Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Temporomandibular Joint Dysfunction when it is determined to be medically necessary because the criteria shown below are met.

Note: Medical treatment for temporomandibular joint (TMJ) dysfunction may be a benefit exclusion. Please review benefit language.

When Policy Topic is covered
The following diagnostic procedures may be considered medically necessary in the diagnosis of temporomandibular joint (TMJ) dysfunction:

- 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 nonsurgical treatments may be considered medically necessary in the treatment of TMJ dysfunction:

- Intraoral removable prosthetic devices/appliances (encompassing fabrication, insertion, adjustment);
- Pharmacologic treatment (eg, anti-inflammatory, muscle relaxing, analgesic medications).

The following surgical treatments may be considered medically necessary in the treatment of TMJ dysfunction:

- 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.

**When Policy Topic is not covered**
The following diagnostic procedures are considered *investigational* in the diagnosis of TMJ dysfunction:
- Electromyography (EMG), including surface EMG;
- Kinesiography;
- Thermography;
- Neuromuscular junction testing;
- Somatosensory testing;
- Transcranial or lateral skull x-rays; intraoral 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 (TMJ) for purely diagnostic purposes;
- Joint vibration analysis.

The following nonsurgical treatments are considered *investigational* in the treatment of TMJ dysfunction:
- 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;
- Acupuncture;
- Hyaluronic acid.

**Description of Procedure or Service**

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<th>Populations</th>
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**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.

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 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 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 have 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 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 the above technologies improved pain and 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 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 that the technology results in a meaningful improvement in the net health outcome.

**Background**

Temporomandibular joint disorder (TMJD) (also known as TMJ dysfunction) 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 2 main categories: articular disorders (eg, ankylosis, congenital or developmental disorders, disc derangement disorders, fractures, inflammatory disorders, osteoarthritis, joint dislocation) and masticatory muscle disorders (eg, myofascial pain, myofibrotic contracture, myospasm, neoplasia).

In the clinical setting, TMJD is often a diagnosis of exclusion and involves physical examination, patient interview, and review of dental records. 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 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).

For many patients, symptoms of TMJD are short-term and self-limiting. Conservative treatments (eg, eating soft foods, rest, heat, ice, avoiding extreme jaw movements) and anti-inflammatory medication are recommended before considering 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.

Rationale
This evidence review was created in November 1996 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through December 11, 2017.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

For treatment of temporomandibular joint disorders (TMJD), literature searches have focused on studies comparing novel treatments with conservative interventions and/or placebo controls (rather than no-treatment control groups) and reporting pain reduction and/or functional outcome improvements (eg, jaw movement).

Diagnosis of TMJD
Several systematic reviews of the literature on specific techniques for diagnosing TMJD were identified and are described next.
Ultrasound
A 2009 literature review identified 20 studies evaluating ultrasound for diagnosing TMJDs; all studies evaluated disc displacement and several also considered osteoarthritis and/or joint effusion. The reported sensitivity of ultrasound to detect disc displacement, compared with the reference standard (magnetic resonance imaging in most studies), ranged from 31% to 100%, and the specificity ranged from 30% to 100%. Reviewers stated that even when changes in ultrasound technology over time were taken into account, study findings were contradictory. They noted unexplained differences between studies conducted by the same group of researchers. Reviewers concluded that additional advances are needed to standardize ultrasound assessment of TMJD before it can be considered an accurate diagnostic tool.

Surface Electromyography
A 2006 systematic review of surface electromyography found a lack of literature on the accuracy of this method of diagnosis, compared with a criterion standard (ie, comprehensive clinical examination and history-taking). Reviewers concluded that there was 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 on joint vibration analysis for diagnosis of TMJDs. 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 nonvalidated 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 TMJD
Systematic Reviews
List and Axelsson (2010) published a review of systematic reviews on treatments for TMJD published through August 2009. They identified 30 reviews; there were 23 qualitative systematic reviews and 7 meta-analyses. Eighteen of the systematic reviews included only RCTs, three only included case-control studies, and nine included a mix of RCTs and case series. TMJDs were defined inconsistently in the primary studies and systematic reviews, and several 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 >1 category). These categories and the main findings are listed in Table 1.

<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>
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<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>
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<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>
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<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 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.</td>
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<td>Behavioral therapy and multimodal treatments</td>
<td>6</td>
<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).^7|

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 exercises, postural training, and some medications could be effective at reducing pain for patients with TMJDs. However, reviewers noted that most of the systematic reviews examined included primary studies with considerable variation in methodologic quality and, thus, it was not possible to draw 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. 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 TMJDs of variable duration and generally reported no significant improvements with occlusal devices regarding pain, mouth opening, or other outcomes.

Orthotics

Intraoral Devices or Appliances

Fricton et al (2010) reported on a systematic review of RCTs on the intraoral treatment of TMJDs and identified 47 publications on 44 trials. 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 different treatment (eg, acupuncture or biofeedback). None of the studies evaluated the use of 1 device during the day and a different device during the night. The primary outcome of the meta-analysis was pain reduction. The 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 the pain was measured by the 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 for pooled analysis. A pooled analysis of 7 RCTs (n=385 patients) that evaluated hard stabilization appliances and use of palatal nonoccluding appliances as a control found a significantly greater reduction in pain with hard appliances (odds ratio, 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 (odds ratio, 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, assessed using PRISMA methodology. Reviewers included 21 articles evaluating some 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 TMJDs with minimal or no therapy. 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 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, -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 no 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 TMJDs. Risk of bias was high for two or more domains for all studies. Splint therapy group patients had greater improvements in pain control than control patients (mean difference, 2.02; 95% CI, 1.55 to 2.49; $I^2=0.558$).

An earlier Cochrane review by Al-Ani et al (2004) identified 12 RCTs that compared stabilization splint therapy for TMJD with a control intervention. (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.

**Section Summary: Orthotics**
Evidence evaluating the use of orthotics in the treatment of TMJD, while sometimes conflicting and inconclusive, suggests that use of orthotics reduces TMJD pain.

**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. 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: Pharmacologic Treatment**
A systematic review found that different pharmacologic agents reduced pain in patients with TMJD.

**Other Nonsurgical Therapies**
Acupuncture

A 2011 systematic review and meta-analysis identified 7 sham-controlled randomized trials evaluating acupuncture for treating TMJD. The studies included a total of 141 patients. Sample sizes of individual studies ranged from 7 to 28 patients. Four studies used a single acupuncture session, and the other 3 used 6 to 12 sessions. All 7 studies reported change in pain intensity as assessed by 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 patients) found a statistically significant reduction in pain intensity, as measured by 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 patients) found acupuncture to be superior to a nonpenetrating sham acupuncture (WMD = -13.73; 95% CI, -21.78 to -5.67; p<0.001). A pooled analysis of 2 studies (n=18 patients) 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 might have been underpowered. Reviewers noted that previous studies had 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 selected 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 TMJDs and thus concluded that there was insufficient evidence on the efficacy of orthodontics. Reviewers defined orthodontic treatment as appliances that would induce stable tooth movement for a sufficient period 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; a new Cochrane review on occlusal interventions for managing TMJDs is planned.

Hyaluronic Acid Injection

Systematic Reviews

Several systematic reviews of studies have assessed use of hyaluronic acid for treating TMJDs. Only one systematic review limited its inclusion criteria to RCTs and pooled study findings—the Cochrane review by Shi et al (2013). The Shi review included RCTs comparing the effect of at least 1 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 with placebo, 3 studies compared hyaluronic acid with glucocorticoids, and 2 studies compared hyaluronic acid plus arthroscopy or arthrocentesis with 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 the subjective feeling and the judgment of the patients, and clinical signs, which reflected the objective judgment of the observer. A meta-analysis of 2 trials did not find a statistically significant difference between hyaluronic acid and placebo for short-term (<3 months) improvement in symptoms (relative risk [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 for 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 for short-term improvement in symptoms (2 studies; RR=0.99; 95% CI, 0.84 to 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 of combination treatments (hyaluronic acid plus arthroscopy or arthrocentesis). Reviewers found that there was insufficient consistent evidence to draw conclusions on the use of hyaluronate for treating patients with TMJDs. This Cochrane review was withdrawn in 2013 for being out of date and not meeting contemporary Cochrane methodologic standards.

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. 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 postprocedure) 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 published RCTs evaluating hyaluronic acid for treating TMJDs have had small sample sizes, short follow-up times, and/or lacked 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. 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 TMJD 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. Sixty (83%) of 72 participants completed the study, with 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 arthrocentesis plus low-molecular-weight hyaluronic acid injections to -38.4% in the group receiving a single-session of arthrocentesis alone. Trial limitations included the small number of patients in each treatment group and the substantial number of dropouts in the absence of an intention-to-treat analysis.

A study by Bjornland et al (2007) in Norway evaluated 40 patients with osteoarthritis of the TMJD in a double-blind RCT. Patients received 2 injections, 14 days apart, of sodium hyaluronate or corticosteroids. The pain was assessed using a VAS ranging 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 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 that evaluating 121 patients with TMJD. Patients had to have a confirmed diagnosis of degenerative joint disease, reducing displaced disc or nonreducing displaced disc (DDN), failure of other nonsurgical 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 57 patients in the degenerative joint disease group, 50 patients in the reducing displaced disc 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. Seven outcomes were assessed, including 3 measures of dysfunction, 2 measures of patient perception of improvement, and 2 measures of change in noise. No significant differences in outcomes were seen for the degenerative joint disease 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. The most consistent between-group differences in the reducing displaced disc 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 posttreatment. 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.

**Surgical Techniques**
A Cochrane review by Guo et al (2009) identified 2 RCTs (total N=81 patients) that compared the effectiveness of arthrocentesis plus lavage with arthroscopy for the treatment of TMJD. Data were pooled only for the outcome of maximum incisal opening. A meta-analysis of the 2 trials found a statistically significant difference between the interventions for this outcome, with a WMD of -5.28 (95% CI, -7.10 to -3.46), favoring arthroscopy. The Cochrane review was withdrawn in 2015 for being out of date and not meeting current Cochrane methodologic standards. Another Cochrane review (2015) 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 temporomandibular joint (ie, arthrocentesis or arthroscopy) with nonsurgical temporomandibular joint treatment. Although reviewers assessed the quality of the studies to be adequate, only one stated that allocation to treatment group was concealed; two did not explicitly state use of an intention-to-treat analysis. The 2 primary outcomes considered were change in pain and maximal mouth opening 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 vs 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, maximal mouth opening (SMD=0.05; 95% CI, -0.33 to 0.23).
**Section Summary: Surgical Techniques**
Systematic reviews of the literature, which includes RCTs, have shown that use of arthrocentesis and arthroscopy 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 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 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 (eg, 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.

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 and systematic reviews of the 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 compared with control interventions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Supplemental Information**
Practice Guidelines and Position Statements

American Association for Dental Research
A 2010 policy statement, reaffirmed in 2015, by the American Association for Dental Research recommended the following for the diagnosis and treatment of temporomandibular joint disorders (TMJDs):

“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 [temporomandibular joint] 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, by the American Society of Temporomandibular Joint Surgeons focused on TMJDs associated with internal derangement and osteoarthritis. For diagnosis of this type of TMJD, a detailed history and, when indicated, a general physical examination was recommended. Imaging of the temporomandibular and associated structures is also recommended. Options for basic radiography to provide information on temporal bone and condylar morphology included the use of plain films, panoramic films, and tomograms. Also recommended was imaging of the disc and associated soft tissue with magnetic resonance imaging or arthrography. Other diagnostic procedures indicated included computed tomography, magnetic resonance imaging, arthrography (for selected cases) and isotope bone scans.

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

- “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, 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.

**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.
**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 2.

### Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></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 (ongoing)</td>
</tr>
<tr>
<td>NCT02880774</td>
<td>Influence of Manual Therapy in Temporomandibular Joint on the Mandibular Movement: Clinical Trial, Randomized, Placebo-controlled and Blind</td>
<td>24</td>
<td>Aug 2016 (ongoing)</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 (ongoing)</td>
</tr>
<tr>
<td>NCT02839967</td>
<td>Influence of Intraoral Phototherapy on Pain, Joint Mobility, Functionality and Quality of Life in Individuals With Temporomandibular Joint Dysfunction</td>
<td>20</td>
<td>Jun 2017 (ongoing)</td>
</tr>
<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 (ongoing)</td>
</tr>
<tr>
<td>NCT02437383</td>
<td>Effect of COMT (Catecholamine-O-methyltransferase) Genetic Polymorphisms on Response to Propranolol Therapy in Temporomandibular Disorder</td>
<td>200</td>
<td>Mar 2018</td>
</tr>
<tr>
<td>NCT02144233</td>
<td>Restoring Masticatory Function as Treatment for Chronic Pain: a Randomized Placebo-controlled Trial</td>
<td>110</td>
<td>Nov 2018</td>
</tr>
<tr>
<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>
</tr>
<tr>
<td>NCT03029494</td>
<td>The Role of Oxidative Stress and Opio[r]phin in Temporomandibular Disorders</td>
<td>80</td>
<td>Sep 2019</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<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>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>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

**References**


Billing Coding/Physician Documentation Information

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20605</td>
<td>Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); without ultrasound guidance</td>
</tr>
<tr>
<td>21010</td>
<td>Arthrotomy, temporomandibular joint</td>
</tr>
<tr>
<td>21116</td>
<td>Injection procedure for temporomandibular joint arthrography</td>
</tr>
<tr>
<td>21050</td>
<td>Condylectomy, temporomandibular joint (separate procedure)</td>
</tr>
<tr>
<td>21060</td>
<td>Meniscectomy, partial or complete, temporomandibular joint (separate procedure)</td>
</tr>
<tr>
<td>21073</td>
<td>Manipulation of temporomandibular joint(s) (TMJ), therapeutic, requiring an anesthesia service (ie, general or monitored anesthesia care)</td>
</tr>
<tr>
<td>21240</td>
<td>Arthroplasty, temporomandibular joint, with or without autograft (includes obtaining graft)</td>
</tr>
<tr>
<td>21242</td>
<td>Arthroplasty, temporomandibular joint, with allograft</td>
</tr>
<tr>
<td>21243</td>
<td>Arthroplasty, temporomandibular joint, with prosthetic joint</td>
</tr>
</tbody>
</table>
replacement

29800  Arthroscopy, temporomandibular joint, diagnostic, with or without synovial biopsy (separate procedure)
29804  Arthroscopy, temporomandibular joint, surgical
70328  Radiologic examination, temporomandibular joint, open and closed mouth; unilateral
70330  Radiologic examination, temporomandibular joint, open and closed mouth; bilateral
70332  Temporomandibular joint arthrography, radiological supervision and interpretation
70336  Magnetic resonance (eg, proton) imaging, temporomandibular joint(s)
70350  Cephalogram, orthodontic
70355  Orthopantogram (eg, panoramic x-ray)
97010  Application of a modality to 1 or more areas; hot or cold packs
97024  Application of a modality to 1 or more areas; diathermy (eg, microwave)
97026  Application of a modality to 1 or more areas; infrared
E1700  Jaw motion rehabilitation system
E1701  Replacement cushions for jaw motion rehabilitation system, package of 6
E1702  Replacement measuring scales for jaw motion rehabilitation system, package of 200
S8948  Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes

ICD-10 Codes
M26.00-M26.09  Major anomalies of jaw size
M26.10-M26.19  Anomalies of jaw-cranial base relationship
M26.50-M26.59  Dentofacial functional abnormalities
M26.601-M26.69  Temporomandibular joint disorders
S03.00xA-S03.03xS  Dislocation of jaw code range
S03.40xA-S03.43xS  Sprain of jaw code range

Additional Policy Key Words
N/A

Policy Implementation/Update Information
01/2018  New Policy. Considered Medically Necessary when criteria is met.
01/2019  No policy statement changes.
State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.