



Louisiana

Temporomandibular Joint Dysfunction

Policy # 00583

Original Effective Date: 01/01/2018

Current Effective Date: 09/01/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Botulinum Toxins is addressed separately in medical policy 00012.

Note: Intra-Articular Hyaluronan Injections for Osteoarthritis of the Knee is addressed separately in medical policy 00075.

Note: Electrical Nerve Stimulation is addressed separately in medical policy 00142.

Note: Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT) is addressed separately in medical policy 00144.

Diagnostic Procedures

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider **ANY** of the following *diagnostic procedures* in the diagnosis of temporomandibular joint dysfunction (TMJD) to be **eligible for coverage****:

- Diagnostic x-ray, tomograms, and arthrograms; **OR**
- Computed tomography (CT) scan (in general, computed tomography [CT] scans are reserved for presurgical evaluations); **OR**
- Magnetic resonance imaging (MRI) of the temporomandibular joint (TMJ) for evaluation of internal derangement or disc displacement when **BOTH** of the following requirements are met:

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- Mechanical symptoms (such as locking, popping, or clicking) which have not improved after at least 3 months of conservative management, including nonsteroidal anti-inflammatory drugs or acetaminophen, a short-term trial of soft diet and proper chewing techniques, and an oral appliance (such as a bite block); **AND**
- Surgical intervention is being considered; **OR**
- Cephalograms (x-rays of jaws and skull); **OR**
- Pantograms (x-rays of maxilla and mandible).

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

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers *diagnostic procedures* in the diagnosis of temporomandibular joint dysfunction (TMJD), including but not limited to the following procedures, to be **investigational***:

- Electromyography (EMG), including surface electromyography (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 jaw that are associated with temporomandibular joint dysfunction [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 temporomandibular joint dysfunction [TMJD]);
- Ultrasound imaging/sonogram;

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- Arthroscopy of the temporomandibular joint (TMJ) for purely diagnostic purposes;
- Joint vibration analysis.

Criteria Applicable to Nonsurgical and Surgical Treatments

When Services May Be Eligible for Coverage

I. Based on review of available data, the Company may consider **eligible for coverage**** treatment of temporomandibular disorder (TMD) when **ALL** of the following diagnostic criteria in section I are met, and criteria for specific treatments listed in sections II and III are met:

- Individual had comprehensive TMD assessment including history, physical examination, and range of motion measurements of the jaw; **AND**
- **ALL** of the following conditions have been ruled out by a medical provider as a cause of TMD symptoms:
 - Acute and chronic rhinosinusitis; **AND**
 - Cervical spine pathology; **AND**
 - Disorders of the parotid gland; **AND**
 - Headache disorders (e.g., migraine, cluster, tension); **AND**
 - Otologic disorders; **AND**
 - Trigeminal neuralgia;

AND

- Imaging confirms internal derangement, disc displacement, or degenerative joint disease of the temporomandibular joint; **AND**
- Symptoms of TMD persist despite simple analgesics (e.g., NSAIDs, acetaminophen), including **TWO OR MORE** of the following:
 - Pain in the jaw, temple, ear, or in front of the ear;
 - Headache;
 - Radiating facial pain;
 - Limited movement of the jaw;
 - Locking of the jaw;

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Louisiana

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Policy # 00583

Original Effective Date: 01/01/2018

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- Painful clicking, popping, or grating in the jaw when opening or closing the mouth;
- Painful chewing;
- Jaw joint and/or muscles tender to palpation;
- Changes in the way the upper and lower teeth fit together;

AND

- A full odontogenic exam has been completed and any dental pathology, including but not limited to dental caries, gingivitis, malocclusion, or bruxism, has been identified and treated by a qualified dentist; **AND**
- Diagnosed by a qualified dentist trained and experienced in the overall care of oral health, the temporomandibular joint, dental occlusion, and associated orofacial structures.

Required documentation:

The following documentation must be submitted:

1. Clinical notes from a recent detailed oral examination documenting the absence of pathology (e.g., dental caries, gingivitis);
2. Clinical records from a medical provider documenting that other pathology (e.g., trigeminal neuralgia, otologic disorders) has been ruled out;
3. Radiographic formal imaging report from an independent radiologist.

Nonsurgical Treatments

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

II. Based on review of available data, the Company may consider **ANY** of the following *nonsurgical treatments* in the treatment of temporomandibular joint dysfunction (TMJD) to be **eligible for coverage**** when the diagnostic criteria in section I have been met:

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Louisiana

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Policy # 00583

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Current Effective Date: 09/01/2024

- Intraoral removable prosthetic devices/appliances providing full-occlusal coverage (encompassing fabrication, insertion, adjustment); **OR**
- Behavioral/ psychological therapy (i.e., relaxation training, cognitive behavioral therapies); **OR**
- Pharmacologic treatment (e.g., anti-inflammatory, muscle relaxing, analgesic medications).

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers *nonsurgical treatments* in the treatment of temporomandibular joint dysfunction (TMJD), including but not limited to the following treatments, to be **investigational***:

- 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;
- Platelet concentrates.
- Dextrose prolotherapy.

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Louisiana

Temporomandibular Joint Dysfunction

Policy # 00583

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Current Effective Date: 09/01/2024

Surgical Treatments

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

III. Based on review of available data, the Company may consider **ANY** of the following *surgical treatments* in the treatment of temporomandibular joint dysfunction (TMJD) to be **eligible for coverage**** when the diagnostic criteria in section I have been met:

- Arthrocentesis; **OR**
- Manipulation for reduction of fracture or dislocation of the temporomandibular joint (TMJ); **OR**
- Arthroscopic surgery in patients with objectively demonstrated (by physical examination and MRI or CT) internal derangements (displaced discs) or degenerative joint disease who have persistent TMJ pain despite at least 6 months of conservative treatment (e.g., intraoral appliances, behavioral changes, pharmacological therapy); **OR**
- Open surgical procedures including arthroplasties, condylectomies, meniscus or disc plication, and disc removal when TMJ dysfunction is the result of congenital anomalies, trauma, or disease in individuals who have failed at least 6 months of conservative treatment (e.g., intraoral appliances, behavioral changes, pharmacological therapy).

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers all other *surgical treatments* in the treatment of temporomandibular joint dysfunction (TMJD) to be **investigational.***

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Background/Overview

Diagnosis of Temporomandibular Joint Disorder

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

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

Treatment

For many patients, symptoms of TMJD are short-term and self-limiting. Conservative treatments (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).

Note that botulinum toxin for TMJD is addressed in medical policy 00012.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Since 1981, several muscle-monitoring devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Some examples are the K7x Evaluation System (Myotronics), the BioEMG III^{TM‡} (Bio-Research Associates), M-Scan^{TM‡} (Bio-Research Associates), and the GrindCare Measure^{®‡} (Medotech A/S). These devices aid clinicians in the analysis of joint sound, vibrations, and muscle contractions when diagnosing and evaluating TMJD. FDA product code: KZM.

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Louisiana

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Policy # 00583

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

Devices	Manufacturer	Date Cleared	510(k) No.	Indication
K7x Evaluation System	Myotronics, Inc	Nov 2000	K003287	Electromyography
BioEMG IIITM	Bio-Research Associates, Inc	Feb 2009	K082927	Electromyography, Joint Vibration Recording
GrindCare Measure	Medotech A/S	Apr 2012	K113677	Electromyography, Nocturnal Bruxism
M-ScanTM	Bio-Research Associates	Jul 2013	K130158	Electromyography
TEETHAN 2.0	BTS S.P.A.	Dec 2016	K161716	Electromyography
GrindCare System	Sunstar Suisse S.A.	Sep 2017	K163448	Electromyography, Sleep Bruxism

FDA product code: KZM.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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.

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Louisiana

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Policy # 00583

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Summary of Evidence

For individuals with suspected temporomandibular joint disorder (TMJD) who receive ultrasound, surface electromyography, or joint vibration analysis, the evidence includes systematic reviews of diagnostic test studies. Relevant outcomes are test validity and other performance measures. None of the systematic reviews found that these diagnostic techniques accurately identified patients with TMJD, and many of the studies had methodologic limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with a confirmed diagnosis of TMJD who receive intraoral devices or appliances or pharmacologic treatment, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A systematic review of intraoral appliances (44 studies) and meta-analyses of subsets of these studies found a significant benefit of intraoral appliances compared with control interventions. Several studies, meta-analyses, and systematic reviews exploring the effectiveness of stabilization splints on TMJD pain revealed conflicting results. Overall, the evidence shows that stabilizing splints may improve pain and positively impact depressive and anxiety symptoms. The evidence related to pharmacologic treatment varies because studies, systematic reviews, and meta-analyses lack consistency in evaluating specific agents. Some systematic reviews have found a significant benefit of several pharmacologic treatments (eg, analgesics, muscle relaxants, and anti-inflammatory medications [vs. placebo]), but other studies showed a lack of benefit with agents such as methylprednisolone and botulinum toxin type A. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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

For individuals with a confirmed diagnosis of TMJD who receive arthrocentesis or arthroscopy, the evidence includes RCTs, systematic reviews of RCTs, and observational studies. Relevant outcomes

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are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One review, which included 3 RCTs, compared arthrocentesis or arthroscopy with nonsurgical interventions for TMJD. Pooled analyses of the RCTs found that arthrocentesis and arthroscopy resulted in superior pain reduction compared with control interventions. A network meta-analysis, which included 36 RCTs, revealed that arthroscopy and arthrocentesis improve pain control and maximum mouth opening. A third meta-analysis (N=8 RCTs) demonstrated superior pain reduction, but no difference in maximum mouth opening, with arthrocentesis compared to conservative therapies. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association for Dental, Oral, and Craniofacial Research

In 2010 (reaffirmed in 2015), the American Association for Dental Research (now the American Association for Dental, Oral, and Craniofacial Research) policy statement 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....”

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Louisiana

Temporomandibular Joint Dysfunction

Policy # 00583

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Current Effective Date: 09/01/2024

“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 Association for Dental, Oral, and Craniofacial Research (AADOCR)

Based on evidence from clinical trials as well as experimental and epidemiologic studies, the AADOCR (formerly known as American Association for Dental Research) strongly recommends that, unless there are specific and justifiable indications to the contrary, treatment of temporomandibular disorder (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. Because those modalities do not produce irreversible changes, they present much less risk of producing harm (AADOCR 2015).

American Association of Oral and Maxillofacial Surgeons (AAOMS)

In the most recent Parameters of Care, the AAOMS makes the following statement regarding surgical procedures of the TMJ: “Surgical intervention for internal derangement is indicated only when nonsurgical therapy has been ineffective, and pain and/or dysfunction are moderate to severe. Surgery is not indicated for asymptomatic or minimally symptomatic patients. Surgery also is not indicated for preventive reasons in patients without pain and with satisfactory function. Pretreatment therapeutic goals are determined individually for each patient” (AAOMS 2017).

Additionally, the AAOMS Recommended Criteria for Orthognathic Surgery (2020), subsection on Facial Skeletal Discrepancies Associated with Documented Temporomandibular Joint Pathology states the following: "In some patients, skeletal malocclusion and TMJ dysfunction may be correlated. While some types of malocclusion have been more commonly implicated, a variety of deformities have been reported to be associated with TMJ symptoms. The rationale for proceeding with surgery to correct skeletal-dental deformities is based on common reports of significant improvement in joint and muscle symptoms after a variety of orthognathic procedures. The literature reports that approximately 80% of patients show improvement of pre-operative symptoms after

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Louisiana

Temporomandibular Joint Dysfunction

Policy # 00583

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Current Effective Date: 09/01/2024

orthognathic surgery. Prior to performing an orthognathic procedure on such patients, non-surgical therapies should be attempted, including those procedures and treatments that mimic the effects of occlusal alteration.”

American Society of Temporomandibular Joint Surgeons

In 2001, the American Society of Temporomandibular Joint Surgeons issued consensus clinical guidelines 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 was 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 (MRI), 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 included 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 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)
- Coronoidotomy/coronoidectomy
- Styloidectomy.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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Temporomandibular Joint Dysfunction

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Current Effective Date: 09/01/2024

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 ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04298554	Comparison of Cannabinoids to Placebo in Management of Arthralgia and Myofascial Pain Disorder of the Temporomandibular Region: A Randomized Clinical Trial.	71	Dec 2022
NCT05162027 ^a	Erenumab as a Therapeutic Approach for the Management of Painful Chronic Temporomandibular Disorders (TMD)	60	April 2025
NCT04936945	Comparative Study Between the Outcome of Intra-articular Injection of Platelet Rich Plasma Versus Hyaluronic Acid in Arthroscopic Management of Temporomandibular Degenerative Joint Diseases: A Randomized Clinical Trial	20	Jun 2023
NCT04884763 ^a	A Randomized, Double Blind, Placebo-Controlled Single Center Phase 2 Pilot Study to Assess the Safety and Efficacy of Off-label Subcutaneous Administration of Erenumab-aooe in Patients With Temporomandibular Disorder	30	Jan 2023

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Louisiana

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Current Effective Date: 09/01/2024

NCT04831346	Effects of Low-Level Laser Therapy Versus Soft Occlusive Splints on Mouth Opening and Surface Electromyography in Temporomandibular Disorders	100	Dec 2022
NCT04819048	Efficacy of Acupuncture and Low-Level Laser in Temporomandibular Disorders	96	Dec 2022
NCT04726683	Trigger Point Dry Needling vs Injection in Patients With Temporomandibular Disorders: a Randomized Placebo-controlled Trial	58	Sep 2023
<i>Unpublished</i>			
NCT05027243	Outcomes of Bilateral Temporomandibular Joint Arthroscopy and the Role of a Second Intervention - Timings and Results	46	July 2021
NCT04827784	The Evaluation Of The Efficacy Of Auriculotemporal Nerve Block In Temporomandibular Disorders	22	Dec 2020
NCT04469088	Effectiveness of Dry Needling vs Manual Therapy in Patients With Temporomandibular Joint Disorders. A Randomized Controlled Trial.	46	Nov 2020

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Louisiana

Temporomandibular Joint Dysfunction

Policy # 00583

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Current Effective Date: 09/01/2024

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Louisiana

Temporomandibular Joint Dysfunction

Policy # 00583

Original Effective Date: 01/01/2018

Current Effective Date: 09/01/2024

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Louisiana

Temporomandibular Joint Dysfunction

Policy # 00583

Original Effective Date: 01/01/2018

Current Effective Date: 09/01/2024

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Louisiana

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Policy # 00583

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Louisiana

Temporomandibular Joint Dysfunction

Policy # 00583

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Current Effective Date: 09/01/2024

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Louisiana

Temporomandibular Joint Dysfunction

Policy # 00583

Original Effective Date: 01/01/2018

Current Effective Date: 09/01/2024

RDC/TMD Consortium Network (International Association for Dental Research) and Orofacial Pain Special Interest Group (International Association for the Study of Pain). J Orol Fac Pain Headache. 2014; 28(1):6-27.

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Current Effective Date: 09/01/2024

- 12/07/2017 Medical Policy Committee review
- 12/20/2017 Medical Policy Implementation Committee approval. New policy.
- 08/01/2018 Coding update.
- 08/16/2018 Coding update
- 12/06/2018 Medical Policy Committee review
- 12/19/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 12/05/2019 Medical Policy Committee review
- 12/11/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 07/02/2020 Medical Policy Committee review
- 07/08/2020 Medical Policy Implementation Committee approval. Created a separate requirement bullet for temporomandibular joint dysfunction for MRI only with 3 sub-bullets to track AIM Guidelines. For MRI criteria, defined conservative management to be at least 3 months duration for mechanical symptoms.
- 08/25/2020 Coding update
- 02/04/2021 Medical Policy Committee review
- 02/10/2021 Medical Policy Implementation Committee approval. Removed the 3rd open bullet requirement for MRI for Diagnostic Procedures that are eligible for coverage. Added platelet concentrates as investigational to nonsurgical treatments for temporomandibular joint dysfunction.
- 02/03/2022 Medical Policy Committee review
- 02/09/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 02/02/2023 Medical Policy Committee review

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Louisiana

Temporomandibular Joint Dysfunction

Policy # 00583

Original Effective Date: 01/01/2018

Current Effective Date: 09/01/2024

- 02/08/2023 Medical Policy Implementation Committee approval. Added dextrose prolotherapy to the list of investigational treatments.
- 09/07/2023 Medical Policy Committee review
- 09/13/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 06/06/2024 Coding update
- 06/06/2024 Medical Policy Committee review
- 06/12/2024 Medical Policy Implementation Committee approval. Coverage eligibility and diagnostic criteria added for treatment of temporomandibular disorder. Clinical Practice Guidelines AADOCR and AAOMS added with Temporomandibular Disorders reference support added to policy.

Next Scheduled Review Date: 06/2025

Coding

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Louisiana

Temporomandibular Joint Dysfunction

Policy # 00583

Original Effective Date: 01/01/2018

Current Effective Date: 09/01/2024

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	21010, 21050, 21060, 21085, 21240, 21242, 21243, 29800, 29804, 70336 Add codes effective 09/01/2024: 20605, 20606, 21073, 21110, 21116
HCPCS	D0370, D7840, D7850, D7852, D7854, D7856, D7858, D7860, D7865, D7872, D7873, D7874, D7875, D7876, D7877, D7899, E1700, E1701, E1702, M0076, Delete code effective 07/01/2024: S8948 Add code effective 09/01/2024: D7880
ICD-10 Diagnosis	M26.00-M26.09, M26.10-M26.19, M26.4, M26.50-M26.59, M26.601-M26.69, M26.9, M79.11, R68.89, S02.412A-S02.412S All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

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Louisiana

Temporomandibular Joint Dysfunction

Policy # 00583

Original Effective Date: 01/01/2018

Current Effective Date: 09/01/2024

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- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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