; 95% CI: -21.78 to -5.67, p=0.001. A pooled analysis of 2 studies (n=18) did not find a significant difference in efficacy between acupuncture and a penetrating sham acupuncture, WMD: -12.95 95% CI:-34.05 to 8.15, p=0.23. The latter analysis may have been underpowered. Reviewers noted that previous studies have found that a 24.2 mm change in pain assessed by a 100 mm VAS represents a clinically significant difference and that only 2 of the included studies had a change of 24.2 mm or more.

Orthodontic Services
A Cochrane review by Luther et al (2010) did not identify any RCTs evaluating orthodontic treatment for treating TMJD and thus concluded that there is insufficient evidence on the efficacy of orthodontics.(17) Reviewers defined orthodontic treatment as appliances that would induce stable tooth movement for a sufficient period of time to bring about permanent change in tooth position. The 2010 Cochrane review was withdrawn in 2016 for being out of date and not meeting current Cochrane methodologic standards;(18) a new Cochrane review on occlusal interventions for managing TMJDS is planned.

Hyaluronic Acid Injection

Systematic Reviews
There are several systematic reviews of studies on hyaluronic acid for treating TMJD.(19-22) Only one of the systematic reviews limited its inclusion criteria to randomized controlled trials and pooled study findings – the 2013 Cochrane review by Shi et al (2013).(21) The Shi review included RCTs comparing the effect of at least one hyaluronic acid injection alone or in combination with other active treatments to placebo or glucocorticoid injections alone or in combination with the same active treatment group. Seven studies met inclusion criteria; 3 studies compared hyaluronic acid and placebo, 3 studies compared hyaluronic acid and
glucocorticoids and 2 studies compared hyaluronic acid plus arthroscopy or arthrocentesis to arthroscopy or arthrocentesis alone. (One study included 3 arms and was included in the first 2 comparisons). Five of the 7 studies included fewer than 50 participants.

Outcomes were categorized as symptoms which reflected subjective feeling and the judgment of the patients and clinical signs which reflected objective judgment of the observer. A meta-analysis of 2 trials did not find a statistically significant difference between hyaluronic acid and placebo on short-term (less than 3 months) improvement in symptoms (risk ratio [RR]: 1.24; 95% CI: 0.72 to 2.14). Similarly, a pooled analysis of 3 trials did not find a significant difference between hyaluronic acid and placebo on short-term improvement of clinical signs (RR: 1.69; 95% CI: 0.80 to 3.57). However, a pooled analysis of 2 studies found a statistically significant between-group difference in long-term effect (≥ 3 months) on clinical signs (RR: 1.71; 95% CI: 1.05 to 2.77). For the comparison between hyaluronic acid and glucocorticoids, only short-term data were available for pooling. There were no significant differences between groups on short-term improvement in symptoms (2 studies, RR: 0.99; 95% CI: 0.84-1.17) or short-term improvement in clinical signs (3 studies, RR: 0.91; 95% CI: 0.66 to 1.25). Data were not pooled for studies on combination treatments (hyaluronic acid plus arthroscopy or arthrocentesis). Reviewers concluded that there was insufficient consistent evidence to draw conclusions on the use of hyaluronate for treating patients with TMJ disorders. This Cochrane review was withdrawn in 2013 for being out of date and not meeting contemporary Cochrane methodologic standards.(23)

Liu et al (2017) conducted a systematic review and meta-analysis of RCTs or cohort studies that compared temporomandibular osteoarthritis outcomes in patients treated with intra-articular corticosteroid, hyaluronate, or placebo injection.(24) All 8 selected studies were RCTs; of these, three contained data on hyaluronate injection. Compared with placebo, corticosteroid injections prompted a significant decrease in long-term (ie, ≥ 6 months post-procedure) pain (3 studies; mean difference, -0.74; 95% CI, -1.34 to -0.13; p=0.02; \( I^2=0\% \)). However, in a pooled analysis of 2 studies (both of which included pretreatment arthrocentesis), long-term maximal mouth opening was increased for placebo more than for corticosteroid injection (mean difference, -2.06; 95% CI, -2.76 to -1.36; p<0.001; \( I^2=28\% \)). Only 2 studies were available for comparing corticosteroid with hyaluronate injections, which precluded strong analysis. Short-term pain and mouth opening measures did not significantly differ between any of the injection groups, nor did the incidence of adverse events. The meta-analysis was limited by the small sample sizes of included trials, as well as by the variety of corticosteroid types used. Reviewers concluded that corticosteroid injection following arthrocentesis may be effective for relief of long-term joint pain, but may be less effective for improving mouth opening.

**Randomized Controlled Trials**
Most of the published RCTs evaluating hyaluronic acid for treating TMJD had small sample sizes, short follow-up times, and/or lack of blinding. Representative RCTs with larger sample sizes and stronger methodology are described next.

Gorrela et al (2017) reported on the efficacy of injecting sodium hyaluronate in patients with TMJDS.(25) The trial comprised 62 individuals with the disorder; some members (n=31) of the trial were treated with arthrocentesis, and some members (n=31) were treated by a combination
of arthrocentesis and an injection of sodium hyaluronate. Follow-up was observed at 1 week, 2 weeks, 1 month, 3 months, and at 6 months. Using a VAS, patients were asked to measure pain from 1 to 10. Pain decreased significantly for patients in both treatment groups (p<0.001) at the 1 week and the 6-month follow-up; however, patients who were injected with sodium hyaluronate reported a significantly stronger decrease in pain at the 6-month follow-up (p<0.001). Preoperative mean VAS pain scores for patients who received injection started at 6.0; by the 6-month follow-up, the mean VAS pain score was 0.23. Preoperative mean pain scores for patients who received arthrocentesis alone started at 6.77; by the 6-month follow-up, the mean pain score was 1.71. While not an overwhelmingly significant difference, the trialists concluded that adding an injection of sodium hyaluronate to arthrocentesis treatment can significantly decrease the pain felt by patients who suffer from TMJD.

A study by Manfredini et al (2012) in Italy randomized 72 patients with TMJ dysfunction to 1 of 6 treatment groups: 1) single-session arthrocentesis alone; 2) single-session arthrocentesis plus corticosteroid; 3) single-session arthrocentesis plus low-molecular weight hyaluronic acid; 4) single-session arthrocentesis plus high-molecular weight hyaluronic acid; 5) 5 weekly arthrocenteses plus low-molecular weight hyaluronic acid; or 6) 5 weekly single-needle arthrocenteses plus low-molecular weight hyaluronic acid.(26) Sixty out of 72 (83%) participants completed the study, between 9 and 12 patients per treatment group. In a per protocol analysis, there were no significant differences among groups on any of the outcome variables at the 3-month follow-up. For example, the percentage change in pain at rest ranged from -29.1% in the group receiving 5 weekly single-needle arthrocenteses plus low-molecular weight hyaluronic acid to -38.4% in the group receiving a single-session of arthrocentesis alone. Limitations of the study include the small number of patients in each treatment group and the substantial number of dropouts in absence of an intention-to-treat (ITT) analysis.

A study by Bjorland et al (2007) in Norway evaluated 40 patients with osteoarthritis of the TMJD in a double-blind RCT.(27) Patients received 2 injections, 14 days apart, of sodium hyaluronate or corticosteroids. The pain was assessed using a visual analogue scale (VAS) from 0 to 100. Patients were followed for 6 months (assessed at 14 days, 1 month and 6 months). There was a statistically significant reduction in pain within each group at all of the follow-up points. At the 6 month follow-up, pain intensity (mean VAS score) was 14 in the hyaluronic acid group and 31 in the corticosteroid group; the between-group difference was statistically significant (p<0.001). The number of patients who were pain-free at 6 months was 7 (35%) of 20 in the hyaluronic acid group and 6 (30%) of 20 in the corticosteroid group (p value not reported).

Bertolami et al (1993) published a double-blind placebo-controlled trial evaluating 121 patients with TMJD.(28) Patients had to have a confirmed diagnosis of degenerative joint disease (DJD), reducing displaced disc (DDR) or non-reducing displaced disc (DDN), failure of other non-surgical treatments, and severe dysfunction. Patients received a single injection of sodium hyaluronate or saline and were followed for 6 months. Eighty patients were randomized to the hyaluronate group and 41 to the placebo group. This included a total of 57 patients in the DJD group, 50 patients in the DDR group, and 14 patients in the DDN group. Fourteen (12%) of 121 patients were excluded from the analysis because they did not meet eligibility criteria. No significant differences in outcomes were seen for the DJD group. In the DDN group, there were significant between-group differences through 1 month, favoring the hyaluronic acid group. The
number of patients in the DDN group who completed follow-up after 1 month was insufficient to
draw meaningful conclusions about efficacy. In the DDR group, there were no statistically
significant differences between groups in any outcome at 1 or 2 months. At 3 and 6 months, 2
out of 7 reported outcomes were significantly better in the hyaluronic acid group than in the
placebo group. At 5 months, 5 out of 7 reported outcomes were significantly better in the
hyaluronic acid group. The 7 outcomes included 3 measures of dysfunction, 2 measures of
patient perception of improvement, 2 measures of change in noise. The most consistent
between-group differences in the DDR group were for the 2 measures of patient perception of
improvement and one of the noise variables. There were fewer between-group differences on
dysfunction measures.

**Section Summary: Nonsurgical Therapies**
A systematic review evaluating the use of orthodontic services to treat TMJD did not find
sufficient literature to draw conclusions about efficacy. The evidence on acupuncture is limited
by the small number of studies, small sample sizes, and in most studies, efficacy assessment
only immediately post-treatment. The evidence on the use of hyaluronic acid to treat TMJD is
inconclusive, given the methodologic issues with the systematic review and RCTs conducted
(eg, small sample sizes) and better surgical options. Overall, the evidence is insufficient to
determine that the technologies result in a meaningful improvement in the net health outcome.

**Surgical Techniques**

**Clinical Context and Therapy Purpose**
The purpose of surgical techniques in patients with a confirmed diagnosis of TMJD is to provide
a treatment option that is an alternative to or an improvement on existing therapies, such as
nonsurgical intervention.

The question addressed in this evidence review is: do surgical therapies improve the net health
outcome for individuals with a confirmed diagnosis of TMJD?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest is individuals with confirmed TMJD.

**Interventions**
The surgical therapies being considered are arthrocentesis and arthroscopy.

**Comparators**
The main comparator of interest is alternative nonsurgical intervention, such as intraoral
devices and appliances, pharmacologic treatment, acupuncture, biofeedback, TENS,
orthodontic services, and hyaluronic acid.

**Outcomes**
The general outcomes of interest are symptoms, functional outcomes, quality of life, and
treatment related morbidity. Symptoms of TMJD are described in the second PICOTS above.
**Timing**
The existing literature evaluating surgical techniques as a treatment for confirmed TMJD has varying lengths of follow-up up to 6 months. While the systematic reviews described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, at least six months of follow-up is considered necessary to demonstrate efficacy.

**Setting**
Patients with confirmed TMJD are actively managed by primary care providers, dentists, and otolaryngologists in an outpatient clinical setting.

**Study Selection Criteria**
Methodologically credible studies were selected using the following principles:

- **a.** To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- **b.** In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- **c.** To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- **d.** Studies with duplicative or overlapping populations were excluded.

A Cochrane review by Guo et al (2009) identified 2 RCTs (total of 81 patients) that compared the effectiveness of arthrocentesis and lavage for the treatment of TMJD.

Data were pooled only for the outcome maximum incisal opening. A meta-analysis of the 2 trials found a significant difference between the interventions for this outcome with a WMD of -5.28 (95% CI: -7.10 to -3.46) in favor of arthroscopy. The Cochrane review was withdrawn in 2015 for being out of date and not meeting current Cochrane methodologic standards.

Another Cochrane review (2015) on surgical interventions for managing TMJD is planned. Another Cochrane review reporting on arthroscopy for TMJD, was also withdrawn from Cochrane from 2015 for being out of date and not meeting current Cochrane methodologic standards.

In a systematic review, Vos et al (2013) identified 3 RCTs (total N=222 patients) that compared the efficacy of lavage of the TMJ (ie, arthrocentesis or arthroscopy) with nonsurgical TMJ treatment.

Although reviewers assessed the quality of the studies to be adequate, only 1 study stated that allocation to treatment group was concealed, and 2 studies did not explicitly state that an intention-to-treat (ITT) analysis was used. The 2 primary outcomes considered were change in pain and maximal mouth opening (MMO) at 6 months compared with baseline. The pain was measured by VAS. Pooled analysis of data from the 3 trials found a statistically significant reduction in pain at 6 months with surgery plus lavage versus nonsurgical therapy (SMD = -1.07; 95% CI, -1.38 to -0.76). There was no statistically significant difference in the efficacy between the 2 treatments for the other outcome variable, MMO (SMD=0.05; 95% CI, -0.33 to 0.23).

In a retrospective cohort study in 2018, Hossameldin and McCain assessed the efficacy of an office-based TMJ arthroscopic technique. The researchers assessed the following outcomes of the procedure: improvement in painless range-of-motion in the mandible, reduced pain on
loading, and improvement in functional jaw pain. The cohort included an initial 363 patients, excluded 41, and an analysis was performed on the joints of the remaining 322 that were compromised. Within the 322 patients, 452 joints were operated on with a 66.6% (n=301 joints) success rate (p=.001). It is stated within the outcome variable section that the primary outcome variable of success or failure was determined by the reduction of joint pain postoperatively. This could be subjective. When the operation failed (n=151 joints, 33.3%), 141 joints were involved in a subsequent procedure that ranged from more advanced arthroscopy to a total joint replacement.(36)

Section Summary: Surgical Techniques
Systematic reviews of the literature, which includes RCTs, have shown that use of arthrocentesis and lavage reduces pain levels in patients with TMJD.

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 accuracy, test validity, and other performance measures. None of the systematic reviews found that these diagnostic techniques accurately identify patients with TMJD and many of the included studies had methodological 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 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 found a significant benefit of several pharmacologic treatments (eg, analgesics, muscle relaxants, and anti-inflammatory medications [vs placebo]). The evidence is sufficient to determine quantitatively 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 and systematic reviews of RCTs and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic reviews did not find that the above technologies improved pain and functional outcomes significantly more than control conditions. Many individual studies had small sample sizes and/or 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 and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Only 1 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 than control interventions. The evidence is sufficient to determine quantitatively that the technology results in a meaningful improvement in the net health outcome.

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**Supplemental Information**

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

**American Association for Dental Research:**
A 2010 policy statement, reaffirmed in 2015, recommended the following for the diagnosis and treatment of TMJ disorders:(33)

> “It is recommended that the differential diagnosis of TMDs [temporomandibular disorders] or related orofacial pain conditions should be based primarily on information obtained from the patient’s history, clinical examination, and when indicated, TMJ radiology or other imaging procedures. The choice of adjunctive diagnostic procedures should be based upon published, peer-reviewed data showing diagnostic efficacy and safety. However, the consensus of recent scientific literature about currently available technological diagnostic devices for TMDs is that except for various imaging modalities, none of them shows the sensitivity and specificity required to separate normal subjects from TMD patients or to distinguish among TMD subgroups...."

> “It is strongly recommended that, unless there are specific and justifiable indications to the contrary, treatment of TMD patients initially should be based on the use of conservative, reversible and evidence-based therapeutic modalities. Studies of the natural history of many TMDs suggest that they tend to improve or resolve over time. While no specific therapies have been proven to be uniformly effective, many of the conservative modalities have proven to be at least as effective in providing symptomatic relief as most forms of invasive treatment...."

**American Society of Temporomandibular Joint Surgeons**
Consensus clinical guidelines, published in 2001, focus on TMJ associated with internal derangement and osteoarthritis.(34) For diagnosis of this type of TMJ dysfunction, a detailed history and, when indicated, general physical examination are recommended. Imaging of the TMJ and associated structures is also recommended. Options for basic radiography to provide information on temporal bone and condylar morphology include use of plain films, panoramic films, and tomograms. Also recommended is imaging of the disc and associated soft tissue with MRI or arthrography. Other diagnostic procedures that may be indicated include computed tomography, MRI, arthrography (for selected cases) and isotope bone scans.

Nonsurgical treatment was recommended as a first-line therapy for all symptomatic patients with this condition. Recommended treatment options include change in diet, nonsteroidal anti-inflammatory drugs, maxillomandibular appliances, physical therapy, injections of corticosteroids or botulinum toxin, and behavior modification. If adequate symptom relief does not occur within 2-3 weeks, surgical consultation is advised. The guideline states that the
following surgical procedures are considered to be accepted and effective for patients with TMJD associated with internal derangement/osteoarthritis:

- Arthrocentesis
- Arthroscopy
- Condylotomy
- Arthrotomy (prosthetic joint replacement may be indicated in selected patients who have severe joint degeneration, destruction, or ankylosis)
- Coronidotomy/coronoidectomy
- Styloidectomy

**American Dental Association**

Selected statements from the American Dental Association’s practice parameters for TMJDS, last revised in 1997, included:(35)

- Initially the dentist should select the least invasive and most reversible therapy that may ameliorate the patient’s pain and/or functional impairment.
- The dentist should evaluate the effectiveness of initial therapy prior to considering more invasive and/or irreversible therapy.
- When articular derangement and/or condylar dislocation has been determined to be the etiology of the patient’s pain and/or functional impairment, manual manipulation of the mandible may be performed by the dentist.
- Oral orthotics (guards/splints) may be used by the dentist to enhance diagnosis, facilitate treatment or reduce symptoms.
- Before restorative and/or occlusal therapy is performed, the dentist should attempt to reduce, through the use of reversible modalities, the neuromuscular, myofascial and temporomandibular joint symptoms.
- The dentist may replace teeth or alter tooth morphology and/or position by modifying occluding, articulating, adjacent or approximating surfaces, and by placing or replacing restorations (prostheses) to facilitate treatment.
- Transitional or provisional restorations (prostheses) may be utilized by the dentist to facilitate treatment.
- Intracapsular and/or intramuscular injection, and/or arthrocentesis may be performed for diagnostic and/or therapeutic purposes.
- Orthodontic therapy may be utilized to facilitate treatment.
- Orthognathic surgery may be performed to facilitate treatment.
- When internal derangement or pathosis has been determined to be the cause of the patient’s pain and/or functional impairment, arthroscopic or open resective or reconstructive surgical procedures may be performed by the dentist.

**U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS**

Not applicable.
ONGOING AND UNPUBLISHED CLINICAL TRIALS
Some currently unpublished trials that might influence this review are listed in Table 3.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
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<tbody>
<tr>
<td>NCT02830067</td>
<td>Influence of Intraoral Phototherapy on Pain, Joint Mobility, Functionality and Quality of Life in Individuals With Temporomandibular Joint Dysfunction</td>
<td>30</td>
<td>Jan 2018</td>
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<tr>
<td>NCT02437383</td>
<td>Effect of COMT (Catecholamine-O-methyltransferase) Genetic Polymorphisms on Response to Propranolol Therapy in Temporomandibular Disorder</td>
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<td>Apr 2018</td>
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<td>NCT03180671</td>
<td>The Effectiveness of Anterior Deprogrammers as a Tool for Reducing Pain and Masticatory Muscles</td>
<td>80</td>
<td>May 2019</td>
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<tr>
<td>NCT03029494</td>
<td>The Role of Oxidative Stress and Opioid in Temporomandibular Disorders</td>
<td>80</td>
<td>Sep 2019</td>
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<tr>
<td>NCT02397070</td>
<td>Effectiveness of a Jaw Exercise Program in Temporomandibular Disorder Patients</td>
<td>30</td>
<td>Jul 2015 (unknown)</td>
</tr>
<tr>
<td>NCT02637544</td>
<td>Treatment Efficacy of Acupuncture in Non-Chronified Pain Patients with TMDs</td>
<td>40</td>
<td>Aug 2016</td>
</tr>
<tr>
<td>NCT02822469</td>
<td>Thermograph Evaluation of Masticatory Muscles Pre and Post Indirect Physiotherapeutic Treatment in TMD Subjects: A Randomized, Placebo-controlled Study</td>
<td>32</td>
<td>Dec 2016</td>
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<tr>
<td>NCT02602483a</td>
<td>Randomized, Double Blind, Placebo Controlled Exploratory Study To Assess the Efficacy and Safety of a Triple Combination of Ibuprofen+Mg+Ascorbic Acid for Acute Pain Treatment in Temporomandibular Joint Disorder (TMJD) Patients</td>
<td>96</td>
<td>Dec 2016 (completed)</td>
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<tr>
<td>NCT02908568</td>
<td>Effect of Stimulation of the Proprioceptive Trigeminocardiac Reflex through Medical Device for the Pain of Patients with Temporomandibular Disorders</td>
<td>36</td>
<td>Aug 2017</td>
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</tbody>
</table>

NCT: national clinical trial
*a Denotes industry-sponsored or cosponsored trial.

Government Regulations
National:
No policy noted regarding treatment of TMJ.

Local:
Local Coverage Determination (LCD): Oral Appliances for Obstructive Sleep Apnea (L33611); Original Effective Date: 10/1/15; Revision date: 1/1/19
For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.
A custom fabricated mandibular advancement ORAL APPLIANCE (E0486) used to treat obstructive sleep apnea (OSA) is covered if criteria A - D are met.
   A. The beneficiary has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the beneficiary for obstructive sleep apnea testing. Refer to the
“ICD-10 Codes that are Covered” section in the LCD-related Policy Article for applicable diagnoses.

B. The beneficiary has a Medicare-covered sleep test that meets one of the following criteria (1 - 3):
   1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
   2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
      a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
      b. Hypertension, ischemic heart disease, or history of stroke; or,
   3. If the AHI> 30 or the RDI> 30 and meets either of the following(a or b):
      a. The beneficiary is not able to tolerate a positive airway pressure (PAP) device; or,
      b. The treating physician determines that the use of a PAP device is contraindicated.

C. The device is ordered by the treating physician following a review of the report of the sleep test. (The physician who provides the order for the ORAL APPLIANCE could be different from the one who performed the clinical evaluation in criterion A.)

D. The device is provided and billed for by a licensed dentist (DDS or DMD).

If all of these criteria (A-D) are not met, the custom fabricated ORAL APPLIANCE (E0486) will be denied as not reasonable and necessary.

Local Coverage Article: Oral Appliances for Obstructive Sleep Apnea (A52512); Original date: 10/01/15; Revision date: 1/1/17; Revision Ending Date: 12/31/18 - Superseded

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”).

Oral appliances used to treat obstructive sleep apnea (OSA) are covered under the Durable Medical Equipment benefit (SSA 1861(s) (6)). In order for a beneficiary’s equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that must be met.

Oral appliances generally are classified as dental devices and are not classified as durable medical equipment. The following items (not all-inclusive) are considered to be dental devices and will be denied as non-covered, not DME:
   • Oral occlusal appliances used to treat TEMPOROMANDIBULAR JOINT (TMJ) disorders
• Tongue retaining devices used to treat OSA and/or snoring
• All oral appliances used only to treat snoring without a diagnosis of OSA
• Oral appliances used to treat other dental conditions
• Oral appliances that require repeated fitting and/or adjustments, beyond the first 90-days, in order to maintain fit and/or effectiveness

All follow-up care, including fitting, adjustments, modifications, professional services (not all-inclusive) required during the first 90 days after provision of the oral appliance are considered to be included in the payment for device. Claims for these will be denied as not separately payable.

After the initial 90-day period, adjustments, modifications and follow-up visits are not eligible for coverage under the DME benefit and are therefore not within the jurisdiction of the DME MAC.

Repairs are covered for items that meet the coverage criteria. To repair means to fix or mend and to put the item back in good condition after damage or wear. Repairs are covered when necessary to make the item serviceable. If the expense for repairs exceeds the estimated expense of purchasing another item, no payment can be made for the excess.

Oral appliances are eligible for replacement at the end of their 5-year reasonable useful lifetime (RUL). These items may be replaced prior to the end of the 5-year RUL in cases of loss, theft, or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (e.g., fire, flood). Replacement due to wear-and-tear as the result of everyday use will be denied as statutorily non-covered prior to the expiration of the 5-year RUL.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies
None

References


37. Centers for Medicare Services. “Local coverage article: Oral appliances for obstructive sleep apnea – policy article (A52512),” Original effective date: 10/1/15; retrieved March 11, 2019 from: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52512&ver=7&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=27&KeyWord=temporomandibular+joint&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAA&.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 6/4/19, the date the research was completed.
## BCN Medical Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Rationale</th>
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<tbody>
<tr>
<td>5/14/01</td>
<td>BCN policy established</td>
</tr>
<tr>
<td>7/8/02</td>
<td>Joint medical policy developed</td>
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<tr>
<td>7/8/04</td>
<td>Joint medical policy retired, changed to a BCN-only medical policy. Updated codes and references</td>
</tr>
<tr>
<td>7/13/05</td>
<td>Routine maintenance and update</td>
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<tr>
<td>9/24/06</td>
<td>Maintenance; diagnostic testing added to policy</td>
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<td>9/10/07</td>
<td>Routine maintenance</td>
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<td>10/15/08</td>
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<td>2/9/10</td>
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<tr>
<td>2/15/12</td>
<td>Routine maintenance; updated codes; added acupuncture and ultrasound imaging/sonogram to exclusions; updated references</td>
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<tr>
<td>6/19/13</td>
<td>Routine maintenance; added exclusion “Hyaluronic Acid”, codes J7321-J7326 are excluded; removed code 29800 from policy, as this is a diagnostic surgical procedure and is excluded.</td>
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<tr>
<td>10/15/14</td>
<td>Routine maintenance; added clarification on BCN Benefit page that there is FEP coverage for corrective orthopedic appliances for non-dental treatment of TMJ.</td>
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<td>9/16/15</td>
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<tr>
<td></td>
<td>• Added to inclusions: Intraoral removable prosthetic devices/appliances</td>
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<tr>
<td></td>
<td>• Removed from exclusions: condylar position indication</td>
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<tr>
<td>7/18/18</td>
<td>• Routine maintenance</td>
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<tr>
<td>7/17/19</td>
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<td>• LCA added</td>
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Next Review: 3rd Qtr, 2020
I. Coverage Determination

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<th>Coverage Details</th>
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<tr>
<td>Commercial HMO (includes Self-Funded groups unless otherwise specified)</td>
<td>Covered, criteria apply; Federal Employee Program (FEP) members have coverage for prostheses and appliances for or related to the non-dental treatment of TMD; Refer to current certificate.</td>
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<tr>
<td>BCNA (Medicare Advantage)</td>
<td>Covered, criteria apply</td>
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<tr>
<td>BCN65 (Medicare Complementary)</td>
<td>Coinsurance covered if primary Medicare covers the service.</td>
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</table>

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member’s certificate and is not guaranteed. Please consult the member’s certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member’s PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.