

Trigger Point Injections Clinical Coverage Criteria

Description

Trigger point injections are a therapeutic modality used to treat myofascial trigger points in symptomatic patients. Myofascial trigger points are described as small, circumscribed, hyperirritable foci in muscles and fascia, often found within a firm or taut band of skeletal muscle (Manchikanti et al., 2001).

Policy

This Policy applies to the following Fallon Health products:

- Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
- MassHealth ACO
- ⊠ NaviCare HMO SNP, NaviCare SCO
- ☑ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- ⊠ Community Care

Prior authorization is not required for trigger point injections. See Coding section for list of ICD-10-CM codes that support medical necessity.

Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for trigger point injections. Medicare does not have an NCD for trigger point injections. National Government Services, Inc. is the Part A/B Medicare Administrative Contractor (MAC) with jurisdiction over Part A and B services in the Plan's service area. National Government Services, Inc. has an LCD for Trigger Point Injections (L39662), Original Effective Date: For Services Performed on or after 04/01/2024. (Medicare Coverage Database search 07/22/2023).

Coverage criteria for trigger point injections are fully established by Medicare.

<u>Link</u>: National Government Services, Inc. LCD Trigger Point Injections L39662 <u>Link</u>: National Government Services, Inc. LCD Reference Article Billing and Coding: Trigger Point Injections (TPI) A59487

MassHealth ACO

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Guidelines for Medical Necessity Determination for Trigger Point Injections (MassHealth website search 07/22/2024), therefore, Fallon Health's Clinical Coverage Criteria will be used to determine medical necessity for trigger point injections for MassHealth ACO members.

NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Trigger point injections are considered medically necessary for the treatment of myofascial pain syndrome when all of the following criteria are met:

- 1. Physical examination documents all five (5) of the following major criteria establishing a diagnosis of myofascial pain syndrome are met:
 - Regional pain complaint, and
 - Pain complaint or altered sensation in the expected distribution of referred pain from a trigger point, and
 - Taut band palpable in an accessible muscle, and
 - Exquisite tenderness at one point along the length of the taut band, and
 - Some degree of restricted range of motion.

AND, one (1) of the following minor criteria are met:

- Reproduction of clinical pain complaint,
- Altered sensation, by pressure on the tender spot,
- Local response elicited by snapping palpation at the tender spot or by needle insertion into the tender spot, and
- Pain alleviated by elongating (stretching) the muscle or by injecting the tender spot.
- 2. After myofascial pain syndrome is established as described above, conservative therapy has been unsuccessful as a first-line treatment for a minimum of 3 months.

Conservative therapy may include the use of analgesics and adjunctive medications, including NSAIDs, muscle relaxants, and anti-depressant medications shown to be effective in the management of chronic pain conditions, preferably in conjunction with passive physical therapy modalities, such as "stretch and spray" heat and cold therapy, passive range of motion and deep muscle massage, and/or active physical therapy, such as active range of motion, exercise therapy and physical conditioning.

 Trigger point injections are provided as a component of a therapeutic exercise or rehabilitation program directed at restoring function including range of motion in the affected muscle(s).

Repeat Trigger Point Injections

No more than four (4) trigger point injection sessions in a 12 month period will be considered medically necessary regardless of the code billed.

Evidence of benefit from trigger point injection is \geq 50% pain relief relative to baseline, lasting for at least six weeks, documented using a standardized pain assessment tool (e.g., Visual Analog Scale). The same pain scale used to measure myofascial pain at baseline must be used to measure effectiveness.

Evidence of improvements in range of motion, but with persistent significant pain, would justify a repeat injection or set of injections in the therapeutic/treatment phase.

In the therapeutic/treatment phase, the frequency should be two months or longer between each injection or set of injections, provided that >50% pain relief is obtained for six weeks.

The patient's medical record must contain documentation that fully supports the medical necessity for trigger point injections. The scale used to measure pain and disability must be documented in the medical record.

The procedure note must be legible and include sufficient detail to allow reconstruction of the procedure. Required elements of the note include a description of the techniques employed, and sites(s) of injections, drugs and doses with volumes and concentrations as well as pre- and post-procedural pain assessments.

Exclusions

- Trigger point injections used on a routine basis, e.g., on a regular periodic and continuous basis, are not considered medically necessary.
- Trigger point injections are considered investigational for all other indications, including but not limited to the treatment of myofascial pain syndrome not meeting the criteria above.
- Ultrasound guidance of trigger point injections is considered investigational.

Summary of Evidence

Background

Myofascial pain syndrome (MPS) is a common musculoskeletal disorder characterized by the presence of trigger points. Manchikanti et al., 2021 define MPS as a regional muscle pain disorder accompanied by trigger points. Many authors have proposed preliminary criteria for the diagnosis, the most frequently cited source for diagnosis, *Myofascial Pain and Dysfunction: The Trigger Point Manual*, defines trigger points "as hypersensitive spots in a taut band of a skeletal muscle that are painful to stimulation (compression or needling), elicit referred pain distant to the spot, and are associated with restricted range of motion."

Even though there is a substantial amount of anecdotal evidence, there is no controlled prevalence data on the prevalence of myofascial pain. Authors exploring the role of trigger points and myofascial pain and whiplash injuries believe that the theory of trigger points lacks demonstrated internal validity. Formal studies also have shown that myofascial experts have difficulty in agreeing as to the presence of a trigger point, which is the cardinal feature of regional myofascial pain syndrome. In addition to this, it has been shown that trigger points of the neck overlay the cervical facet joints, and it has been reported that pain patterns of cervical trigger points are identical to those of referred pain from the facet joints. The same theories can be extrapolated to the lumbar spine (Manchikanti et al., 2001).

Despite the popularity of trigger point injections, the exact pathophysiology of MPS remains unclear. Localization of a trigger point is often based on the physician's examination. However, such examination is often unreliable (Wong and Wong, 2012).

There are several proposed histopathologic mechanisms to account for the development of trigger points and subsequent pain patterns, but scientific evidence is lacking. Many researchers agree that acute trauma or repetitive microtrauma may lead to the development of a trigger point. Lack of exercise, prolonged poor posture, vitamin deficiencies, sleep disturbances, and joint problems may all predispose to the development of microtrauma. Occupational or recreational activities that produce repetitive stress on a specific muscle or muscle group commonly cause chronic stress in muscle fibers, leading to trigger points (Alvarez and Rockwell, 2002).

Myofascial trigger points have no gold standard diagnostic criterion, and no diagnostic laboratory or imaging test (Simons DG, 2004). Objective diagnostic studies are reported to be useful for ruling out other suspected pathology, but are not at this time used to confirm a diagnosis of MPS (Tantanatip and Chang, 2023). The theory that MPS is caused by trigger points has been challenged (Quinter, et al., 2015).

MPS is easy to confuse with many diseases with similar clinical symptoms. Other diseases with similar symptoms include fibromyalgia, polymyalgia rheumatica, chronic fatigue syndrome and polymyositis (Cao et al., 2021).

Fibromyalgia is a condition characterized by chronic widespread musculoskeletal pain, fatigue, cognitive disturbances, and other symtoms. Thirty to 50% of patients have anxiety and/or depression at the time of diagnosis. More than 50% of the patients have headaches which include migraines and tension types. Fibromyalgia has an unknown etiology and uncertain pathophysiology. There is no evidence of tissue inflammation despite symptoms of soft tissue pain. The 1990 American College of Rheumatology diagnostic criteria for fibromyalgia included three 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 were occipital, low cervical, trapezius, supraspinatus, second rib, lateral epicondyle, gluteal, greater trochanter, and knee medial fat pad. However, 2010 diagnostic criteria from the American College of Rheumatology did not include a tender point exam noting that physicians did not know how to examine tender points, were performing the exam incorrectly or were simply refusing to do so. Modifications to the 2010 American College of Rheumatology criteria we made in 2011 and 2016. A patient fulfills the diagnostic criteria for fibromyalgia if the following three conditions are met:

- 1. The widespread pain index is 7, and the symptom severity scale score is 5, or widespread pain index equals 3 to 6, and the symptom severity scale score of 9.
- 2. Symptomatology has been present at a similar level for at least 3 months.

3. The patient does not demonstrate any other disorder that would otherwise explain the pain. (Bhargava and Hurley, 2023).

MPS must be differentiated from fibromyalgia syndrome, which involves multiple tender points. The terms trigger point and tender point are not synonymous. Trigger points are defined by the presence of discrete focal tenderness located in a palpable taut band of skeletal muscle, which produces both referred regional pain (zone of reference) and a local twitch response. Tender points, by comparison, are associated with pain at the site of palpation only, are not associated with referred pain, and occur in the insertion zone of muscles, not in taut bands in the muscle belly (Alvarez and Rockwell 2002). Tender points tend to occur at muscle-tendon junctions. When tender points occur in a widespread manner, they are usually considered characteristic of fibromyalgia.

At present, the diagnosis of myofascial trigger points very much depends on the subjective experience of the physician. The commonly encountered locations of trigger points and their pain reference zones are consistent (Alvarez and Rockwell, 2002). The predilection sites of MPS are the neck, shoulders and back (Cao et al., 2021).

The American Society of Interventional Pain Physicians (ASIPP) Practice Guidelines (Manchikanti et al., 2001) recommend the following clinical criteria to establish a diagnosis of MPS consistent with the Simons textbook *Myofascial pain and dysfunction: The Trigger Point Manual*. All five major criteria must be present:

- 1. Regional pain complaint,
- 2. Pain complaint or altered sensation in the expected distribution of referred pain from a trigger point,
- 3. Taut band palpable in an accessible muscle,
- 4. Exquisite tenderness at one point along the length of the taut band,
- 5. Some degree of restricted range of motion, when measurable.

Minor criteria of which only one of the four is required include:

- 1. Reproduction of clinical pain complaint,
- 2. Altered sensation, by pressure on the tender spot,
- 3. Local response elicited by snapping palpation at the tender spot or by needle insertion into the tender spot, and
- 4. Pain alleviated by elongating (stretching) the muscle or by injecting the tender spot.

Rivers et al., 2015 conducted a survey of clinician members of the International Association for the Study of Pain and the American Academy of Pain Medicine. Four thousand one hundred forty-three surveys were mailed and 214 were returned, for a response rate of 5.2%. When asked about palpatory findings in MPS, only two findings were were endorsed as essential for the diagnosis of MPS by more than 50% of the respondents: a tender spot causing local pain (72%), and recognition of symptoms upon palpation of the tender spot (58%). More than 90% of the respondents agreed that all the following palpatory findings were essential to or associated with the diagnosis of MPS: tender spot causing local pain, recognition of symptoms upon palpation of tend spot, taut band, tender spot referring pain/dyesthesia, and tender nodule. These survey data indicate that there is a general consensus of the signs and symptoms that constitute MPS among clinician members of the of the International Association for the Study of Pain and the American Academy of Pain Medicine. A similar survey performed in 1998 revealed similar opinions and degrees of agreement (Harden et al., 2000).

Patients who have trigger points often report regional, persistent pain that usually results in a decreased range of motion of the muscle in question. Often, the muscles used to maintain body posture are affected, namely the muscles in the neck, shoulders, and pelvic girdle, including the upper trapezius, scalene, sternocleidomastoid, levator scapulae, and quadratus lumborum. Although the pain is usually related to muscle activity, it may be constant. It is reproducible and does not follow a dermatomal or nerve root distribution. Patients report few systemic symptoms, and associated signs such as joint swelling and neurologic deficits are generally absent on physical examination (Alvarez and Rockwell, 2002).

The goals of MPS treatment are pain relief and correction of predisposing and perpetuating factors. For trigger points in the acute stage, effective treatment may be delivered through physical therapy (Alvarez and Rockwell, 2002).

Nonpharmacologic treatment modalities for MPS have been studied, but no standardized treatment protocol has been established. Treatments include oral nonsteroidal anti-inflammatory drugs, acetaminophen, and muscle relaxants. Evidence for the use of medications in trigger point management is lacking. Other non-invasive treatments include massage, osteopathic manual medicine, physical therapy, and the spray and stretch technique. Invasive strategies include acupuncture, dry needling, and trigger point injections using pharmacologic agents.

The lack of objective clinical criteria has also been a barrier for critically evaluating the efficacy of the the therapeutic methods (Wong and Wong, 2012).

Practice Guidellines

The American Society of Interventional Pain Physicians (ASIPP) Practice Guideline, Interventional Techniques in the Management of Chronic Pain, Part 2.0 (Manchikanti et al., 2001) identified seven controlled studies for trigger point injections. In five of the seven controlled studies the results were positive. In terms of quality, the studies were graded the studies as moderate to limited (Level III to IV). The strength of evidence of efficacy is moderate to limited. The Prqactice Guideline also highlights the challenges in diagnosis of trigger points. With regard to the frequency and total number of injections, the authors divide the injections into diagnostic or stabilization phase and therapeutic phase. In the diagnostic phase they state injections should be at least one week apart and preferably two weeks, and the number of injections should be limited to no more than four times per year. In therapeutic phase, injections should be at least two months apart, provide that >50% improvement is obtained for six weeks. In the therapeutic phase, trigger point injections should be repeated only as necessary and should be limited to a maximum of six injections for local anesthetic and steroid injections.

The 2010 American Society of Anesthesiologists Practice Guidelines for Chronic Pain Management reviewed evidence for the efficacy of modalities used in the treatment of chronic pain. In all cases, these modalities are components of a multimodality* approach to pain management. The authors concluded "The literature is insufficient to evaluate the efficacy of trigger point injections (e.g., compared with sham trigger point injection) as a technique for providing pain relief for patients with chronic pain (Category D evidence). Studies with observational findings suggest that trigger point injections may provide relief for patients with myofascial pain for assessment periods ranging from 1 to 4 months (Category B2 evidence). Consultants, ASA members, and ASRA members agree that trigger point injections should be used for patients with myofascial pain. The recommendations for TPI within the guidelines was that TPI may be considered for treatment of patients with myofascial pain as part of a multimodal approach to pain management."

Summary of Recommendations: Trigger point injections: These injections may be considered for treatment of myofascial pain as part of a multimodal approach to pain management.

* Multimodal interventions constitute the use of more than one type of therapy for the care of patients with chronic pain. Multidisciplinary interventions represent multimodality approaches in the context of a treatment program that includes more than one discipline. The literature indicates that the use of multidisciplinary treatment programs compared with conventional treatment programs is effective in reducing the intensity of pain reported by patients for periods of time ranging from 4 months to 1 yr (Category A2 evidence).

A systematic review of the literature summarized the evidence for the performace of peripheral nerve blocks and trigger point injections in the treatment of headache (Ashkenazi et al., 2010). The systematic review found few controlled studies on the efficacy of peripheral nerve blocks and virtually none on the use of trigger point injections for headache disorders. The most widely examined procedure was greater occipital nerve block, with the majority of studies being small and non-controlled. Ashkenazi et al. found that technique, as well as the type and doses of local anesthetics, used for nerve block, varied greatly among studies. The specific conditions treated also varied, and included both primary (eg, migraine, cluster headache) and secondary (eg, cervicogenic, posttraumatic) headache disorders. While results for nerve block were generally positive, they should be taken with reservation given the methodological limitations of the studies. The authors conclude there is a need to perform more rigorous clinical trials to clarify the role of peripheral nerve blocks and trigger point injections in the management of various headache disorders. Results of a parallel survey published in 2010 by Blumenthal et al.. described significant variability in the patterns of use of nerve blocks and trigger point injections by adult

headache specialists. Electronic invitations were sent to 1,230 American Headache Society members and 161 provided usable data (13.1%). Of the responders, 75.3% performed trigger point injections in headache managment. The most common indications for the use of trigger point injections were chronic tension-type headache (81.5%) and chronic migraine (67.7%). Trigger point injections were also reported to being used for a variety of other headache disorders in this survey: new daily persistent headache (47.6%), status migrainoosus (46.8%), episodic tension-type headache (41.1%), chronic cluster headache (30.6%), migraine without aura (29.8%), hemicrania continua (29%), migraine with aura (25%) and episodic cluster headache (23.4%). Following publication of the systematic review (Ashkenazi et al., 2010) and survey (Blumenthal et al., 2010), the Peripheral Nerve Blocks and Other Interventional Procedures Special Interest Section of the American Headache Society developed consensus recommendations for the performance of peripheral nerve blocks (Blumenfeld et al., 2013) and trigger point injections (Robbins et al., 2014).

Robbins et al. (2014) reviewed the recent literature for trigger point injections for headache disorders. Trigger points in head and neck areas have been associated with various headache disorders. In one study, an association was found between active trigger points in the upper trapezius, sternocleidomastoid, and temporalis muscles, and chronic tension-type headache (Fernández-de-Las-Peñas et al., 2006). The presence of active trigger points was associated with greater intensity and longer duration of headache in that study. Calandre et al., 2006, examined the prevalence of trigger points in migraine, which were found in 94% as compared with 29% of controls (Calandre et al., 2006). The number of trigger points was related to both attack frequency and disease duration. The majority of trigger points were found in the temporal and suboccipital areas. In another study by the same group, trigger points were found in all 12 patients with cluster headache who were examined (Calandre et al., 2008). Despite the widely reported use of trigger point injections for headache, data to support the use of trigger point injections for headache, are very limited. Robbins et al. reviewed some of the more recently published studies.

- Three double-blind, placebo-controlled RCTs evaluating the use of trigger point injections for the treatment of episodic and chronic tension-type headache were identified. Karadaş et al., 2013, randomized 108 patients with frequent episodic tension-type headache into 4 groups, comparing normal saline single injection (group 1), lidocaine single injection (group 2) versus normal saline multiple injections (group 3) and lidocaine multiple injections (group 4). The multiple injections groups received 5 injections on alternate days. The frontal, temporal, masseter, sternocleidomastoid, semispinalis capitis, trapezius and splenius capitis muscles were injected bilaterally. At 2, 4 and 6 months after treatment, the frequency of painful days per month (FPD) scores improved significantly in group 2, 3 and 4 at 2 months post-treatment compared to pretreatment (all p < 0.05), and also VAS scores improved significantly in group 2 and 4 at 2 months post-treatment (p < 0.05) but this improvement persisted at the 6 month only in group 4. Group 2 had better VAS and FPD than group 1 only at 2 and 4 months after treatment (for VAS p < 0.0121, p = 0.0232; for FPD p = 0.0003, p = 0.0004, respectively). Group 4 had better scores than group 3 at the 2, 4 and 6 months after treatment in both parameters (all p < 0.05). Group 2 had better scores than group 1 in FPD at the 2 and 4 months posttreatment (p = 0.0003, p = 0.0004, respectively), but not at the 6. month.
- Two prospective cohort studies examined the use of trigger point injections in patients with episodic and chronic migraine, and one retrospective chart review examined the use of trigger point injections in patients with cervicogenic headache. Garcia-Leiva et al., 2007, evaluated trigger point injections in 52 patients, of whom 61.5% had chronic migraine and 53% had medication overuse. All of the subjects had one or more trigger points, located in temporal and/or suboccipital areas in most of the cases. Weekly injections of ropivacaine 10 mg (1 mL) were performed for 12 weeks. In 9 (17.3%) patients the frequency of attacks was reduced ≥50%. There was 11%–49% reduction in the frequency of attacks in 19 (36.5%) patients. A total of 31 (59.6%) patients reported to be much or very much improved after finishing the injection period. Rescue medication intake was reduced ≥50% in comparison with baseline period in 11 (21.2%) and the attacks of severe intensity decreased significantly. Eight (26.6%) out of 30 patients suffering from chronic migraine reverted to episodic

migraine, though specific data regarding the patients with chronic migraine and medication overuse were not provided.

Robbins et al. conclude that more studies are needed to assess the effect of trigger point injections on headache disorders, independent of the effect of peripheral nerve blocks, which are often performed inconjunction with trigger point injections in clinical practice. In these future studies, the patient population should be as homogenous as possible with regard to their headache diagnosis. In addition, the treatment protocols (indications for treatment, location of injections, type, dose, and volume of injected drugs) should be predetermined and standardized. Outcome measures should be predetermined and be assessed in a blinded fashion. After obtaining and analyzing the results of such studies, more rational, evidence-based, and standardized treatment protocols for the use of trigger point injections in various headache disorders can be developed.

Randomized Controlled Trials and Systematic Reviews

Scott et al., 2009 conducted a systematic review of randomized controlled trials to assess the efficacy and safety of using trigger point injections to treat patients with chronic non-malignant musculoskeletal pain that had persisted for at least 3 months published. The review was limited to studies published to July 2006. Fifty-one studies were identified, but only 15 RCTs met inclusion criteria. No systematic reviews were identified. Ten of the 15 studies had very small sample sizes, with less than 20 patients in each study arm. With respect to the efficacy/effectiveness of trigger point injections, Scott et al. (2009) found that trigger point injections relieved symptoms when used as a sole treatment for patients with whiplash syndrome or chronic head, neck, shoulder, and back pain, regardless of the injectant used, but trigger point injections were not more effective than other less invasive treatments such as laser and ultrasound. Very limited evidence suggested that the combined use of simulated dry needling and trigger point injection with procaine offers no obvious clinical benefit beyond a placebo effect in the treatment of chronic craniofacial pain. The effectiveness of TPI for the treatment of cervicogenic headache is unclear. In the absence of a control group that received only physical therapy it is impossible to tell what contribution trigger point injection made to the overall treatment effect. Shaw et al. conclude that in general, trigger point injections were felt to be safe, however, the efficacy of trigger point injection is no more certain than it was a decade ago as, overall, there is no clear evidence of either benefit or ineffectiveness.

"Trigger point injection is generally considered an adjunctive rather than a primary treatment for chronic musculoskeletal pain, and its routine, solitary use in patients with chronic pain syndrome is not recommended. Most of the included studies attempted to quantify the effects of trigger point injections as a stand-alone therapy, rather than in the adjunct capacity in which it is routinely used in clinical practice. Thus, it is possible that the effectiveness of trigger point injection was underestimated. Although there is some suggestion that the addition of trigger point injection to stretching exercises in patients with chronic head, neck, shoulder, and back pain augments treatment outcomes, this was also true of stretching plus other therapies such as ultrasound and laser. The absence of a control arm made it impossible to assess what contribution, if any, trigger point injections made to patient outcomes. A control group is essential in trigger point injection at underesting such as generated to addition of the significant placebo effect associated with subcutaneous needle insertion and injection (Scott et al., 2009)."

"When trigger point injection is used as the primary therapy, patients may become dependent on it for pain relief, which may divert them from tackling the underlying factors causing and perpetuating their pain. Thus, it is important that physicians are aware of the danger of relying on trigger point injections as a sole treatment for chronic non-malignant musculoskeletal pain (Scott et al., 2009)."

A RCT was conducted by Lugo et al. (2016) to determine whether lidocaine trigger point injections combined with a physical therapy program would be more effective than each separate treatment alone in improving pain, function, and quality of life in a group of patients with MPS of

the shoulder girdle and cervical region. Three groups comprised of 127 patients with shoulder girdle MPS for more than 6 weeks and pain greater than 40 mm on the visual analog scale (VAS) were assigned. The 3 intervention groups were: physical therapy (PT), Lidocaine trigger point injection (LI), or the combination of both (PT + LI). The final sample was comprised of 135 patients resulting in 45 patients randomly allocated to each of the 3 groups. No significant intergroup differences were reported in VAS at 1 month PT + LI, 40.8 [25.3] vs. PT, 37.8 [21.9], p = 0.560 and vs. LI, 44.2 [24.9], p = 0.545. Secondary outcomes resulted in no differences between groups except the PT and PT + LI groups had higher right upper limb hand-back maneuver scores as compared to the LI alone group at both 1 and 3 months (p =0.013 and p = 0.016 respectively). Limitations include short term follow up, small sample size, and variation in intervention application.

Nouged et al. 2019 performed a systematic review and meta-analysis to evaluate the effectiveness of local anesthetic trigger point injections for MPS in the head, neck, and shoulder regions as compared to dry needling, placebo, and other interventions. In total, 15 RCTs were included which was comprised of 884 adult patients. Meta-analysis showed a significant improvement in VAS pain scale of 1.585 units at 1 to 4 weeks follow up in the local anesthetic trigger point injection group as compared to the dry needling group (95% confidence interval – 2.926 to –0.245; P = 0.020). However, when only double-blinded studies were considered, the local anesthetic resulted in an improvement of 1.478 VAS units (95% CI = –4.458 to 1.502) which was not statistically significant (P = 0.331). Significant improvements in pain of 0.767 units was reported in the local anesthetic group at 2 to 8 weeks as compared to the placebo group (95% confidence interval – 1.324 to –0.210; P = 0.007). Limitations in this study include heterogeneity, high risk of bias and a modest sample size. Most of the studies did not control for the use of concurrent therapies, compliance with treatment prescribed and had high risk of bias. The authors acknowledge the need for well-designed studies in the future.

A 2019 systematic review and meta-analysis was conducted by Ahmed et al., 2019 to compare the effectiveness of local anesthetics and botulinum toxin-A (BTX-A) trigger point injections in patients with myofascial pain by: (1) assessing the effects of local anesthetics and BTX-A on reported pain over several follow-up periods; (2) assessing the effects of single and multiple injection sessions of each injectate type on changes in reported pain; and (3) to determine whether reported pain differs based on the region of injection for each type of injectate. A total of 18 articles assessed the effect of local anesthetic trigger point injections and 16 assessed the effect of BTX-A injections on reported pain. The search included RCTs, control trials, and randomized trials. The authors conducted a meta-analysis comparing local anesthetic and BTX-A injections across these follow-up week periods: 0 (immediately following the injection), 1 to 2, 3 to 4, 5 to 6, 7 to 8, 9 to 10, 11 to 12, 16, 18, 24 weeks with local anesthetics and BTX-A as subgroups. They also performed subgroup analyses comparing the effectiveness of local anesthetic injections and BTX-A injections at various muscle locations and comparing the effectives of single versus multiple injection sessions. Qualitative analysis suggested that local anesthetics and BTX-A were inconsistently effective at mitigating pain across all follow-up periods. The meta-analyses revealed that local anesthetic injections were more effective than BTX-A at mitigating pain intensity. A small effect size in pain reduction for trigger point injections was reported as pain intensity at 1 to 2, 3 to 4, 7 to 8-, 16-, 18-, and 24-weeks follow-up. The effect size for trigger point injections was significant only at the 3 to 4 weeks follow-up period (P=0.02). High heterogeneity was reported among studies assessing the effect of local anesthetic injections (p < 0.001). No serious adverse events were reported. The authors conclude that additional studies are needed to determine sources of heterogeneity mediating the observed differences in effectiveness of local anesthetic and BTX-A injections among the studies.

An expert panel was asked to develop recommendations for the multidisciplinary preventive treatment of migraine, including interventional strategies (Barad et al., 2022). The committee conducted a systematic review and (when evidence was sufficient) a meta-analysis. Clinical questions addressed adults with migraine who should be offered prevention. Examined outcomes included headache days, acute medication use, and functional impairment. Acute management of

migraine was outside the scope of this guideline. The committee screened 1,195 studies and assessed 352 by full text, yielding 16 randomized controlled trials that met the inclusion criteria. Regarding trigger point injections, the committee researched the following clinical question, "Are TPI with LA more effective than saline injections in reducing headache days per month, acute medication use per month, and impairment as defined by patient reported outcomes?" The committee found insufficient evidence to assess trigger point injections in migraine prevention.

Analysis of Evidence (Rationale for Determination)

Myofascial pain syndrome (MPS) is a common musculoskeletal disorder characterized by the presence of trigger points. There is no "gold standard" diagnostic test for MPS; diagnosis relies on clinical judgment based on signs and symptoms. The most frequently cited source for the diagnosis of myofascial trigger points is the Simons et al. textbook *Myofascial Pain and Dysfunction: The Trigger Point Manual.* Trigger points are a focus of hyperirritability in a tissue, that, when compressed, is locally tender and, if sufficiently hypersensitive, gives rise to referred pain.

A 2023 review of the literature conducted by Shipton et al. found that although some statistically significant benefits have been noted in some randomized trials of trigger point injections, the results are at high risk of bias. Studies have typically had small sample sizes, with difficulty blinding patients to the interventions. In studies, no single pharmacologic agent used in trigger point injections has been proven superior to another, nor has any single agent been proven superior to placebo. The benefits observed using different injection compositions (including normal saline) suggest a strong placebo response to trigger point injection. The underlying source of pain relief from trigger point injections may be the placebo effect. The absence of post-treatment patient follow-up in RCTs of trigger point injections hinders drawing conclusions about long-term clinical effects. The authors advocate that trigger point injections should be reserved for patients whose myofascial pain has been refractory to other measures, and that trigger point injections should be part of a comprehensive, multimodal and team-based approach to patients with myofascial pain.

Evidence suggests that early conservative measures, such as physical therapy, may prevent the need for injections. Therefore, trigger point injections are covered for MPS that does not respond to conservative therapy or in patients with significant limitations in mobility that can be improved by the trigger point while undergoing conservative treatment. A single diagnostic trigger point can play a role in the diagnosis of MPS. There is evidence to support a role for treatment of headache associated with the presence of a trigger point.

The use of trigger point injections for conditions other than MPS is not supported by evidence and therefore considered investigational.

The frequency of trigger point injections is not well established in the literature. It is unclear how long the effects last in patients who do have a positive response. Most experts agree that the benefit should typically last several months. There is a lack of evidence on long term use of trigger point injections and most studies are limited to 12-16 weeks follow-up.

References

- National Government Services, Inc. Local Coverage Determination (LCD) Pain Management (L33622). Original Effective Date For services performed on or after 10/01/2015. Revision Effective Date For services performed on or after 03/19/2023. Revision Ending Date 03/31/2024. Available at: https://www.cms.gov/medicare-coveragedatabase/view/lcd.aspx?lcdid=33622&ver=31&. Accessed 07/22/2024.
- National Government Services, Inc. Local Coverage Article (LCA) Billing and Coding: Pain Management (A52863). Original Effective Date 10/01/2015. Revision Effective Date 10/01/2023. Revision Ending Date 03/31/2024. Available at: https://www.cms.gov/medicarecoverage-database/view/article.aspx?articleid=52863&ver=46&. Accessed 07/22/2024.

- Hammi C, Schroeder JD, Yeung B. Trigger Point Injection. [Updated 2023 Jul 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK542196/.
- Manchikanti L, Singh V, Kloth D, Slipman CW, Jasper JF, Trescot AM, Varley KG, Atluri SL, Giron C, Curran MJ, Rivera J, Baha AG, Bakhit CE, Reuter MW. Interventional techniques in the management of chronic pain: Part 2.0. Pain Physician. 2001 Jan;4(1):24-96.
- 5. Simons D. Muscular pain syndromes, in Myofascial Pain and Fibromyalgia, Fricton JR, Awad EA, editors. Press: New York Raven 1990:1-43.
- 6. Alvarez DJ, Rockwell PG. Trigger points: diagnosis and management. Am Fam Physician. 2002 Feb 15;65(4):653-60.
- Simons DG, Travell JG, Simons LS. Travell & Simons' Myofascial Pain and Dysfunction: The Trigger Point Manual. 2nd ed. Baltimore: Lipincott Williams & Wilkins; 1999:21-22.
- Harden RN, Bruehl SP, Gass S, Niemiec C, Barbick B. Signs and symptoms of the myofascial pain syndrome: a national survey of pain management providers. Clin J Pain. 2000 Mar;16(1):64-72.
- 9. Hong CZ. Lidocaine injection versus dry needling to myofascial trigger point. The importance of the local twitch response. Am J Phys Med Rehabil. 1994 Jul-Aug;73(4):256-63.
- Rivers WE, Garrigues D, Graciosa J, Harden RN. Signs and Symptoms of Myofascial Pain: An International Survey of Pain Management Providers and Proposed Preliminary Set of Diagnostic Criteria. Pain Med. 2015 Sep;16(9):1794-805.
- 11. American Society of Anesthesiologists Task Force on Chronic Pain Management: Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. 2010;112(4):810-33.
- 12. Wolfe F, Simons DG, Fricton J, Bennett RM, et al. The fibromyalgia and myofascial pain syndromes: a preliminary study of tender points and trigger points in persons with fibromyalgia, myofascial pain syndrome and no disease. J Rheumatol. 1992 Jun;19(6):944-51.
- Bhargava J, Hurley JA. Fibromyalgia. [Updated 2023 Jun 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK540974/.
- 14. Borg-Stein J, Stein J. Trigger points and tender points: one and the same? Does injection treatment help? Rheum Dis Clin North Am. 1996 May;22(2):305-22.
- 15. Schneider MJ. Tender points/fibromyalgia vs. trigger points/myofascial pain syndrome: a need for clarity in terminology and differential diagnosis. J Manipulative Physiol Ther. 1995 Jul-Aug;18(6):398-406.
- Wolfe F, Clauw DJ, Fitzcharles MA, et al. The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity. Arthritis Care Res (Hoboken). May 2010; 62(5): 600-10.
- 17. Bourgaize S, Newton G, Kumbhare D, Srbely J. A comparison of the clinical manifestation and pathophysiology of myofascial pain syndrome and fibromyalgia: implications for differential diagnosis and management. J Can Chiropr Assoc. 2018 Apr;62(1):26-41.
- 18. Wong CS, Wong SH. A new look at trigger point injections. Anesthesiol Res Pract. 2012;2012:492452. doi: 10.1155/2012/492452.
- Hong CZ, Hsueh TC. Difference in Pain Relief after Trigger Point Injections in Myofascial Pain Patients with and Without Fibromyalgia: Arch Phys Med Rehabil 1996 Nov;77(11):1161-6.
- Ferrante FM, Bearn L, Rothrock R, King L. Evidence against trigger point injection technique for the treatment of cervicothoracic myofascial pain with botulinum toxin type A. Anesthesiology. 2005 Aug;103(2):377-83.
- Tantanatip A, Chang KV. Myofascial Pain Syndrome. [Updated 2023 Jul 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK499882/.
- 22. Simons DG. Review of enigmatic MTrPs as a common cause of enigmatic musculoskeletal pain and dysfunction. J Electromyogr Kinesiol. 2004 Feb;14(1):95-107.

- 23. Kamanli A, Kaya A, Ardicoglu O, Ozgocmen S, Zengin FO, Bayik Y. Comparison of lidocaine injection, botulinum toxin injection, and dry needling to trigger points in myofascial pain syndrome. Rheumatol Int. 2005 Oct;25(8):604-11.
- 24. Kwon J, Kim HS, Chang WH, Park C, Lee SC. Characteristics of Myofascial Pain Syndrome of the Infraspinatus Muscle. Ann Rehabil Med. 2017 Aug;41(4):573-581.
- 25. Cao QW, Peng BG, Wang L, Huang YQ, Jia DL, Jiang H, Lv Y, Liu XG, Liu RG, Li Y, Song T, Shen W, Yu LZ, Zheng YJ, Liu YQ, Huang D. Expert consensus on the diagnosis and treatment of myofascial pain syndrome. World J Clin Cases. 2021 Mar 26;9(9):2077-2089.
- 26. Desai MJ, Saini V, Saini S. Myofascial pain syndrome: a treatment review. Pain Ther. 2013 Jun;2(1):21-36.
- 27. Chen CK, Nizar AJ. Myofascial pain syndrome in chronic back pain patients. Korean J Pain. 2011 Jun;24(2):100-4.
- 28. Scott NA, Guo B, Barton PM, Gerwin RD. Trigger point injections for chronic non-malignant musculoskeletal pain: a systematic review. Pain Med. 2009 Jan;10(1):54-69.
- 29. Nouged E, Dajani J, Ku B, Al-Eryani K, Padilla M, Enciso R. Local Anesthetic Injections for the Short-Term Treatment of Head and Neck Myofascial Pain Syndrome: A Systematic Review with Meta-Analysis. J Oral Facial Pain Headache. 2019 Spring;33(2):183–198.
- Ahmed S, Subramaniam S, Sidhu K, et al. Effect of Local Anesthetic Versus Botulinum Toxin-A Injections for Myofascial Pain Disorders: A Systematic Review and Meta-Analysis. Clin J Pain 2019;35(4):353-67.
- Barad M, Ailani J, Hakim SM, Kissoon NR, Schuster NM. Percutaneous Interventional Strategies for Migraine Prevention: A Systematic Review and Practice Guideline. Pain Med. 2022 Jan 3;23(1):164-188.
- 32. Guzmán-Pavón MJ, Cavero-Redondo I, Martínez-Vizcaíno V, et al. Effect of manual therapy interventions on range of motion among individuals with myofascial trigger points: a systematic review and meta-analysis. Pain Med. 2022;23(1):137-143.
- Moraska AF, Stenerson L, Butryn N, Krutsch JP, Schmiege SJ, Mann JD. Myofascial trigger point-focused head and neck massage for recurrent tension-type headache: a randomized, placebo-controlled clinical trial. Clin J Pain. 2015 Feb;31(2):159-68.
- 34. Ashkenazi A, Blumenfeld A, Napchan U, et al.Peripheral nerve blocks and trigger point injections in headache management a systematic review and suggestions for future research.Headache. 2010;50:943-952.
- Blumenfeld A, Ashkenazi A, Grosberg B, et al. Patterns of use of peripheral nerve blocks and trigger point injections among headache practitioners in the USA: Results of the American Headache Society Interventional Procedure Survey (AHS-IPS). Headache. 2010; 50(6):937– 942.
- 36. Blumenfeld A, Askenazi A, Napchan U, et al. Expert consensus recommendations for the performance of peripheral nerve blocks for headaches--a narrative review. Headache. 2013; 53(3):437–446.
- Madore S, Ross MK, Hayden A. The Use of Occipital Nerve Blocks & Trigger Point Injections in Headaches with Occipital Tendernes. *Osteopathic Family Physician*. 2017 Jan-Feb;9(1):12-16.
- Szperka CL, Gelfand AA, Hershey AD. Patterns of Use of Peripheral Nerve Blocks and Trigger Point Injections for Pediatric Headache: Results of a Survey of the American Headache Society Pediatric and Adolescent Section. Headache. 2016 Nov;56(10):1597-1607.
- Robbins MS, Kuruvilla D, Blumenfeld A, et al. and Other Interventional Procedures Special Interest Section of the American Headache Society. Trigger point injections for headache disorders: expert consensus methodology and narrative review. Headache. 2014 Oct;54(9):1441-59.
- Touma J, May T, Isaacson AC. Cervical Myofascial Pain. [Updated 2023 Jul 3]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK507825/.
- Urits I, Schwartz RH, Patel P, et al. A Review of the Recent Findings in Minimally Invasive Treatment Options for the Management of Occipital Neuralgia. Neurol Ther. 2020 Dec;9(2):229-241.

- 42. Pan W, Peng J, Elmofty D. Occipital Neuralgia. Curr Pain Headache Rep. 2021 Jul 21;25(9):61.
- 43. Swanson D, Guedry R, Boudreaux M, et al. An Update on the Diagnosis, Treatment, and Management of Occipital Neuralgia. J Craniofac Surg. 2022 May 1;33(3):779-783.
- 44. Barmherzig R, Kingston W. Occipital Neuralgia and Cervicogenic Headache: Diagnosis and Management. Curr Neurol Neurosci Rep. 2019 Mar 19;19(5):20.
- 45. Williams KA, Lawson RM, Perurena OH, Coppin JD. Management of Chronic Migraine and Occipital Neuralgia in Post 9/11 Combat Veterans. Mil Med. 2019 Jul 1;184(7-8):e207-e211.
- 46. Karadaş Ö, Gül HL, Inan LE. Lidocaine injection of pericranial myofascial trigger points in the treatment of frequent episodic tension-type headache. J Headache Pain. 2013 May 22;14(1):44.
- Karadaş Ö, Inan LE, Ulaş Ü, Odabaşi Z. Efficacy of local lidocaine application on anxiety and depression and its curative effect on patients with chronic tension-type headache. Eur Neurol. 2013;70(1-2):95-101.
- 48. Do TP, Heldarskard GF, Kolding LT, Hvedstrup J, Schytz HW. Myofascial trigger points in migraine and tension-type headache. J Headache Pain. 2018 Sep 10;19(1):84.
- Hamzoian H, Zograbyan V. Trigger Point Injections Versus Medical Management for Acute Myofascial Pain: A Systematic Review and Meta-Analysis. Cureus. 2023 Aug 13;15(8):e43424.
- 50. Li X, Wang R, Xing X, et al. Acupuncture for Myofascial Pain Syndrome: A Network Meta-Analysis of 33 Randomized Controlled Trials. Pain Physician. 2017 Sep;20(6):E883-E902.
- 51. Shah JP, Thaker N, Heimur J, Aredo JV, Sikdar S, Gerber L. Myofascial Trigger Points Then and Now: A Historical and Scientific Perspective. PM R. 2015 Jul;7(7):746-761.
- Tough EA, White AR, Richards S, Campbell J. Variability of criteria used to diagnose myofascial trigger point pain syndrome--evidence from a review of the literature. Clin J Pain. 2007 Mar-Apr;23(3):278-86.
- 53. Fernández-de-Las-Peñas C, Alonso-Blanco C, Cuadrado ML, Gerwin RD, Pareja JA. Myofascial trigger points and their relationship to headache clinical parameters in chronic tension-type headache. Headache. 2006 Sep;46(8):1264-72.
- Calandre EP, Hidalgo J, Garcia-Leiva JM, Rico-Villademoros F. Trigger point evaluation in migraine patients: An indication of peripheral sensitization linked to migraine predisposition? Eur J Neurol. 2006;13:244-249.
- Calandre EP, Hidalgo J, Garcia-Leiva JM, Rico-Villademoros F, Delgado-Rodriguez A. Myofascial trigger points in cluster headache patients: A case series. Head Face Med. 2008;4: 32.
- 56. Ashkenazi A, Young WB. The effects of greater occipital nerve block and trigger point injection on brush allodynia and pain in migraine. *Headache*. 2005;45:350-354.
- 57. Garcia-Leiva JM, Hidalgo J, Rico-Villademoros F, et al. Effectiveness of ropivacaine trigger points inactivation in the prophylactic management of patients with severe migraine. *Pain Med.* 2007;8:65-70.
- Fernández-de-Las-Peñas C, Nijs J. Trigger point dry needling for the treatment of myofascial pain syndrome: current perspectives within a pain neuroscience paradigm. J Pain Res. 2019;12:1899-1911.
- 59. Quintner JL, Bove GM, Cohen ML. A critical evaluation of the trigger point phenomenon. Rheumatology (Oxford). 2015 Mar;54(3):392-9.
- 60. Shipton B, Sagar S, Mall JK. Trigger Point Management. Am Fam Physician 2023;107(2):159-64.
- 61. National Government Services, Inc. Local Coverage Determination (LCD) Trigger Point Injections (TPI). Original Effective Date For Services Performed on or after 04/01/2024. Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=39662. Accessed 07/2202024.
- National Government Services, Inc. LCD Reference Article Billing and Coding: Trigger Point Injections (TPI). Original Effective Date 04/01/2024. Available at: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59487&ver=5. Accessed 07/22/2024.

Coding

CPT/HCPCS

The following CPT/HCPCS codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Only one trigger point injection procedure (i.e., CPT 20552 or 20553) should be reported on any particular day, no matter how many sites or regions are injected.

Code	Description
20552	Injection(s); single or multiple trigger point(s), one or two muscle(s)
20553	Injection(s); single or multiple trigger point(s), three or more muscle(s)

ICD-10-CM Diagnosis

The following ICD-10-CM codes support medical necessity. The use of an ICD-10-CM code below does not assure coverage of the service. The service must be medically necessary and reasonable for the member and must meet the coverage criteria listed in this policy.

Code	Description
M79.10	Myalgia, unspecified site
M79.11	Myalgia of mastication muscle
M79.12	Myalgia of auxiliary muscles, head and neck
M79.18	Myalgia, other site

Policy history

Origination date: Approval(s): 12/01/2023 Technology Assessment Committee: 09/26/2023 (policy origination), 07/23/2024 (annual review, updated Medicare regulatory information in Policy section, criteria unchanged, updated References)

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.