2.01.103	Trigger Point and Tender Point Injections		
Original Policy Date:	November 1, 2016	**Effective Date:**	June 1, 2025
Section:	2.0 Medicine	**Page:**	Page 1 of 16

Policy Statement

I. Trigger point injections with anesthetic and/or corticosteroid may be considered **medically necessary** for the treatment of myofascial pain syndrome when all of the following criteria have been met:
   A. Conservative therapy (e.g., physical therapy, active exercises, ultrasound, heating or cooling, massage, activity modification, or pharmacotherapy) for 6 weeks fails or is not feasible
   B. No more than 4 injections are given in a 12-month period
   C. There is a regional pain complaint in the expected distribution of referral pain from a trigger point
   D. There is restricted range of motion
   E. There is spot tenderness in a palpable taut band in a muscle
   F. Trigger point injections are provided as a component of a comprehensive therapy program

II. Trigger point and tender point injections are considered **investigational** for all other indications, including the following:
   A. Abdominal wall pain
   B. Complex regional pain syndrome
   C. Fibromyalgia
   D. Treatment of myofascial pain syndrome not meeting the criteria above

III. Ultrasound and other imaging guidance of trigger point injections are considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

See the Codes table for details.

Description

Trigger points are discrete, focal, hyperirritable spots within a taut band of skeletal muscle fibers that produce local and/or referred pain when stimulated. Tender points also produce local pain when stimulated but lack the taut band of tissue and hyperirritability when palpated. Injection of an anesthetic agent or botulinum toxin into trigger points and tender points is being evaluated for the management of a variety of pain syndromes.

Summary of Evidence

For individuals who have myofascial pain syndrome who receive trigger point injections, the evidence includes several randomized controlled trials (RCTs) and a systematic review of RCTs. Relevant

outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Lidocaine injections have been compared with physical therapy, lidocaine patches, sham stimulation, and dry needling. Some trials have reported that injecting lidocaine into trigger points improves subjective pain ratings to the same degree as physical therapy or lidocaine patches but only slightly more than sham stimulation. Other trials have found that lidocaine injection was superior to dry needling on subjective pain ratings but there was no significant benefit with lidocaine injection assessed on objective outcome measures. These results suggest a strong placebo effect of the treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have complex regional pain syndrome who receive trigger point injections, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Evidence on treatment of complex regional pain syndrome with trigger point injections is very limited, with only case series published and no recent literature identified for this treatment approach. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have abdominal wall pain who receive trigger point injections, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single RCT evaluated lidocaine injections in women who had chronic pelvic pain and abdominal wall trigger points. Additional study in a larger population is needed to permit greater certainty about the efficacy of this treatment approach. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
For individuals who have fibromyalgia who receive tender point injections, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single RCT identified evaluated the efficacy of lidocaine injections in patients with fibromyalgia. It found a strong placebo effect, with lidocaine injection being not more effective than saline at reducing fibromyalgia pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

2016 Input

In response to requests, input was received from 6 specialty societies (10 reviewers) and 3 academic medical centers while this policy was under review in 2016. Input focused on trigger point injections for myofascial pain syndrome. There was general consensus that trigger point injections are considered medically necessary for select individuals with myofascial pain syndrome who have failed conservative therapy when administered as part of a comprehensive therapy program. Input concurred that ultrasound guidance was investigational.

Related Policies

- Dry Needling of Trigger Points for Myofascial Pain

Benefit Application

Benefit determinations should be based in all cases on the applicable member health services contract language. To the extent there are conflicts between this Medical Policy and the member health services contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal law may prohibit health plans from denying FDA-approved Healthcare Services as investigational or experimental. In these instances, Blue Shield of California may be obligated to determine if these FDA-approved Healthcare Services are Medically Necessary.

Regulatory Status

Although medications used with invasive trigger point and tender point procedures are regulated by the U.S. Food and Drug Administration (FDA), trigger and tender point injections are procedures and, as such, are not subject to regulation by FDA.

Rationale

Background

Trigger Points

Definition

Trigger points are discrete, focal, hyperirritable spots within a taut band of skeletal muscle fibers that produce local and/or referred pain when stimulated. Trigger points are associated with local ischemia and hypoxia, a significantly lowered pH, local and referred pain and altered muscle activation patterns.

Treatment

Trigger point injections with local anesthetic, saline, steroid, or botulinum toxin type A are a potential treatment for pain associated with trigger points. Alternative nonpharmacologic treatment modalities for trigger point pain include manual techniques, massage, acupressure, ultrasonography, application of heat or ice, diathermy, transcutaneous electrical nerve stimulation, and spray cooling with manual stretch.[1,]

Associated Disorders

Myofascial Pain Syndrome

Myofascial pain syndrome is a chronic regional pain disorder caused by the activation of at least 1 trigger point in muscles, tendons, or muscle fascia. It can cause local or referred pain, tightness, tenderness, stiffness and limitation of movement, muscle weakness, and often autonomic phenomena. The severity of symptoms and degree of functional impairment vary. Some individuals will have few trigger points with mild symptoms and no functional impairment, while others will have multiple satellite trigger points, widespread and severe pain, and major functional impairments. Conditions that can lead to myofascial pain syndrome include chronic repetitive minor muscle strain, poor posture, systemic disease, strain, sprain, enthesopathy, and arthritis. Management of chronic myofascial pain typically includes behavioral and pharmacologic approaches and physical therapy. Injection of a local anesthetic or botulinum toxin has also been reported.

Complex Regional Pain Syndrome

Complex regional pain syndrome (previously called sympathetic dystrophy) refers to a chronic and disabling condition characterized by persistent pain that is disproportionate to the extent and duration of the primary injury and is not restricted to the distribution of a specific peripheral nerve.[2,] Complex regional pain syndrome occurs most commonly following wrist fracture but may follow many other types of injury, even when the preceding injury is relatively minor. Complex regional pain syndrome may also occur when there is no known injury. Complex regional pain syndrome is classified into type I when a specific nerve lesion has not been identified and type II when there is an identifiable nerve lesion. The pain may consist of thermal or mechanical allodynia (pain that occurs from a stimulus that normally does not elicit a painful response such as light touch or warmth) dysesthesia (a constant or ongoing unpleasant or electrical sensation of pain), and/or hyperalgesia (an exaggerated response to normally painful stimuli). Management of complex

regional pain syndrome includes oral and topical pharmacotherapy, physical therapy, psychological therapies, and interventional procedures such as regional anesthetic blocks, sympathetic blocks, or spinal cord stimulation. Amputation of the affected limb has also been performed.

Abdominal Wall Pain

A source of chronic abdominal wall pain is anterior cutaneous nerve entrapment syndrome, which typically presents as sharp and focal abdominal pain, and is often found near a scar. One hypothesis is that anterior cutaneous nerve entrapment syndrome results from the entrapment and ischemia of an anterior cutaneous branch of a thoracic nerve as it passes through the rectus abdominus muscle.[3,] Anterior wall pain can be distinguished from intra-abdominal pain by documenting that pain increases with maneuvers that tense the abdominal muscles. It has also been proposed that abdominal wall pain may be due to a myofascial trigger point in the rectus abdominus muscle.

Tender Points

Definition

Tender points are focal areas of hyperalgesia that tend to occur at muscle-tendon junctions. Tender points are differentiated from trigger points due to the absence of a taut band of muscle tissue or local hyperirritability ("jump response") when palpated.

Despite the lack of local hyperirritability or a palpable band of tissue, some practitioners have treated tender points with injections of local anesthetic, corticosteroids, or botulinum toxin, similar to the treatment of trigger points.

Associated Disorders

Fibromyalgia

Fibromyalgia is a chronic condition characterized by widespread pain with hyperalgesia and allodynia. Constitutional symptoms such as fatigue, impaired cognition, and disrupted sleep can also occur.[4,] Early diagnostic criteria for fibromyalgia (1990) included 3 or more months of widespread pain above and below the waist, on both sides of the body, and along the midline, with at least 11 of 18 specific tender points. The defined bilateral areas from the American College of Rheumatology criteria are occipital, low cervical, trapezius, supraspinatus, second rib, lateral epicondyle, gluteal, greater trochanter, and knee medial fat pad. However, 2010 diagnostic criteria from the College, which were designed to facilitate diagnosis in a general practice setting, did not include a tender point exam but instead relied on the presence of widespread pain and other symptoms.[5,]

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, 2 domains are examined: the relevance, and 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.

.Trigger Point Injections
Myofascial Pain Syndrome

Clinical Context and Therapy Purpose
The purpose of trigger point injections in individuals who have myofascial pain syndrome is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with myofascial pain syndrome. Myofascial pain syndrome is a chronic regional pain disorder caused by the activation of at least 1 trigger point in muscles, tendons, or muscle fascia. It can cause local or referred pain, tightness, tenderness, stiffness and limitation of movement, muscle weakness, and often autonomic phenomena.

Interventions
The therapy being considered is trigger point injections. Trigger points are discrete, focal, hyperirritable spots within a taut band of skeletal muscle fibers that produce local and/or referred pain when stimulated. Trigger point injections with local anesthetic, saline, steroid, or botulinum toxin type A are a potential treatment for pain associated with trigger points.

Comparators
The following therapies are currently being used to make decisions about trigger point injections. Relevant comparators are pharmacologic management and physical therapy (PT). Alternative nonpharmacologic treatment modalities for trigger point pain include manual techniques, massage, acupressure, ultrasonography, application of heat or ice, diathermy, transcutaneous electrical nerve stimulation, and spray cooling with manual stretch.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

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

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

Review of Evidence
Randomized Controlled Trials

Lidocaine Injection versus Physical Therapy
An RCT by Lugo et al (2016) evaluated the efficacy of lidocaine injection and PT to treat myofascial pain syndrome.[6,] Strengths of this trial included the randomization procedures, power analysis, and assessor blinding. Patients (N=127) with shoulder girdle myofascial pain syndrome for at least 6 weeks and visual analog scale scores for pain greater than 40 mm received PT, a single injection of lidocaine, or both treatments together. The primary outcome (visual analog scale pain rating at 1 month) did not differ significantly across the 3 groups (lidocaine, 44.2; PT, 37.8; combined therapy, 40.8). Most secondary outcome measures (function, depression, quality of life) were also similar across groups.

Lidocaine Injection versus a Lidocaine or Placebo Patch

An RCT by Affaitati et al (2009) compared use of a lidocaine infiltration, lidocaine patch, or placebo patch in 60 patients being treated for myofascial pain syndrome.[7] Strengths of this trial included allocation concealment for the lidocaine and placebo patches, blinded evaluation, and sample size calculations for adequate power. Similar reductions in pain and pain thresholds with the 2 lidocaine treatments were reported but significantly less discomfort was associated with the lidocaine patch than with injection ($p<.001$). With the lidocaine patch, pain decreased from 84.0 to 17.25; with lidocaine injection, pain decreased from 79.95 to 14.30 (baseline vs. posttreatment $p<.001$; scale range, 0-100). With the placebo patch, pain on movement remained unchanged (78.35 at baseline vs. 77.50 on day 9).

Lidocaine Injection versus Dry Needling or Sham Stimulation

Couto et al (2014) reported on a sham-controlled, double-blind randomized trial of 78 patients that compared trigger point injections using lidocaine with paraspinal intramuscular stimulation, or sham stimulation.[8] Trial strengths included intention-to-treat analysis, adequate power, and Bonferroni correction for multiple comparisons. Lidocaine 0.2 to 0.5 mL was injected with each needle penetration when a visible local twitch response was evoked. Paraspinal dry needling was applied in the spinal segment of the nerve roots associated with the dermatome, myotome, or sclerotome where the trigger points were found. The placebo control used an electroacupuncture device with no current passing through the electrodes. At baseline, visual analog scale scores were similar across the 3 groups, with mean scores ranging from 6.59 to 6.66 out of 10. All 3 groups improved over time for the primary outcomes of pain and pain threshold. Outcomes were significantly improved for both intervention groups than for sham, although the difference in visual analog scale scores between the lidocaine injection group and sham stimulation was only 1.01 on a 10-point scale.

Local anesthetic (n=35) injected into a trigger point was compared with dry needling (n=23) in the upper trapezius muscle in a study by Hong et al (1994).[9] For the lidocaine injection, a needle was inserted into the trigger point with in-and-out movement within the subcutaneous tissue (20 to 60 insertions), with a drop of anesthetic released each time the needle was inserted into the taut band. This procedure was followed by stretching exercises at home. Dry needling was performed in the same manner but without lidocaine. Twenty-six (74%) patients treated with local anesthetic and 15 (65%) with dry needling exhibited a local twitch response and were included in the analysis. Pain intensity at baseline, measured by a 0-to-10 numeric rating scale for pain, was similar for both groups (lidocaine, 7.88; dry needling, 7.80). All patients who had a local twitch response reported minimal-to-no pain immediately postprocedure. Two weeks posttreatment, pain intensity remained significantly lower in the lidocaine group (0.96) than in the dry needling group (4.98). Blinded evaluation found no significant differences between groups for pain threshold or range of motion.

Corticosteroid Injection versus Dry Needling

Brennan et al (2017) reported on a partially blinded, noninferiority RCT comparing corticosteroid injections (n=25 hips) with dry needling (n=25 hips) for patients who had greater trochanteric pain syndrome (previously called greater trochanteric bursitis), a chronic, intermittent pain syndrome involving tenderness over the lateral hip.[10] The trial was powered with a planned enrollment of 50 patients, using a 2-sample *t* test for noninferiority and a noninferiority margin of 1.5. Patients were randomized to a corticosteroid injection or to a dry injection by an orthopedic surgeon or a physician assistant and followed at the provider's discretion over 6 weeks. At 6 weeks, numeric rating scale scores for pain did not differ significantly between groups (difference, -1.12; 95% confidence interval, -2.99 to 0.74). Similarly, there were no significant differences in functional outcomes or medication use.

Section Summary: Myofascial Pain Syndrome

The evidence on the treatment of myofascial pain syndrome with lidocaine injections includes randomized comparisons with PT, lidocaine patches, sham stimulation, and dry needling. Lidocaine injections into trigger points were effective at improving subjective pain ratings to the same degree as PT or lidocaine patches, and slightly more effective than sham stimulation. Lidocaine injection was

less effective for improving pain ratings than paraspinal dry needling in one trial and more effective than dry needling in another. In the latter trial, there was no significant benefit of lidocaine injection on objective outcome measures. The small number of trials, different comparators, and lack of consistent improvements in outcomes limit the ability to make conclusions. Further high-quality RCTs are needed to determine whether trigger point injections improve outcomes for patients with myofascial pain syndrome.

Complex Regional Pain Syndrome

Clinical Context and Therapy Purpose

The purpose of trigger point injections in individuals who have complex regional pain syndrome is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with complex regional pain syndrome. Complex regional pain syndrome refers to a chronic and disabling condition characterized by persistent pain that is disproportionate to the extent and duration of the primary injury, and that is not restricted to the distribution of a specific peripheral nerve. Complex regional pain syndrome occurs most commonly following wrist fracture but may follow many other types of injury, even when the preceding injury is relatively minor. It may also occur when there is no known injury.

Interventions

The therapy being considered is trigger point injections. Trigger points are discrete, focal, hyperirritable spots within a taut band of skeletal muscle fibers that produce local and/or referred pain when stimulated. Trigger point injections with local anesthetic, saline, steroid, or botulinum toxin type A are a potential treatment for pain associated with trigger points.

Comparators

The following therapies are currently being used to make decisions about trigger point injections. Relevant comparators are pharmacologic management and PT. Management of complex regional pain syndrome includes oral and topical pharmacotherapy, PT, psychological therapies, and interventional procedures such as regional anesthetic blocks, sympathetic blocks, or spinal cord stimulation. Amputation of the affected limb has also been performed.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

Review of Evidence

No RCTs on injections for the treatment of complex regional pain syndrome were identified. One case report (2000) described the treatment of complex regional pain syndrome with progressive trigger point manipulations, beginning with desensitization and gentle massage followed by steroid injections.[11,] Trigger point injection for complex regional pain syndrome is also described as a

treatment modality in a 2000 review.[12,] A Cochrane review (2013) on interventions for complex regional pain syndrome included a variety of allopathic and alternative treatment approaches but not trigger point injections.[2,]The 2023 update to the Cochrane review also did not identify any literature related to trigger point injections in this population.[13,]

Section Summary: Complex Regional Pain Syndrome

Evidence on treatment of complex regional pain syndrome with trigger point injections is very limited, with no recent literature identified for this treatment approach.

Abdominal Wall Pain

Clinical Context and Therapy Purpose

The purpose of trigger point injections in individuals who have abdominal wall pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with abdominal wall pain. A source of chronic abdominal wall pain is anterior cutaneous nerve entrapment syndrome, which typically presents as sharp and focal abdominal pain, and is often found near a scar. Anterior wall pain can be distinguished from intra-abdominal pain by documenting that pain increases with maneuvers that tense the abdominal muscles.

Interventions

The therapy being considered is trigger point injections. Trigger points are discrete, focal, hyperirritable spots within a taut band of skeletal muscle fibers that produce local and/or referred pain when stimulated. Trigger point injections with local anesthetic, saline, steroid, or botulinum toxin type A are a potential treatment for pain associated with trigger points.

Comparators

The following therapies are currently being used to make decisions about trigger point injections. Relevant comparators are pharmacologic management and PT. Alternative nonpharmacologic treatment modalities for trigger point pain include manual techniques, massage, acupressure, ultrasonography, application of heat or ice, diathermy, transcutaneous electrical nerve stimulation, and spray cooling with manual stretch.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

Review of Evidence

Systematic Review

Oor et al (2016) reported on a systematic review of therapies for abdominal cutaneous nerve entrapment syndrome.[14,] Seven studies met reviewers' inclusion criteria, 4 (n=179 patients) of which

evaluated treatment with trigger point injections and 4 of which evaluated treatment with anterior neurectomy (1 study included patients in both groups). All studies that evaluated trigger points injections were case series or retrospective cohorts, in which 70% to 100% of patients reported improvements in pain in the short term.

Randomized Controlled Trial

Lidocaine Injection versus Ischemic Compression Therapy

Montenegro et al (2015) published an RCT with 30 women who had chronic pelvic pain with abdominal wall trigger points.[15,] Patients were assigned to lidocaine injection into a trigger point or ischemic compression using PT; both treatments were administered once a week for 4 weeks. The primary outcome, assessed in blinded fashion, was the clinical response rate, defined as a reduction of at least 50% in visual analog scale score or a significant subjective impact on activities of daily living. Secondary outcomes were the proportion of patients who experienced pain relief, pain threshold**,** and pain tolerance on the trigger point. Clinical response rates and pain relief were significantly better in the injection group at 1, 4, and 12 weeks posttreatment. At 1 and 4 weeks after treatment, the clinical response rate was 80% for lidocaine injection and 40% for ischemic compression (p=.018). At 12 weeks, clinical response rates were 73.3% for lidocaine injection and 13.3% for ischemic compression (p<.001). Power analysis had indicated that 60 subjects would be needed, but after interim analysis, the trial was discontinued due to the lower efficacy of ischemic compression.

Section Summary: Abdominal Wall Pain

A single RCT was identified that evaluated lidocaine injection in women who had chronic pelvic pain with abdominal wall trigger points. Additional study in a larger population is needed to permit greater certainty on the efficacy of this treatment approach.

Tender Point Injections

Fibromyalgia

Clinical Context and Therapy Purpose

The purpose of tender point injections in individuals who have fibromyalgia is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with fibromyalgia. Fibromyalgia is a chronic condition characterized by widespread pain with hyperalgesia and allodynia. Constitutional symptoms such as fatigue, impaired cognition, and disrupted sleep can also occur.

Interventions

The therapy being considered is tender point injections. Tender points are focal areas of hyperalgesia that tend to occur at muscle-tendon junctions. Tender points are differentiated from trigger points due to the absence of a taut band of muscle tissue or local hyperirritability ("jump response") when palpated.

Despite the lack of local hyperirritability or a palpable band of tissue, some practitioners have treated tender points with injections of local anesthetic, corticosteroids, or botulinum toxin, similar to the treatment of trigger points.

Comparators

The following therapies are currently being used to make decisions about tender point injections. Relevant comparators are pharmacologic management, PT, and multidisciplinary therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

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

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

Review of Evidence
Randomized Controlled Trial
Staud et al (2014) reported on a double-blinded RCT evaluating 62 patients with fibromyalgia who received injections of lidocaine (100 or 200 mg) or saline.[16,] Each patient received 4 injections containing 5 mL of saline or lidocaine into the trapezius (shoulder) and gluteal (low back) muscles. Ratings of mechanical and heat pulses to the shoulders, arms, back, and legs were reduced with lidocaine. However, overall clinical fibromyalgia pain decreased by a similar amount (overall visual analog scale score decreased »38%) in all 3 groups, suggesting a large placebo effect of the injection with no additional benefit of the anesthetic. Patients' estimates of receiving lidocaine or placebo were similar across groups, demonstrating successful allocation concealment in this double-blinded trial.

Section Summary: Fibromyalgia
A single RCT was identified that evaluated the efficacy of lidocaine injections in patients with fibromyalgia. It found a strong placebo effect, with lidocaine injection not being more effective than saline at reducing fibromyalgia pain.

Supplemental Information
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies And Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2016 Input
In response to requests, input was received from 6 specialty societies (10 reviewers) and 3 academic medical centers while this policy was under review in 2016. Input focused on trigger point injections for myofascial pain syndrome. There was general consensus that trigger point injections are considered medically necessary for select patients with myofascial pain syndrome who have failed conservative therapy when administered as part of a comprehensive therapy program. Input concurred that ultrasound guidance was investigational.

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 Society of Regional Anesthesia and Pain Medicine

In 2010, the American Society of Regional Anesthesia and Pain Medicine (ASRA) in conjunction with the American Society of Anesthesiologists published practice guidelines on chronic pain management.[17,] The 2 Societies found insufficient evidence to evaluate the efficacy of trigger point injections to provide pain relief compared with sham injections (category D evidence). Based on observational findings, the societies concluded that "trigger point injections may be considered for treatment of patients with myofascial pain as part of a multimodal approach to pain management." In 2024, ASRA, in conjunction with the American Academy of Pain Medicine, the American Society of Interventional Pain Physicians, the International Pain and Spine Intervention Society, and the North American Spine Society, published practice guidelines on the use of corticosteroids as trigger point injections as an adult chronic pain intervention.[18,] The guideline states that trigger point injections are common procedures for symptom resolution, although this is based on limited evidence.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06013644	Comparative Efficacy of Acupuncture, Dry Needle and Botox Injection in Management of Patient With Myofascial Pain Dysfunction Syndrome Using Electromyography and Visual Analogue Scale: A Randomized Clinical Trial	39	Feb 2024 (recruiting)
NCT06555523	Comparison of Trigger Point Injection Application Methods in Patients With Fibromyalgia Syndrome and Myofascial Pain Syndrome	20	Sep 2024 (recruiting)
NCT04732507	Investigating the Minimum Number of Needling Required to Optimize Trigger Point Injections Outcome	300	Dec 2025
NCT05792111	Analgesic Effects of Trigger Point Injection Added to Caudal Epidural Steroid	72	Dec 2024 (recruiting)

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

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Conservative treatment(s), duration, and patient response
  - Diagnostic evaluation
  - Functional limitation(s)
  - Distribution of pain
  - Physical exam noting areas of tenderness and any other abnormal findings
- Prior procedure(s) and response (if applicable)
- Radiology report(s) (if applicable)

- Electrodiagnostic studies (if applicable)

Post Service (in addition to the above, please include the following):

- Procedure report(s)

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	20552	Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)
	20553	Injection(s); single or multiple trigger point(s), 3 or more muscles
	76942	Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation
	77002	Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device) (List separately in addition to code for primary procedure)
	77012	Computed tomography guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), radiological supervision and interpretation
	77021	Magnetic resonance imaging guidance for needle placement (e.g., for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
11/01/2016	BCBSA medical policy adoption
06/01/2017	Policy revision without position change
06/01/2018	Policy revision without position change
07/01/2019	Policy revision without position change
07/01/2020	Annual review. No change to policy statement. Literature review updated.
06/01/2021	Annual review. No change to policy statement. Literature review updated.
06/01/2022	Annual review. No change to policy statement. Literature review updated.
06/01/2023	Annual review. No change to policy statement. Policy guidelines and literature updated.
06/01/2024	Annual review. Policy statement, guidelines and literature review updated.
06/01/2025	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary: Healthcare Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield of California, are: (a) consistent with Blue Shield of California medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the member; and (e) 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 the member's illness, injury, or disease.

Investigational or Experimental: Healthcare Services which do not meet ALL of the following five (5) elements are considered investigational or experimental:

A. The technology must have final approval from the appropriate government regulatory bodies.
   - This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration ("FDA") or any other federal governmental body with authority to regulate the use of the technology.
   - Any approval that is granted as an interim step in the FDA's or any other federal governmental body's regulatory process is not sufficient.
   - The indications for which the technology is approved need not be the same as those which Blue Shield of California is evaluating.

B. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
   - The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
   - The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.

C. The technology must improve the net health outcome.
   - The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

D. The technology must be as beneficial as any established alternatives.
   - The technology should improve the net health outcome as much as, or more than, established alternatives.

E. The improvement must be attainable outside the investigational setting.
   - When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy Criteria C and D.

Feedback

Blue Shield of California is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/provider.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Trigger Point and Tender Point Injections 2.01.103 **Policy Statement:** I. Trigger point injections with anesthetic and/or corticosteroid may be considered **medically necessary** for the treatment of myofascial pain syndrome when **all** of the following criteria have been met: A. Conservative therapy (e.g., physical therapy, active exercises, ultrasound, heating or cooling, massage, activity modification, or pharmacotherapy) for 6 weeks fails or is not feasible B. No more than 4 injections are given in a 12-month period C. There is a regional pain complaint in the expected distribution of referral pain from a trigger point D. There is restricted range of motion E. There is spot tenderness in a palpable taut band in a muscle F. Trigger point injections are provided as a component of a comprehensive therapy program II. Trigger point and tender point injections are considered **investigational** for all other indications, including the following: A. Abdominal wall pain B. Complex regional pain syndrome C. Fibromyalgia D. Treatment of myofascial pain syndrome not meeting the criteria above III. Ultrasound and other imaging guidance of trigger point injections are considered **investigational**.	**Trigger Point and Tender Point Injections 2.01.103** **Policy Statement:** I. Trigger point injections with anesthetic and/or corticosteroid may be considered **medically necessary** for the treatment of myofascial pain syndrome when all of the following criteria have been met: A. Conservative therapy (e.g., physical therapy, active exercises, ultrasound, heating or cooling, massage, activity modification, or pharmacotherapy) for 6 weeks fails or is not feasible B. No more than 4 injections are given in a 12-month period C. There is a regional pain complaint in the expected distribution of referral pain from a trigger point D. There is restricted range of motion E. There is spot tenderness in a palpable taut band in a muscle F. Trigger point injections are provided as a component of a comprehensive therapy program II. Trigger point and tender point injections are considered **investigational** for all other indications, including the following: A. Abdominal wall pain B. Complex regional pain syndrome C. Fibromyalgia D. Treatment of myofascial pain syndrome not meeting the criteria above III. Ultrasound and other imaging guidance of trigger point injections are considered **investigational**.