Local Coverage Determination (LCD)

LCD - Trigger Point Injections (TPI) (L39671)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Palmetto GBA	A and B MAC	10111 - MAC A	J - J	Alabama
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10211 - MAC A	J - J	Georgia
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10311 - MAC A	J - J	Tennessee
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11201 - MAC A	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11301 - MAC A	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11401 - MAC A	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
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LCD Information

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Issue

Issue Description

This LCD outlines limited coverage for this service with specific details under **Coverage Indications, Limitations and/or Medical Necessity**.

Issue - Explanation of Change Between Proposed LCD and Final LCD

Under **Coverage Indications, Limitations and/or Medical Necessity** removed requirement that there should be at least 6 weeks duration before TPI is repeated in the same location. Under **Summary of Evidence** additional literature and reviews were added for MPS and Headache. A new subsection titled, Frequency of Injections was added. Under **Bibliography** additional resources were added.

CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A) allows coverage and payment for only those services that are considered to be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1862(a)(1)(D) states no payment can be made for services that are for research or experimentation.

Title XVIII of the Social Security Act, Section §1862(a)(7) states Medicare will not cover any services or procedures associated with routine physical examinations.

Title XVIII of the Social Security Act, Section §1861(s)(2) Medical and Other Health Services

42 CFR §410.74 Physician assistants' services, §410.75 Nurse practitioners' services and §410.76 Clinical nurse specialists' services

CMS Internet-Only Manual, Pub. 100-08, Medicare Program Integrity Manual, Chapter 13, §13.5.4 Reasonable and Necessary Provision in LCDs

CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 1 §30.3.3 Acupuncture for Chronic Lower Back Pain (cLBP)

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Initial Trigger Point Injection

TRIGGER POINT INJECTIONs (TPI) will be considered medically reasonable and necessary to treat myofascial pain caused by trigger points when all the following requirements are met:

1. There is a focal area of pain in the skeletal muscle;
2. There is clinical evidence of a trigger point defined as pain in a skeletal muscle that is associated with at least 2 of the following findings: the presence of a hyperirritable spot and/or taut band identified by palpation and possible referred pain; **AND**
3. The physical examination identifies a focal hypersensitive bundle or nodule of muscle fiber harder than normal consistency with or without a local twitch response and referred pain; **AND**
4. Non-invasive conservative therapy is not successful as first line treatment **OR** movement of a joint or limb is limited or blocked **OR** the TPI is necessary for diagnostic confirmation.

Subsequent TPI

Repeat TPI in previously injected trigger points will be considered medically reasonable and necessary to treat myofascial pain syndrome (MPS) when all the following requirements are met:

1. There is a positive pain response from the most recent TPI defined as providing consistent minimum of 50% relief of primary (index) pain after the TPI measured by the SAME pain scale* at baseline and post-injection; **AND**
2. Consistent pain relief from the most recent previous TPI lasting at least 6 weeks[1]; **AND**
3. The myofascial pain has reoccurred and is causing objective functional limitations measured by a functional scale* obtained at baseline and after TPI which demonstrated at least 50% functional improvement from the previous TPI.

*Note: The scales used to measure pain and/or disability must be documented in the medical record. Acceptable scales include but are not limited to: verbal rating scales, Numerical Rating Scale (NRS) and Visual Analog Scale (VAS) for pain assessment, and Pain Disability Assessment Scale (PDAS), Oswestry Disability Index (ODI), Oswestry Low Back Pain Disability Questionnaire (OSW), Quebec Back Pain Disability Scale (QBPDS), Roland Morris Pain Scale, Back Pain Functional Scale (BPFS), and the Patient-Reported Outcomes Measurement Information System (PROMIS®) profile domains to assess function.

Limitations: No more than 3 TPI sessions will be reimbursed per rolling 12 months.

Requirements:

1. Patients must be part of an ongoing conservative treatment program and documentation to support the patient is actively participating in a rehabilitation program, home exercise program or functional restoration program is in the medical record.
2. Trigger point primary index pain must be measured prior to the injection at the beginning of the session.
3. The post procedure pain level must be measured after the TPI at the conclusion of the session using the same pain scale* utilized at baseline.
4. When documenting the percentage of pain relief from the primary (index) pain compared to the post-injection pain levels, it is insufficient to report only a percentage of pain relief and/or a nonspecific statement of the duration of pain relief. The documentation must include a specific assessment of the duration of relief being consistent or inconsistent with the agent used for the injection and the specific dates the measurements were obtained using the SAME pain scale* used at baseline.
5. When documenting the ability to perform previously painful movements and activities of daily living (ADLs) it is insufficient to provide a vague or nonspecific statement regarding the improvement of previously painful movements and ADLs. The documentation must include a functional assessment to show clinically meaningful improvement with painful movements and ADLs, if this metric is used to justify the efficacy of the TPI procedure. Providers must use established and measurable goals and objective scales to assess functionality and ADLs measures.

Limitations:

1. A TPI involves the use of a local anesthetic and does not include injections of biologics (e.g., platelet rich plasma, stem cells, amniotic fluid, etc.) and/or any other injectates.
2. It is not considered medically reasonable and necessary to perform TPI into multiple muscle groups in different anatomical regions during the same session.
3. It is not considered medically reasonable and necessary to perform multiple blocks (e.g., epidural steroid injection (ESI), sympathetic blocks, facet blocks, etc.) during the same session as TPI.
4. TPI for treatment of headache, neck pain or low back pain in absence of actual trigger points, diffuse muscle pain, a chronic pain syndrome, lumbosacral canal stenosis, fibromyalgia, non-malignant multifocal musculoskeletal pain, complex regional pain syndrome, sexual dysfunction/pelvic pain, whiplash, neuropathic pain, and hemiplegic shoulder pain are considered investigational and therefore are not considered medically reasonable and necessary.
5. Use of fluoroscopy or magnetic resonance imaging **(**MRI) guidance for performance of TPI is not considered reasonable and necessary.
6. The use of ultrasound guidance for the performance of TPI is considered investigational.
7. TPI used on a routine basis (e.g., on a regular periodic and continuous basis) for patients with chronic non-malignant pain syndromes are not considered medically necessary.

Provider Qualifications:

The Medicare Program Integrity Manual states services will be considered medically reasonable and necessary only if performed by appropriately trained providers.

Patient safety and quality of care mandate that healthcare professionals who perform TPI/procedures for chronic pain (not surgical anesthesia) are appropriately trained and/or credentialed by a formal residency/fellowship program and/or are certified by either an accredited and nationally recognized organization or by a post-graduate training course accredited by an established national accrediting body or accredited professional training program whose core curriculum includes the performance and management of the procedures addressed in this policy. Credentialing or privileges are required for procedures performed in inpatient and outpatient settings.[2]

All aspects of care must be within the provider's medical licensure and scope of practice. Reimbursement for procedures utilizing imaging techniques may be made to providers who meet training requirements for the procedures in this policy only if their respective state allows such in their practice act and formally licenses or certifies the practitioner to use and interpret these imaging modalities (e.g., ionizing radiation and associated contrast material, magnetic resonance imaging, ultrasound). At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics as well as proficiency in diagnosis and management of disease, the technical performance of the procedure, and utilization of the required associated imaging modalities.

Summary of Evidence

Definitions

Acupuncture- Placement of (diameter/solid not thin) needles to strategic points to treat pain and disease without injection of a medicine.

Anatomical Region – An area of the body defined by structures which are palpable or visible. Typically described as cervical region, lumbar region, scapular region, thoracic region, cephalic region, facial region, etc.

Dry needling- A technique that involves the insertion of solid filament needles into the skin and underlying tissue to disrupt pain sensory pathways and relax contracted fibers.

Fibromyalgia – A chronic pain syndrome which presents with tender points, somatic symptoms and widespread musculoskeletal pain associated with the development of peripheral and central sensitization.

Grading of Recommendations, Assessment, Development and Evaluation (GRADE) – A system developed by the GRADE Working Group to address the shortcomings of present grading systems in healthcare. The GRADE system uses a common, sensible, and transparent approach to grading the quality of evidence. The results of applying the GRADE system to clinical trial data are displayed in a table known as a GRADE profile.

Muscle group - A group of muscles that are contiguous and that share a common function (e.g., flexion, stabilization or extension of a joint). Muscles that are widely separated anatomically and have different functions may be separate muscle groups.

Myofascial pain – A chronic pain syndrome characterized by myofascial trigger points associated with the development of peripheral and central sensitization.

Nerve block - An invasive procedure where medication is injected directly into (neurolysis) or around a nerve.

Session – A time period, which includes all procedures [e.g., medial branch blocks (MBB), intraarticular injections (IA), facet cyst ruptures, and radiofrequency ablations (RFA)] performed during 1 day.

Tender Point- Areas of tenderness occurring in muscles, muscle-tendon junction, bursa or fat pad.[3]

Tendon sheath injection – An invasive procedure where medication is injected into a tendon sheath.

Trigger point- Pain in a skeletal muscle that is associated with at least 2 of the following: a hyperirritable spot, taut band and referred pain.[3,4]

TRIGGER POINT INJECTION **(TPI)**- An invasive procedure where medication is injected directly into a trigger point.[5]

Background

Trigger points are discrete, focal hyperirritable spots located in a taut band of skeletal muscle. They are characterized by pain with palpation and can also produce referred pain described as tenderness, motor dysfunction and autonomic phenomena.[4,5] Trigger points are usually (but not always) accompanied by other hypertonic muscle groups. The most common finding on physical exam is that on palpation the hypersensitive bundle or nodule of muscle fiber is harder than normal consistency. In addition to elicitation of pain with palpation, there is often an associated local twitch response.[5]

TPI involves the insertion of a needle into muscle bands, muscle knots and trigger points with an intramuscular (IM) injection which is typically a local anesthetic.[5] Dry needling is a similar technique performed without the IM injectant and is not considered in this local coverage determination (LCD).

A 2017 International Consensus sought to create a diagnostic criterion for the diagnosis of trigger points.[4] Before this consensus, 19 criteria were found in the literature, resulting in a call for a standardized definition. Using a Delphi survey, experts endorsed that 2 palpatory findings and 1 symptom were central criteria for trigger point diagnosis by more than 70% of the experts including a taut band (N=56, 93%), a hypersensitive spot (N=46, 76.5%), and referred pain (N=43, 71.5%) as central criteria. The experts agreed that referred pain could include pain spreading to a different deep or dull pain, as well as some tingling or burning sensation within the region.[4]

A Multi-jurisdictional Contract Advisory Committee (CAC) meeting of Subject Matter Experts (SMEs) was convened on 4/27/23 regarding TPI. The transcript and audio are available on each Medicare Administrative Contractor's (MAC) website. The panel consisted of experts in anesthesiology, physical medicine and rehabilitation, musculoskeletal radiology, rheumatology, certified nurse anesthetist, and a physical therapist with representation throughout the country and included representation from major pain societies. The panel will be referred to as SMEs, and their input incorporated through the review to correlate the evidence with expert input.

A SME summarized the following: "The nonspecific diagnosis (note, for example the difficulty in distinguishing a "tender point" and "trigger point") and variability of clinical measurement make research for TPI inconsistent. The efficacy of TPI is not clear for the population, but specific patients benefit. Likely, a reasonable approach is to approve TPI for limited, short courses in which clinicians are asked to provide documentation of benefit prior to continued therapy. It is a low-cost therapeutic approach with a high safety index and seems reasonable with adequate documentation."

Conservative Management

The SME representing the American Physical Therapy Association (APTA®) explains there is moderate to high quality evidence for physical therapy (PT) depending on the condition or diagnosis and they acknowledge in some cases TPI aids in achieving patient goals. Evidence to support early and direct access to PT as first course of care is available for low back pain, neck pain and osteoarthritis. PT literature supports the concept that early PT can avoid need for

injection.[5]

TRIGGER POINT INJECTION**s (TPI)**

TPIs are administered directly into the taut muscle band. The mechanism of how trigger points work is not clear, however it is postulated that the physical act of placing the needle into the muscle triggers an inflammatory response and that improvement can be made regardless of the injectate just from the physical response to the needle.

Injectants including sterile saline, local anesthetics (LA), and other agents have been investigated.

SMEs report there is little evidence to support corticosteroids alone or in addition to LA to improve outcomes. Another SME shared that use of steroids is common in rheumatology practice for TPI. There is some literature that suggest the addition of steroids does not reduce pain more than local anesthesia alone.[6] Concerns for side effects associated with corticosteroids including hyperglycemia, weight gain, effect on bone mineral density if used long term and hypertension were discussed.

The literature reports that the duration of effect after a TPI is variable. The literature has wide variability in protocols ranging from repeating injections weekly to up to 3-4 months. The SMEs agree that most often injections are not being administered more frequently than every 3 months.

Image Guidance

There are no standard criteria regarding imaging for TPI. Trigger points are commonly identified by manual palpation of the trigger point and elicitation of the local twitch response both of which are performed without imaging. In cases of deep muscles that are not palpable, some investigators report a benefit to ultrasound to visualize the twitch response and ensure the injection has been localized to the trigger point. Evidence to support this role is limited to case reports[7,8], case studies[9,10] and 1 exploratory study[11]. SMEs felt that there are individualized cases where ultrasound may provide benefit.

A descriptive (exploratory) study was conducted to describe the ultrasound characteristics of myofascial trigger points (MTrPs) and adjacent soft tissue. The study included physical exam findings, pressure algometry, and 3 types of ultrasound imaging including grayscale, vibration sonoelastography and doppler. Ultrasounds were performed by a team blinded to the physical findings. They concluded that the MTrPs appeared as focal, hypoechoic regions on 2D ultrasound (grayscale), had higher tissue image scores compared to normal myofascial tissue and retrograde flow in diastole indicating a higher resistive vascular bed. The authors concluded that ultrasound imaging techniques can be used to distinguish myofascial tissue containing trigger points from normal myofascial tissue and enable visualization and some characterization of the trigger points and adjacent soft tissue.[11] Limitations of this study include small sample size, lack of standardization of scan technique and the lack of a control group. Additional studies further define ultrasound findings in the presence of trigger points.[12]

A 2019 study compared ultrasound guided TPI (n=21) to blind injection technique (n=20) using shear wave elastography for measurement of stiffness at the trigger point site for trapezius myofascial pain syndrome (MPS). The authors reported a statistically significant difference in VAS, Neck Disability Index and Shoulder Pain and Disability Index scores at 4 weeks from baseline between the 2 groups ($p = 0.003$, 0.012, and 0.018, respectively). The authors concluded that the ultrasound guided TPI are more effective than the blind injections.[13] Limitations include small sample size, lack of control group or standardization of ultrasound technique or findings.

A 2008 paper is a descriptive report introducing the technique of ultrasound for guidance of TPI. In this report, the authors emphasize that correct needle placement into the trigger point is vital to prevent complications and improve efficacy of the procedure. This can be challenging in obese patients. Misguided or misplaced injection is a risk for pneumothorax. The authors explain that ultrasound guidance could help avoid potential complications and increase efficacy. However, this was not investigated in this report or subsequent reports, so this hypothesis has not been confirmed.[14]

SMEs felt there is benefit of image guidance in areas at elevated risk for pneumothorax, a reported complication of TPI. Injections in the thoracic zone should be done with image guidance to improve safety. Also, it should be used in highly vascular areas and deep tissue to ensure proper location. However, there was no evidence to support these recommendations. There is a lack of standardization of the ultrasound technique in studies and lack of data to support that ultrasound improves outcomes for TPI.

Myofascial Pain Syndrome (MPS)

SME representing the Coalition of State Rheumatology Organizations (CSRO) states that rheumatologists diagnose and manage a wide array of musculoskeletal conditions including MPS, which is essentially "knots" in the muscles that do not release. They comment that despite lack of external validity, MPS caused by trigger points is an accepted condition.[15] They explain TPI with LA and sometimes corticosteroid to reduce inflammation is an effective tool.

A 2023 review of the literature concludes that while randomized trials have found statistically significant improvement related to TPI, the studies are limited by the low number of participants, lack of blinding, potential for placebo effect, and lack of post treatment follow up. The studies are inconclusive regarding a single pharmacological agent proving superiority to another. Evidence rating B is inconsistent or limited quality patient-orientated evidence. The following received an evidence score of B: placebo effect may be the underlying source of pain of relief from TPI. Massage and PT should be considered first line less invasive treatment for trigger points, and routine use of TPIs is not supported in clinical trials. The authors advocate for reserving TPIs for myofascial pain that is refractory to other measures and management as part of a comprehensive, multimodal and team-based approach to patients with myofascial pain.[16]

A 2023 systematic review/meta-analysis compares TPI to medical management for acute myofascial pain including 4 randomized controlled trials (RCTs). They report TPI are effective in reducing pain scores compared to medical treatment (SMD = -2.09 [95% CI: -3.34 to -0.85, P = 0.001]).[17] Included studies report on pain intensity and Risk of Bias to assessment, which was completed for each included paper. Two reports were in patients with myofascial pain, 1 was low back pain and the fourth was rotator cuff disease. Only 1 had low risk of bias. Heterogeneity was elevated due to variation in pain scores and medication used during the TPI (I^2=60%). This did not account for variation in condition being investigated which further limits the generalizability of the results. The results are also limited by the risk of bias in the included studies, lack of standardized dosing for injections and variation in outcome measures.

A 2020 systematic review reports on 13 RCTs that evaluate efficacy of TPI with LA, botulinum toxin A (BTX-A), or dry needling for MTrPs pain.[18] Included studies had a minimum of single blinding and primary outcome of reduction of pain score as measured by VAS. Six studies compared lidocaine injection (LI) (n=139) to dry needling (n=103) and VAS was measured at 1 month following initial treatment for 5/6. Clinical success was defined as >50% reduction in baseline pain scores and was found for 3/4 TPI with local anesthetics and 1/4 of the dry needling group. Adverse events in all groups were classified as minor. The author concludes that there were not statistically significant improvements in pain in comparing dry needling to TPI with LA. Since the rate of muscle soreness and discomfort at the time of the procedure was significantly higher in the dry needling group (7.8%) as compared to TPI with LA (1.4%) they conclude TPI with LA may result in better overall patient experience. Risk of bias of the included studies

was not included in this analysis. The interval between injections and frequency of treatment was not discussed in the paper.

A 2019 systematic review and meta-analysis was conducted to compare the effectiveness of LAs and BTX-A in patients with myofascial pain by: (1) assessing the effects of LAs 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 comprehensive literature search was performed utilizing EMBASE, Cochrane CENTRAL, and Medline, which produced 33 studies that were included for analysis. A total of 18 articles assessed the effect of LA TPIs and 16 assessed the effect of BTX-A injections on reported pain. The search included RCTs, control trials, and randomized trials. The VAS and the Neck Pain and Disability Scale (NPAD) were utilized in this study. A small effect size in pain reduction for TPIs 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 TPIs 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 LA injections, I^2 =92% ($\chi 27$ =82.67, P< 0.001). No serious adverse events were reported. This study was limited by high study heterogeneity especially among LA injection studies, response bias, variations in quantity and type of LA used across studies and inclusion of various study designs with various adjunct treatments given to participants.[19]

A 2019 systematic review and meta-analysis was performed to evaluate the effectiveness of LA TPIs in adults with 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. The LA group showed a significant improvement in VAS pain scale (1.585 units) at 1 to 4 weeks follow up 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 LA 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 were reported in the LA 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. Authors acknowledge the need for well-designed studies in the future.[20]

A 2016 RCT was conducted to determine whether LA into trigger points combined with a PT 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 VAS were assigned. The 3 intervention groups were: PT, Lidocaine 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.[21]

A 2015 prospective study was performed to investigate the efficacy of LI in the IM innervation zone (IZ) for the treatment of chronic neck pain caused by MTrPs in the trapezius muscle. A total of 120 patients with MPS of the trapezius muscle were randomly divided in 1 of 5 groups. The first group (n=24) received saline (0.9% NaCl) injections at the MTrPs. The second group (n=24) received 0.5% LIs at the MTrPs. The third group (n=24) received saline (0.9% NaCl) injections at the mid-upper trapezius. The fourth group (n=24) received 0.5% LIs at 2 separate points of the lower trapezius. LI treatments in the IM IZ yielded a significant reduction in the degree and frequency of neck pain at 6 months as compared to the MTrPs injection group. The authors reported that the degree and frequency of pain was most improved with the group receiving injections to the IZ of both the mid-upper trapezius and the lower trapezius (all P <0.05). Limitations include small sample size, study design and short term follow up.

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A 2021 retrospective study was performed to evaluate and compare the effectiveness of LA, BTX, and platelet-rich plasma (PRP) injections for the treatment of MTrPs in the masseter muscle. Between 2016 and 2019 patients were included if they were treated with myofascial TPI in masseter muscle. Patients were divided into 1 of 3 groups: Group 1 (LA injection), Group 2 (BTX injection), Group 3 (PRP injection). The primary outcome was average pain at rest, while chewing, pressure pain intensity (PPI) and Jaw Functional Limitation Scale (JFLS) value. Secondary outcomes included the quality-of-life [measured using Oral Health Impact Profile-14 (OHIP-14)]. Outcomes were assessed at diagnosis, and 1-, 3-, and 6-months post-treatment. A total of 82 patients were enrolled [Group 1 (n=27), Group 2 (n=26), and Group 3 (n=29)]. Improvements in all parameters were seen in Group 1 and Group 2 as compared to Group 3 at 3 months follow up. Significant results were seen in Group 2 as compared to Group 1 at 3 months follow up in VAS pain, JFLS, and OHIP-14 ($P = .009$; $P = .004$; $P = .002$). Significant improvements were seen in Group 2 in VAS pain, JFLS, and OHIP-14 ($P = .008$; $P < .001$; $P < .01$) at 6 month follow up. Limitations include lack of control group, comorbidities were not considered, small sample size and short follow up. Authors conclude that all procedures showed improvement in symptoms of TrPs in the masseter muscle at 1 and 3 month follow up but note that BTX injections resulted in superior results at 3 months follow up and remained effective until 6 month follow up.[23]

Headache

Injection of BTX for headache is not included in this LCD as it is out of the scope of this policy.

A 2022 systematic review aimed to evaluate percutaneous interventional treatments for prevention of migraines. Both qualitative and quantitative analysis methods were utilized. An expert panel was formed and evidence-based recommendations for the preventative and interventional treatment of migraines was developed. Clinical outcomes considered included: headache days, acute medication use, and functional impairment. A total of 16 RCTs were included in qualitative synthesis and 2 articles were excluded from quantitative synthesis because of inadequate outcomes reporting. Regarding TPIs, 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 TPIs in migraine prevention. Support for the Migraine Prevention Project of the American Academy of Pain Medicine Foundation (AAPMF) was received as unrestricted grants from Amgen Inc., Lilly USA, LLC, Supernus® Pharmaceuticals, and Teva Pharmaceuticals.[24]

A 2015 RCT comprised of 70 patients was conducted to examine the effect of blocking trigger points in the temporal muscles of patients with masticatory MPS, fibromyalgia and headache. Patients with 1 trigger point were randomly divided into 3 groups: injection with saline (n=26) or anesthetic (n=21) and non-injected (control) (n=23). After lost to follow up and exclusions, the patients analyzed for the 3 groups were: injection with saline (n=14) or anesthetic (n=17) and non-injected (control) (n=16). Both saline and anesthetic treatments significantly reduced the intensity of facial pain, ($p = 0.004$ and $p < 0.001$) and showed a decrease in headache frequency which were statistically significantly different ($p = 0.037$ and $p = 0.002$) and yielded effective results regarding headache intensity, differing from the control group ($p = 0.008$ and $p = 0.001$). Limitations included small sample size, short duration of follow up, and lost to follow up. Authors conclude decreased facial pain and frequency and intensity of headache resulted in treatment with TPI treatments. LA and saline were effective whereas the control group was not statistically significant.[25]

A 2013 randomized double-blind controlled study aimed to assess the efficacy, safety, and tolerability of local LIs in the prophylaxis of chronic tension-type headache (TTH). A total of 48 patients referred to neurology clinics and diagnosed as chronic TTH were randomized into 1 of 2 groups: the 0.5% LI (n=24) or saline (0.9% NaCl) injection

(n=24) group. The inclusion criteria were headache for 15 days or more in a month, between 18 and 65 years of age, chronic TTH with a history of at least 6 months since the beginning, and not responding to optimal doses of antidepressants for at least 3 months. Evaluations and injections were performed by separate physicians and the evaluator was blind to the treatment group. There was no statistically significant difference between mean age and distribution of male and female participants between groups ($p = 0.937$ and $p = 1.000$, respectively). When compared to the pre-treatment values, the lidocaine group demonstrated a statistically significant decrease in post-treatment after the first month in number of painful days, number of analgesics tablets used, VAS and Hamilton depression and anxiety scores ($p<0.001$). When comparing in the placebo group, favorable therapeutic response rates were observed the first month following treatment when considering the number of painful days and number of analgesics used, VAS scores, and Hamilton depression and anxiety scores ($p< 0.001$). No serious adverse events were reported. Authors conclude LI may be an effective treatment in patients with chronic TTH that did not respond sufficiently to analgesics and antidepressants. This study was limited by small sample size and short-term follow up.[26]

A 2011 retrospective review comprised of 147 consecutive patients aimed to determine if a wider spectrum of cervically mediated symptoms exist, and to investigate a potential role of greater occipital nerve blocks (GON) and TPIs in these patients. Chief complaints included: dizziness (93%), tinnitus (4%), headache (3%), and ear discomfort (0.7%) while general symptoms included: dizziness (97%), headache (88%), neck pain (63%), tinnitus (23%), and ear discomfort (22%). A combination of betamethasone sodium phosphate 6mg as 1mL and 0.25% bupivacaine hydrochloride as 2mL in a syringe made the GON and TPI treatment. Results after GON/TPI treatments: "neck range of motion (ROM) (71%), headache (57%), neck pain (52%), ear discomfort (47%), dizziness (46%), and tinnitus (30%). Dizziness responders had neck position asymmetries (84%), reproducible dizziness by cervical and suboccipital musculature vibration (75%), and pre-injection posterior vertex sensory changes (60%)." Limitations included small sample size, study design, and recall bias. Authors concluded a wider array of cervically mediated symptoms may influence the "trigeminocervical and vestibular circuitry through cervical afferent neuromodulation."[27]

A 2010 systematic review was conducted. PubMed was systematically searched for literature addressing peripheral nerve blocks (PNBs) and TPI treatments for headaches. Authors report a paucity of data on the efficacy of TPI for headache disorders. Authors note the lack of standardization of injection schedule for TPI. Limitations include lack of classifying headaches according to standardized criteria. A considerable number of patients did not meet the current International Headache Society criteria for chronic daily headache (CDH).[28]

A 2009 RCT comprised of 45 patients was conducted to compare the use of 2 different substances for trigger point injectate to dry-needling to alleviate headache. Assessed outcomes included levels of pain intensity, frequency and duration, local post-injection sensitivity, obtainment time and duration of relief and the need to use analgesics to control headaches. A random draw method was utilized to divide the patients into 3 groups: Group 1 (dry needling), Group 2 (lidocaine at 0.25%), and Group 3 (BTX 25 or 50U). Outcome measures were obtained by employing the Symptom Severity Index (SSI), Palpation of the trigger point and reproduction of the chief complaint (headache), Pain diary, and Pain questionnaire. Except for rescue medication and local post injection sensitivity, all treatment groups yielded promising results ($p\leq0.05$). Limitations include small sample size, short follow up and recall bias. Authors conclude lidocaine may be considered as the substance of choice while, for refractory cases, BTX may be the best choice.[29]

A 2023 small prospective observational trial included 23 patients who had ultrasound-guided interfascial blocks of the trapezius muscle for cervicogenic headache. The authors reported improvement in numerical rating scale from baseline immediately after the procedure and continued at 1-, 2-, and 4-weeks post treatment. Pain frequency was reduced at 1 and 2 weeks.[30] This study is limited by observational design, very small sample size and short-term follow-up.

Anterior Cutaneous Nerve Entrapment (ACNES)

A 2016 systematic review was conducted to outline the current available literature concerning the treatment of patients diagnosed with Abdominal Cutaneous Nerve Entrapment Syndrome (ACNES). A total of 7 studies were included for analysis and were comprised of 381 patients that were undergoing treatments using TPI or anterior neurectomy as a standalone procedure, and TPI followed by anterior neurectomy refractory ACNES. One study was a RCT[31], 4 retrospective reviews and 2 case series. Authors defined short-term success as "a ≥50% pain reduction using pain intensity numerical rating scale and/or a minimal 2-point reduction using verbal numerical rating score (VNRS) at 1 to 3 months follow-up and long-term success was defined as "pain intensity numerical rating scale scores ≤50% of preoperative pain levels or if the present VNRS was at least 2 points lower". Short term success was found in 70% of patients, while long term success was reported in 61% of patients. Following TPI treatment, a positive response was seen in 86% of patients and 73% still showed a positive response at a mean follow up of 32 months. Successful treatment was reported in 50% of patients in 2 other studies. The trial utilizing anterior neurectomy resulted in a successful pain response, 73% in the treatment group versus 18% in the sham group. Two cohort studies yielded 69% of patients were satisfied at 18 months and 61% patients were satisfied at 32 months follow up in the neurectomy groups.[32] Limitations include small sample size, varying study designs including retrospective, risk of selection bias, 3 studies from the same group, and different reporting methods for outcomes.

A 2013 RCT was conducted with the intent to clarify the role of LA injection in diagnosing ACNES. The hypothesis was LI would yield a greater decrease in pain than that after saline injection. A total of 48 patients with suspected ACNES were randomized to receive 10 ml 1% lidocaine (n=24) or saline injection (n=24). Injections were made into the point of maximal abdominal wall pain just beneath the anterior fascia of the rectus abdominis muscle. A VAS and verbal rating scale (VRS) were utilized just before the injection and 15-20 mins following injection. A successful response was defined as ≥50% reduction of pain on the VAS and/or a reduction of 2 points on the VRS. Successful responses occurred in 4 patients in the saline group compared to 13 patients in the lidocaine group (P =0·007). No severe adverse events occurred. Authors concluded entrapped branches of intercostal nerves may contribute to chronic abdominal pain. A reduction of pain was seen in patients following local infiltration which authors state was based on anesthetic mechanism rather than mechanical effect or placebo effect. Limitations include small sample size; a blinded experienced investigator was able to predict the type of injected agent correctly in the majority (three-quarters) of patients.[31]

A 2012 RCT reported on 48 adults suspected of ACNES who received an injection with LA (n=24) or saline (n=24) to the point of maximum abdominal wall pain just beneath the anterior fascia of the rectus abdominal muscle. Pain was measured before and after injection and 50% reduction was considered a successful response, which was significantly higher in the group receiving lidocaine (13 of 24 versus 4 of 24 in saline group; P = 0·007). The authors conclude that pain reduction after lidocaine infiltration may play a diagnostic role for ACNES.[31]

A 2011 cohort study of 139 consecutive patients with chronic abdominal pain suggestive of ACNES were assessed to evaluate the efficacy of a diagnostic workup protocol and treatment regimen. This study was performed between January 2003 and August 2008 in the Maxima Medical Center, Veldhoven, The Netherlands. A visual analog reduction of at least 50% was seen in 81% (n=94) after the first injection. After injection therapy alone, 33% (n=44) remained pain-free permanently while 71% (n=49) of the neurectomy patients were considered successful. Authors report a long-term efficacy was achieved in 71% with a satisfying visual rating scale of 1-2 results, however the median follow up was 18 months (range, 1-64 months). Attenuated levels of pain (VRS 3) were reported in 9%. Authors conclude consecutive local TPI are effective in 1/3 of ACNES patients. Authors report surgical neurectomy is effective in 2/3 of refractory patients. This paper provides support for the use of a single diagnostic TPI for diagnosis of ACNES.[33] Limitations include recall bias, referral bias, small sample size, short follow up, and study design.

Low Back Pain

A 2008 systematic review of RCTs to assess if injection therapy is more effective than placebo or other treatments for patients with subacute or chronic low back pain (cLBP). This study was an update of a previous systematic review and included searches of the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, and EMBASE databases. The search included RCTs with effects of injection therapy involving epidural, facet, or local sites for subacute or cLBP publications up to March 2007. A total of 18 trials (n=1179) were included. Ten of 18 studies were rated as high quality. Due to the heterogeneity among studies, statistical pooling was not performed. A variety of drugs were studied including LAs , corticosteroids, and a variety of other drugs. The studies were subdivided by injection site, pharmaceutical agent, and comparison of treatment. Authors concluded that there was no strong evidence either for or against the use of injection therapy of any type. They go further to state more research is needed to identify a subgroup of patients that some type of injection would benefit. Limitations included high heterogeneity among included studies, variations in injections sites, and different drugs were utilized.[34]

A 2014 guideline update was published by the American Association of Neurological Surgeons (AANS)/ Congress of Neurological Surgeons (CNS) Joint Guidelines Committee (JGC) focusing on injection therapies, low-back pain and lumbar fusion based on evidence. Lumbar TPI (Grade B) "performed as dry needling, with anesthetics alone or with steroids, are not recommended in patients with cLBP without radiculopathy from degenerative disease of the lumbar spine because a long-lasting benefit has not been demonstrated (Level II evidence)." Authors state "there is insufficient evidence to support or refute the use of TPIs for cLBP without radiculopathy."[35]

A 2011 randomized trial was performed to compare the effects of trigger point (TRP) mesotherapy and acupuncture (ACP) mesotherapy in the treatment of patients with cLBP. A total of 62 subjects were recruited between July 2006 and May 2008 at outpatients Physical Medicine and Rehabilitation Clinic at the University of Rome. Patients were randomized to receive 4-week treatments with either trigger point mesotherapy (n = 29) or acupoints mesotherapy (n = 33). Outcomes were measured utilizing the VAS, McGill Pain Questionnaire Short Form (SFMPQ), Roland Morris Disability Questionnaire (RMQ) and Oswestry Low Back Pain Disability Questionnaire. Mean values at baseline were performed and a comparative analysis was completed at the end of the treatment (after 4 weeks) and follow-up (12 weeks from the last treatment). A statistically significant difference was seen for ACP over TRP in SF-MPQ measures over time ($p = .035$). Patients reported slight neck pain (15%) in the ACP group between the first and second sessions. Authors conclude their results "suggest that the response to ACP mesotherapy may be greater than the response to TRP mesotherapy in the short-term follow-up (12 weeks after the end of last treatment) and show that the stimulation site is important." Authors go on to acknowledge that more studies with robust design are needed to evaluate the efficacy and safety of mesotherapy and especially as it pertains to musculoskeletal pain management. Limitations include small sample size, short follow up, response bias, and sample bias.[36]

A 2019 randomized study compared intravenously (IV) administered non-steroidal anti-inflammatory drugs (NSAIDs) and TPI in the treatment of low back pain (LBP) patients admitted to the emergency department (ED) due to pain caused by trigger points. Patients were randomized into the NSAID (group 1, n=32) or TPI (group 2, n=22). The TPI group showed a significant decrease in pain scores. A mean VAS decreased by 0.41 ± 1.30 in the TPI group and by 2.59 ± 2.37 in the NSAID group ($p < 0.001$) after the 60 min follow up period. Authors conclude results showed TPI was superior to IV NSAIDs in the treatment of LBP. Limitations include small sample size, study method, and short follow up of only 60 mins.[37]

A 2014 prospective study was performed to determine the prevalence of active trigger points accompanying lumbosacral radiculopathy and to evaluate the effect of TPI on patient's pain scores and straight leg raise (SLR). A total of 98 patients were enrolled. All patients were referred to an orthopedic clinic for lumbosacral radiculopathy. Baseline examination included history and physical, labs, radiology services, and pain severity. VAS and SLR were utilized. A positive SLR was defined as patients feel pain during 0 to 70 degrees of leg raising. A negative SLR was defined as no pain was experienced during leg raising. Disc disease was confirmed by MRI and lumbosacral x-ray. An oral dose of Diclofenac Na (25mg) was given 4 times a day to each patient. The presence of trigger points and degree of pain was evaluated after a week. Patients who did not have trigger point pain were excluded from the

study and patients who did were divided into 2 groups, TP (n=32, TP injections, 1ml lidocaine 2%) and N (n=32, former conservative therapy). "Pain scores (Mean ± SD) in TP group was 7.12 ± 1.13 and in N group was 6.7 ± 1.16, P = 0.196. Following the treatment, pain scores were 2.4 ± 1.5 in TP group and 4.06 ± 1.76 in N group P = 0.008. SLR test became negative in all patients in TP group but only in 6 (19%) patients in N group, P = 0.001." Authors conclude that TPI can significantly improve recovery in patients with chronic lumbosacral radiculopathy.[38]

A 2022 RCT compared effectiveness of gluteal TPIs to ESI for lumbosacral canal stenosis in 44 patients. Pain was measured at baseline, 2 weeks and 8 weeks. The authors report both groups had a decrease in pain; however, the trigger point group had more sustained relief than the epidural group at weeks 2, 4 and 8 ($p<0.001$ $p=0.008$, and $p<0.001$, respectively).[39] Limitations include lack of blinding, lack of control, short term follow up and small sample size.

Up To Date addresses trigger points in "Subacute and chronic low back pain nonsurgical interventional treatment".[40] They stated a systematic review[34] found no clear difference between local or TPIs with local anesthetic, with or without corticosteroids, and control interventions such as saline, dry needling or ethyl chloride plus acupressure, for short-term pain relief in 3 trials of patients with sub-acute or chronic low back pain. The trials were criticized for methodological shortcomings and high level of heterogeneity and did not support widespread use. The author stated TPI may be beneficial in patients with tender points associated with MPS.

Whiplash

A 2013 systematic review did not find benefit of BTX-A compared to saline for management of whiplash or other injectants reviewed including LA, steroids, and saline.[41]

A 2009 controlled case series reported on 17 patients with chronic neck pain following whiplash who received TPI with anesthetic in the upper trapezius and compared it to 10 controls who received anesthetic injection into the thigh. The authors reported immediate improvement in cervical range of motion and pain following an average of 3.8 injections into the identified trigger points with an increased range of motion ranging from 27-49%.[42] Limitations include lack of blinding, small sample size, variable in number of injections/dosing and short-term follow-up.

Neck Pain

Literature search did not find any articles that addressed the role of TPIs for non-radicular neck pain. MPS in the neck is addressed above.

A systematic review was conducted, and strength of evidence measured with GRADE methodology. GRADE analysis for IM lidocaine with stretch for chronic myofascial pain was rated Very Low, for chronic non-specific mechanical neck pain vs. dry needling was rated Low, and steroid injection (with or without LA) for chronic neck pain with radiculopathy and radiation was rated Low.[41]

Fibromyalgia

Prior to 2010 tender points were part of the diagnostic criteria for fibromyalgia. SMEs discussed the differences between tender points and trigger points. The main difference is the presences of a taut band and referral pattern associated with trigger point and absent in tender point. It is possible for both to occur in the same patient. Most papers in literature search were case reports or review articles.

A 2014 RCT included 60 female subjects divided into 3 groups. Group 1 received lidocaine only, Group 2 saline only and Group 3 lidocaine and saline injections into the trapezius and gluteal muscles. The authors reported a decrease in hyperalgesia more after lidocaine than saline (p=.004), but all lead to improvements.[43] Limitations of this study included insufficient sample size to draw conclusions and lack of placebo control group.

A prospective study evaluated patients with MPS caused by active trigger points with (n=9) and without fibromyalgia (n=9) who received TPI into the upper trapezium muscle. Pain intensity, threshold and ROM were measured before, immediately after and 2 weeks after TPI was reported. Significant improvement in ROM in both groups after TPI was reported.[44] Sample size was too small for reliable conclusion.

A 2004 systematic review focused on optimal management of fibromyalgia syndrome including TPI as a treatment option. At the time of this review there were no RCTs and a few uncontrolled articles for TPI for fibromyalgia. The authors conclude there is no evidence for TPIs in this review.[45]

Non-Malignant Musculoskeletal Pain

A 2009 systematic review of 15 studies was conducted to assess the evidence on the efficacy and safety of using TPI to treat patients with chronic non-malignant musculoskeletal pain that had persisted for at least 3 months. Ten trials assessed TPI in patients with head, neck, shoulder, and/or back pain. The authors report that these studies were limited by small sample size, high heterogeneity, and reporting bias. The authors conclude "no clear evidence of either benefit or ineffectiveness." They state that the procedure is safe when performed by appropriately trained providers and can aid in symptom relief regardless of injectant used and may be a useful adjunctive therapy.[46]

Complex Regional Pain Syndrome

Complex regional pain syndrome is a condition characterized by pain that is disproportionate to the extent and duration of the primary injury and extends beyond the specific peripheral nerve involved. Literature on the role of TPI in management of complex regional pain syndrome is limited to case reports, case series, and reports with very small sample sizes.

Sexual Dysfunction/Pelvic Pain

The role of TPI for sexual dysfunction and pelvic pain is limited to case reports and small pilot studies. A 2014 pilot study reported on 29 women (17 with PT and 12 with TPI) with pelvic floor dysfunction. Both groups reported reduction in vaginal pain from baseline.[47] Limitations include small sample size, variation in treatment duration, number of interventions, and lack of controls.

A 2022 retrospective longitudinal study reported on 186 women with chronic pelvic pain treated with ultrasound guided PNBs and TPIs to pelvic floor muscles in conjunction with pelvic floor PT once weekly for 6 weeks. Pain was measured using VAS and functional pelvic pain scale. They report statistically significant improvement in pain after treatment.[48] Limitations include no comparison to PT alone which is known to provide benefit in chronic pelvic pain, short term follow-up and retrospective study design.

Hemiplegic Shoulder Pain

A 2012 RCT of 24 patients with hemiplegic shoulder pain randomized 12 patients to standard therapy and 12 received segmental neuromyotherapy. This involved injection of LA into the taut band and trigger points using a needle which is the same technique as TPI. The authors report improvement in pain scores before and after the

injections in the treatment group.[49] The study is limited by lack of blinding, small sample size and short term follow up.

A 2021 systematic review and meta-analysis included 1 RCT.[49] Meta-analysis was conducted; however, since there was only 1 trial with 9 patients that addressed this population that result was inconclusive.

Neuropathic Pain

A 2019 prospective study evaluated the effect of a piriformis TPI on neuropathic pain in 30 patients with piriformis syndrome. All patients received a TPI under ultrasound guidance into the piriformis muscle with LA and steroid. Pain assessments before and after the injection reported statistically significant improvement ($p<0.001$) for all scores at 1 week and 1 month compared to baseline values with the greatest improvement at the first week post injection. The authors conclude that the pyriformis injection is effective for both somatic and neuropathic pain in pyriformis syndrome patients.[50] The study is limited by lack of randomization and control, and small sample size.

Frequency of Injections

The frequency of TPI is not well established in the literature, but most experts agree that the benefit should last at least 4 weeks and typically several months. This aligns with expert opinions from the SMEs and most societal guidance.[51]

Raeissadat et al.[52] evaluated 62 patients receiving ozone injection (n=22), LI (n=20) or dry needling (n=20) weekly for 3 weeks for trigger point pain. Pain was measured at baseline and 4 weeks after injections. They reported improvement in pain with all 3 interventions and that ozone and lidocaine had slightly better results than dry needling. The study is limited by small sample size and lack of a functional assessment tool. Since pain was not measured at each treatment, it was uncertain if the repeat injections were necessary or per protocol and the duration of pain relief after the final injection due to short term follow-up.

Korkmaz et al.[53] also investigated oxygen-ozone injection compared to lidocaine for myofascial pain on the trigger point in 46 patients of which 23 received ozone injection and 23 lidocaine weekly for 3 weeks. Assessments were made at baseline, 4 and 12 weeks after treatment. No assessment was made in pain between the injections administered weekly to determine timing of improvement in score from baseline. The authors report both modalities improved pain. This is limited by small sample size, lack of blinding, and lack of control group.

ASIPP recommends weekly injections during the diagnostic phase which was limited to no more than 4 times per year and at least 2 months apart thereafter to a maximum of 6/12 months.[1] There was no supporting evidence for these recommendations which were developed in 2001.[18]

Societal Guidance

- A 2010 guideline by the American Society of Anesthesiologists™ (ASA) produced practice guidelines for chronic pain management. Authors concluded the literature is "insufficient to evaluate the efficacy of TPIs (e.g., compared with sham TPI) as a technique for providing pain relief for patients with chronic pain (Category D evidence). Studies with observational findings suggest that TPIs may provide relief for patients with myofascial pain for assessment periods ranging from 1 to 4 months (Category B2 evidence). Consultants, ASA members, and American Society of Regional Anesthesia and Pain Medicine (ASRA) members agree that TPI should be used for patients with myofascial pain. The recommendations for TPI within the guidelines were that TPI may be considered for treatment of patients with myofascial pain as part of a multimodal approach to pain

management.[54]

- AANS/CNS guidelines state there is insufficient evidence to support or refute the use of TPIs for cLBP without radiculopathy because long-lasting benefit has not been established (Level II evidence).[35]
- American College of Occupational and Environmental Medicine (ACOEM)[51] review concludes trigger and/or tender point injections are not recommended with moderate confidence for treatment of acute back pain. Trigger and/or tender point injections may be recommended (C) low confidence as a reasonable second or tertiary option for the treatment of subacute or cLBP that is not resolving with conservative measures. They state that the injectant should contain topical anesthetic or dry needle laying without an injection. Repeat injection should be based on improvements and should be in conjunction with an active program. At least 3 to 4 weeks between injections is recommended. They state if a first set of injections is not satisfactory, a second set is reasonable but if improvement after that point is not achieved further injections are not recommended. The use of glucocorticosteroids is not recommended (C) moderate confidence for use in TPI.
- In reference to Interventional Question 13: "In patients with low back pain, do TPIs decrease the duration of pain, decrease the intensity of pain, increase in the functional outcomes of treatment and improve the return-to-work rate?" The North American Spine Society[55] responded, "There is insufficient evidence to make a recommendation for or against the use of TPIs in the treatment of LBP. The type of injectate does not influence outcomes. Grade of Recommendation: I".
- American Society of Interventional Pain Physicians (ASIPP) Practice Guideline, Interventional Techniques in the Management of Chronic Pain, Part 2.0 reviewed 7 RCTs and conclude Level III-IV strength of evidence in addition to "overwhelming support from respected authorities".[1] The paper also highlights the challenges in diagnosis of trigger points and if the pain is from other sources. The authors divide the injections into diagnostic/stabilization phase and therapeutic phase. In the diagnostic phase they state injections should be at least 1 week apart and not exceed 4 in 1 year. In therapeutic phase injections should be at least 2 months apart with >50% improvement lasting at least 6 weeks and not exceed 6 in a year.

Analysis of Evidence (Rationale for Determination)

TPI has been described as an overall safe and effective modality for the treatment of pain associated with MTrPs. There is moderate evidence to support the role of TPI for myofascial pain related to the presence of a trigger point. Nonetheless, there are no high quality RCTs or large observational studies to support this. Most studies that have investigated TPI are not blinded, lack controls, have standardized patient selection and assessment of improvement, have small sample sizes and lack of long-term follow-up.

Evidence suggests that early conservative measures, such as PT, may prevent the need for injections. Therefore, TPI are covered for refractory pain associated with trigger points that do 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. Additionally, a single diagnostic trigger point can play a role in diagnosis for myofascial pain and ACNES. There is evidence to support a role for treatment of headache if associated with the presence of a trigger point. The frequency of TPI is not well established in the literature, but most experts agree that the benefit should last at least 4 weeks and typically several months. There is a lack of evidence to support more frequent injections are effective and beneficial for management of myofascial pain. There is a paucity of evidence on long term use of TPI and most literature is limited to 2 to 8 weeks. Use of TPI beyond 6 months is not supported in current literature.

The use of TPI for other conditions other than myofascial pain including non-specific LBP, complex regional pain syndrome, widespread diffuse pain, chronic pain syndrome, fibromyalgia, pelvic floor myalgia, hemiplegic shoulder pain, lumbosacral canal stenosis, whiplash, non-malignant musculoskeletal pain, and neuropathic pain is not supported by evidence and therefore considered investigational.

There are some emerging studies that help define the ultrasound characteristics associated with trigger points and exploring a role of ultrasound guidance for TPI. However, there is not a clear standard for characterization of the trigger points and adjacent soft tissue by ultrasound. There is a paucity of evidence that ultrasound improves

effectiveness of TPI and a lack of evidence that it improves safety. Therefore, its use is considered investigational.

General Information

Associated Information

N/A

Sources of Information

N/A

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A59498 - Billing and Coding: Trigger Point Injections (TPI)

A59648 - Response to Comments: Trigger Point Injections (TPI)

LCDs

DL39671 - Trigger Point Injections (TPI)

Related National Coverage Documents

N/A

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