

Dry Needling

Optum Health Solutions Musculoskeletal (MSK) Utilization Management Policy Policy Number: 489

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Policy Statement

Dry needling (DN) therapy is considered unproven and not medically necessary for the treatment of neuromusculoskeletal disorders due to insufficient scientific evidence of effectiveness as either a single intervention or when combined with other treatment. According to Chys et al. (2023) high quality studies are needed to monitor midand long-term effects of DN as well as a standardization in DN protocols.

Purpose

This policy describes the position of Optum regarding the effectiveness and safety associated with the use of DN therapy.

Scope

The application of this policy is limited to those services and supplies best described as DN. Traditional acupuncture methods are excluded from the scope of this policy. This policy is not applicable to DN services when performed by auxiliary personnel acting under the direct supervision of a physician. This policy applies to all other in and out of network programs involving all provider types, where utilization review determinations about DN are rendered.

Description

DN is an invasive procedure that encompasses the superficial or deep insertion of needles without injectate into, alongside, or around nerves, muscles, or connective tissue for the management of pain and dysfunction in neuromusculoskeletal conditions; and does not follow the principles of the Traditional Chinese Medicine (Dunning, et al. 2014; Espejo, et al. 2017).

Background

DN, also known as trigger point DN or intramuscular stimulation, is a skilled intervention performed by physical therapists, physicians, and chiropractors to treat musculoskeletal pain related to myofascial trigger points (MTrPs). In this technique a fine sterile needle is utilized to penetrate the skin, subcutaneous tissues, fascia, and muscle, with the goal of deactivating TrPs without the use of an anesthetic. DN can be performed either superficially (to a depth of 5–10 mm) or in depth, with penetration of the involved muscle belly. In most deep DN procedures, the needle is then incrementally manipulated within the tissue to elicit a localized twitch response (LTR) and removed once the MTrP has been released (inactivated). Various treatment effects are being credited to DN, such as: decreased pain and muscle tension, improved range of motion, muscle strength, and coordination (Cagnie et al., 2013).

There is some emerging DN research, but the exact mechanisms of action of direct needling in the deactivation of trigger points are not yet unraveled (Cagnie et al., 2013). DN may cause a reduction in spontaneous electrical activity associated with trigger points that results in reducing the tension of the muscle fibers and modulates pain via stimulation of mechanoreceptors. DN may increase muscle blood flow and oxygenation by causing the release of a vasoactive substance. Pain may be mediated via the neurophysiological effects of DN on peripheral and central sensitization, and/or through the release of pain-inhibitory neurotransmitters. DN may also produce significant placebo analgesia due to the fact that patient expectancy of a beneficial effect and needling stimulate similar regions of the brain involved in pain perception.

DN is one of several different interventions used to treat MTrPs. In comparing different nonpharmacologic techniques, Charles et al. (2019) concluded the evidence for DN is not greater than placebo, while there is moderate evidence for manual therapy in myofascial pain treatment. The authors identified a number of limitations in the body of evidence regarding DN including small sample sizes, unclear methodologies, poor blinding, and lack of control groups (Charles et al., 2019).

Clinical Evidence

Dry Needling for General Musculoskeletal Disorders

The application of DN for general musculoskeletal disorders or myofascial pain syndromes (MPS) was investigated in the following systematic reviews. None of these studies was adequately supportive of DN as proven and medically necessary for the conditions evaluated.

Sánchez-Infante et al. (2021) sought to determine the short-, medium-, and long-term effectiveness of DN to MTrPs for the treatment of MSK pain. Forty-two RCTs (n=3642) were included in the analysis. Sixty-two percent of studies related to neck (16), shoulder (5), and knee (5) disorders. This meta-analysis found low-quality evidence of a large effect with pain favoring DN compared to no treatment, sham, and other therapies immediate to 72-hours post treatment, at 4- to 12-weeks and at 13- to 24-weeks follow up. There was moderate-quality evidence of a moderate effect on pain at one to three weeks favoring DN compared to inert and active controls. The findings comparing DN to placebo and to other interventions for long-term outcomes were each based on data from a single study. The overall quality of evidence most likely should be rated as very-low quality due to study limitations, imprecision, and inconsistences. The clinical relevance of the results was uncertain.

In a moderate quality systematic review of six (n=384) RCTs, Sousa-Filho et al. (2021) compared the effects on pain and disability of corticosteroid injection and DN for MSK conditions at short-, medium-, and long-term follow-up periods. At short- and medium-term, corticosteroid injection seemed to be superior to DN for reducing pain and disability in musculoskeletal conditions. At long-term, DN seemed to be more effective than corticosteroid injection. However, the quality of evidence behind these findings was judged to be very low. Most included studies were at high risk of bias, which likely affected the strength of the results. Most studies presented with small sample sizes. Blinding of participants and personnel and allocation concealment were the main sources of bias. The overall quality of the evidence was rated by the authors as very low for all outcomes and follow up periods. Although both interventions presented effects for pain at short-, medium-, and long-term follow-up in the assessed MSK conditions, these findings were supported by insufficient evidence. The reviewers suggested that corticosteroid injections and DN should be used with caution in the clinical settings.

Nuhmani et al. (2022) conducted a systematic review of seven RCTs to evaluate the effectiveness of DN for tendinopathy. The authors concluded DN showed improvement in short-term and medium-term relief of symptoms associated with tendinopathy. The majority of the studies assessed short-term effects of DN. High-quality RCTs that can assess long-term outcomes are needed.

Chys et al. (2022) performed a review of the effectiveness of DN for musculoskeletal pain. Thirty six systematic reviews without meta-analysis and 26 systematic reviews with meta-analysis were included. Reviews examined the entire body including neck, shoulder, temporomandibular joint region, elbow, lower extremity, low back pain, knee, and heel. Review included participants with acute and chronic musculoskeletal complaints. Results from the AMSTAR qualify appraisal show 2 studies as high overall score, 19 moderate, 11 low and 4 critically low. Results show there is a need for more research as evidence is limited. There is a need to standardize DN protocols. More studies are needed to evaluate mid- and long-term effects of DN across body systems.

Headache and Neurological Disorders

A single systematic review and meta-analysis of RCTs evaluated the effectiveness of DN on headaches and three systematic reviews investigated the effect of DN on muscle spasticity following stroke or in association with brain tumor. None of these studies was sufficiently supportive of DN as proven and medically necessary for the conditions evaluated.

Pourahmadi et al. (2021) included 11 RCTs (n=685) in a systematic review and meta-analysis of the effectiveness of DN for the treatment of individuals diagnosed with tension-type, cervicogenic, and migraine headache. In this highquality review, the authors found very low-quality evidence suggesting that DN is not statistically better for decreasing headache pain intensity but it is significantly more effective for improving related disability than other interventions in the short-term in patients with headaches. The authors noted the results of the review were inconclusive and should be interpreted with caution. Specifically, the results of the selected studies may be compromised by selection bias and overestimation of the treatment effect magnitude induced by inappropriate random-sequence generation and allocation concealment.

Núñez-Cortés et al. (2020) performed a systematic review of six RCTs (n=221) to determine the effectiveness of DN in the treatment of spasticity for individuals with stroke. In this moderate quality study, the reviewers determined the data was insufficient for drawing conclusions on the effects of DN. Although a significant decrease in spasticity was observed in most of the muscles evaluated, the certainty of the evidence was low. The effects were only evaluated in the short-term in all included studies and the sample size was small. These results should be taken with caution because the included studies were few and had different comparators. Additionally, the effects of DN were difficult to isolate in some of the studies and clinical relevance was uncertain. More RCTs are needed to cover aspects of biases found in the literature, in particular the blinding of participants and personnel.

Carusotto et al. (2021) systematically reviewed the effect of DN on spasticity in adults with neurological disorders (nine studies involved cerebrovascular accident and one case report described a patient with a brain tumor). The findings revealed low to moderate evidence in support of using DN to decrease spasticity in adults with neurological disorders, particularly in those with a history of stroke. Limitations included small sample sizes. Few trials included large samples, as five of the ten articles were case studies, which limits generalizability to the larger population of individuals with stroke. In addition, further research is required to analyze the long-term effects of DN on reducing spasticity. Overall, this review was judged to be of critically low quality, (i.e., the review has more than one critical flaw and should not be relied on to provide an accurate and comprehensive summary of the available studies). In addition to including six of ten very low-quality study designs (5 case reports and a small n=6 case series), three small RCTs and a quasi-experimental pre-/post-test design were also part of the review. The authors did not assess for risk of bias; instead, study quality was determined by the design. The "Results" section did not include any narrative or quantified information or analysis about the findings, including clinical relevance, of the studies.

A systematic review by Vazquez-Justes et al. (2022) of eight RCTs with a total of 577 patients with cervico-genic, tension type, migraine, and mixed-type headache found wide ranging quality of evidence. The authors were unable to perform a meta-analysis due to the heterogeneity of methodologies and the highly variable results. Until specific protocols to increase reproducibility and comparability of studies into DN are developed, it remains an unproven treatment option for headache.

Valencia-Chulián et al. (2020), included seven RCTs and nine nonrandomized studies of DN in a moderate quality systematic review summarizing the available evidence about the effectiveness of DN on spasticity, pain-related outcomes, and range-of-motion (ROM) in adults after stroke. The results showed the current evidence suggests a positive, but inconclusive effect of DN. Overall, a significant improvement of spasticity, pain-related outcomes, and ROM were demonstrated in the immediate and short-term after DN alone or combined with exercise training, electrical stimulation, or conventional physical therapy. The long-term effect of needling therapies on spasticity remains uncertain. Confident conclusions cannot be made due to lack of high-quality trials, the inclusion of low-quality studies (case reports and case series), the absence of measurable outcomes, inconsistent results, and uncertainty about the long-term efficacy of DN.

Kandeel et al. (2024) performed a systematic review and meta-analysis of DN as a treatment to improve disability and pain in subjects with varying types of headache disorders. Thirteen RCTs were included in the systematic review, and ten of those were included in the meta-analysis. After one and three months post intervention the authors found a reduction in headache intensity in the DN group compared to the control group. The meta-analysis displayed a significant reduction in the frequency of headaches in the DN group compared to the control group. The limitations of this review included differing therapies across the trials. Some trials used DN alone and others combined DN with manual manipulations, exercise, or mobilizations. Another limitation is a short follow-up period of three months, which may not be long enough to yield results of chronic or recurrent headache disorders. A secondary analysis of changes from baseline at different follow-up periods for outcome variables was unable to be performed due to the limited number and heterogeneity of the included trials. The authors concluded DN does not significantly affect disability scores when compared to the control group. DN was found to reduce headache frequency and intensity; however, the effectiveness in improving disability scores is inconclusive. Due to the considerable heterogeneity and biases in the included studies, the authors concluded further research is needed to refine the application of DN as a pain management strategy for chronic and recurrent headache conditions.

Orofacial Pain/Temporomandibular Joint Dysfunction (TMD)

Al-Moraissi et al. (2020) compared different needling techniques for the treatment of myofascial pain affecting the masticatory muscles in a network meta-analysis (NMA) derived from 10 RCTs with low-quality evidence. This NMA showed dry and sham needling produced comparable pain reduction that was clinically insignificant in the short-term (1-20 days). In longer-term follow-up, DN could not show any difference in post-treatment pain intensity compared to passive or active placebo. The effectiveness of DN analyzed in the NMA was not compared to other treatments such as occlusal splint therapy, manual therapy, or counselling therapy; thus, no conclusions could be drawn regarding any possible superiority of DN therapy over other treatments of TMD-M. Taken together, this NMA did not provide enough support for DN for the management of myogenous TMD.

Menéndez-Torre et al. (2023) performed a systematic review and NMA to evaluate the effectiveness of deep DN versus manual therapy in the treatment of myofascial TMD. Seventeen RCTs met the authors' inclusion criteria for qualitative analysis and eight were included in the NMA. A total of 867 patients were included in the systematic review; 258 received DN or were in the control groups where DN was evaluated. The other 609 patients were in treatment or control groups for manual therapy. The limitations of this review included a small number of trials, differences in the number of treatment sessions, and variability in DN and manual therapy techniques used. Many studies included in the meta-analysis consisted of good methodological quality, however, some showed a low level of methodological quality according to the PEDro scale (<6). The authors concluded when comparing DN to manual therapy to treat TMD there were no significant differences in reducing pain. Further research is needed through RCTs with larger sample sizes to evaluate the effects of DN for the treatment of TMD.

Regional Neck Pain

Four systematic reviews of RCTs with meta-analyses reported on the effects of DN for the treatment of myofascial trigger points (TrPs) related to neck and upper back pain. The quality of these reviews ranged from moderate to low. Taken in aggregate the evidence did not support DN for regional neck pain as proven or medically necessary.

Navarro-Santana et al. (2020) evaluated 28 RCTs in assessing the effect of DN alone as compared to sham needling, no intervention, or other physical interventions applied over TrPs related with neck pain symptoms. DN reduced pain immediately after (MD -1.53, 95% CI -2.29 to -0.76) and at short-term (MD -2.31, 95% CI -3.64 to -0.99) when compared with sham/placebo/waiting list/other form of DN and, also, at short-term (MD -0.51, 95% CI -0.95 to 0.06) compared with manual therapy. No differences in comparison with other physical therapy interventions were observed. An effect on pain-related disability at the short-term was found when comparing DN with sham/placebo/waiting list/other forms of DN (SMD -0.87, 95% CI -1.60 to -0.14) but not with manual therapy or other interventions. No between-treatment effect was observed in any outcome at mid-term. Low to moderate evidence suggests that DN can be effective for improving pain intensity and pain-related disability in individuals with neck pain symptoms associated with TrPs at the short-term. An appraisal of these findings found that in the short-term, compared to inert interventions and other forms of DN, TrP DN reduced pain; however, the effects ranged from small to trivial. For all other comparators, outcomes, and timing to follow up, DN demonstrated no clinically relevant differences. The authors judged all trials to be at a low risk of bias (RoB); however, 16 of 28 (57%) of the RCTs were judged to be unclear concerning allocation concealment and should be regarded as having a high RoB. This would likely reduce the confidence in the estimates of effect.

Navarro-Santan et al. (2021) examined the effects of DN against TrP injections (wet needling) applied to TrPs associated with neck pain. A total of seven RCTs (six in the meta-analysis) were included in this moderate quality review. The authors found low-quality evidence suggesting a superior effect of TrP injection (wet needling) for

decreasing pain of cervical muscle TrPs at short-term as compared to DN. No significant effects on other outcomes (very low-quality evidence) were observed.

Lew et al. (2021) compared the effectiveness of DN and manual therapy for reducing pain and pressure pain threshold (PPT) scores and improving function over the short to medium term (1-28 days) in patients with neck and upper back myofascial pain syndrome (MPS). This moderate quality review included six RCTs (n=241). The effect size of difference between DN and manual therapy was non-significant for VAS [d = 0.41 (-0.18, 0.99)], for PPT [d = 0.64 (-0.19, 1.47)], and for NDI [d = -0.66 (-1.33, 0.02)]. Both DN and manual therapy improve pain and function in the short to medium term. Neither is more superior than the other.

Fernández-De-Las-Peñas et al. (2021) evaluated the effects of combining DN with other physical therapy interventions versus the application of the other interventions or DN alone applied over TrPs associated with neck pain. DN combined with other physical therapy interventions did not exhibit a significant effect on pain immediately after treatment, compared to other physical therapies or DN-alone. Low-to-moderate evidence suggests a positive effect with the combination of DN with other interventions for improving pain intensity, pain-related disability, pressure pain thresholds, and cervical range of motion in people with neck pain associated with TrPs at short-term. The effects were not, however, clinically significant. These results were based on 5 of the 8 studies that did not provide adequate information of the assessment of allocation concealment. These studies should be viewed as having concerns about a high RoB. No mid- or long-term effects were observed. The heterogeneity and imprecision of the results of the trials were serious; therefore, current results should be taken with caution.

Upper Extremity Disorders

Two systematic reviews and meta-analyses of RCTs involving upper extremity disorders reported positive effects. Both reviews were rated as low quality primarily due to critical flaws associated with the assessment of RoB in the included studies and the impact on the interpretation of the results. Taking these limitations into consideration, neither of these studies was adequately supportive of DN as proven and medically necessary for the conditions evaluated.

Navarro-Santana et al. (2021) included six RCTs (n=381) to evaluate the effects of TrP DN alone or as an adjunct to other interventions on pain intensity and related disability in nontraumatic shoulder pain (subacromial pain syndrome, rotator cuff disorder, subacromial impingement syndrome, or nonspecific shoulder pain). The authors reported, moderate- to low-quality evidence is suggestive of positive effects of TrP DN for pain intensity (small effect) and pain-related disability (large effect), mostly at short term. DN had no statistical effect on pain in the mid- and long-terms. DN showed statistically significant effects on pain-related disability in the short- and long-terms; however, there was very serious heterogeneity (I2 >90%) between studies. Future clinical trials investigating long-term effects are needed. A critical appraisal of the study found two of six trials had a high RoB regarding allocation concealment. The overall RoB should be rated high for these studies. This would likely reduce confidence in the interpretation of the review and meta-analysis. Point estimates for disability outcomes in the short- and long-terms approximated a minimal clinically important effect (small effect); however, the Cls showed effects ranging from small to trivial.

Navarro-Santana et al. (2020) investigated the effect of DN alone or combined with other treatment interventions on pain, related-disability, pressure pain sensitivity, and strength in people with lateral epicondylalgia of musculoskeletal origin. Seven RCTs (n=320) were included in the analysis. Low to moderate evidence suggests a positive effect of DN for pain, pain-related disability, pressure pain sensitivity, and strength at short-term in patients with lateral epicondylalgia of musculoskeletal origin. The clinical relevance of these results is uncertain. These conclusions should be taken with caution due to the low-quality of the evidence (imprecision, heterogeneity) and that most studies investigated just short-term effects, with only one study investigating long-term (six months) effects.

Thoraco-Lumbo-Pelvic Disorders

Funk et al. (2020) conducted a scoping review to determine the current state of the literature regarding DN for patients with spine related disorders. Twenty-two studies (45.5% RCTs) were identified describing the application of DN in the thoraco-lumbo-pelvic region for nonspecific or myofascial diagnoses. Although scoping reviews do not critically appraise the quality of the literature, it appears most of the studies concluded that DN contributes to improved outcomes. Favorable outcomes were demonstrated regardless of diagnosis, number of treatments, or patient population. Future studies that look at strict diagnostic and inclusion criteria, detailed treatment methods and most applicable outcome measures would be helpful in filling the gaps in the literature as it relates to the effectiveness of DN for thoracolumbar-pelvic MSK pain.

Lower Extremity Disorders

Three systematic reviews and meta-analyses of RCTs and a single network meta-analysis described the effects of DN for painful disorders of the hip, knee, and foot.

Gazendam et al. (2021) performed an NMA to compare the efficacy of the various nonoperative treatments for greater trochanteric pain syndrome. For pain and function scores at one to three months follow-up DN demonstrated no significant reductions compared with no treatment.

Rahou-EI-Bachiri et al. (2021) systematically reviewed and meta-analyzed the evidence to evaluate the effect of trigger point DN alone or as an adjunct with other interventions on pain and related disability in people with knee pain (patellofemoral pain syndrome, osteoarthritis, post-surgical pain). The authors found low to moderate evidence suggesting a positive effect (ranging from trivial to large) of trigger point DN on pain and related disability in patellofemoral pain, but not knee osteoarthritis or post-surgery knee pain, at short-term. No significant effects were observed at mid- or long-term follow-ups. The risk of bias was generally low, but the heterogenicity and the imprecision of the results downgraded the level of evidence. The results of the current meta-analysis should be considered with caution. For pain outcomes at short-term, the overall mean difference was -0.85 (95% CI -1.35 to -0.34) points on a 0–10 numerical pain rate scale. This difference was not clinically significant. Four of the 10 studies should be rated as having a high RoB due to uncertainty about randomization sequencing and allocation concealment. Critical appraisal determined this review to be of low quality; it may not provide an accurate and comprehensive summary of the available studies.

In a critically low-quality review, Ughreja et al. (2021) appraised the evidence available on the effectiveness of different DN techniques in knee OA and analyze the short-term and long-term implications of these techniques on pain and function. The reviewers found moderate-quality evidence on the short-term effect of periosteal stimulation technique on pain and function in knee osteoarthritis. Future studies comparing the effects of various techniques of DN with different dosages and long-term follow up needs to be conducted. This review was judged to be of critically low quality due to multiple critical and non-critical flaws. The overall quality of the evidence for each outcome and follow-up period was not described. Domains critical to making qualitative judgments (consistency, directness, and precision) were omitted from the review. The inspection of the Cochrane RoB assessment showed that at least four of the nine studies should likely be judged as having a high RoB due to uncertainties about allocation concealment and the blinding of outcome assessors. The clinical relevance of the results was not well-described.

Llurda-Almuzara et al. (2021) systematically reviewed and quantitatively analyzed six RCTs (n=395) in evaluating the effects of DN over TrPs associated with plantar heel pain on pain intensity and related disability or function. The authors reported that moderate- to low-quality evidence suggests a positive effect of TrP DN for improving pain intensity and pain-related disability in the short term and long term, respectively, in patients with plantar heel pain of MSK origin. The RoB of the trials was generally low, but the heterogeneity of the results downgraded the level of evidence. The present results should be considered with caution because of the small number of trials. Critical appraisal showed this to be judged a low-quality systematic review. The overall quality of evidence was likely overstated. None of the studies was rated as having a high risk of bias, despite four of six studies not reporting appropriate allocation concealment. The between group differences for all outcomes and follow-up periods did not demonstrate clinically relevant results.

Coding Information

Note: The Current Procedural Terminology (CPT) codes listed in this policy may not be all inclusive and are for reference purposes only. The listing of a service code in this policy does not imply that the service described by the code is a covered or non-covered health service. Coverage is determined by the member's benefit document.

CPT [®] Code	Description
20560	Needle insertion(s) without injection(s); 1 or 2 muscle(s)
20561	Needle insertion(s) without injection(s); 3 or more muscle(s)

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Review and Approval History

Date	Action
04/30/2020	Original effective date
04/22/2021	Annual review and approval completed
05/03/2022	Annual review and approval complete; Literature review updated
06/29/2022	Updated legal entity name "OptumHealth Care Solutions, LLC." to *Optum™ Physical Health ("Optum") includes OptumHealth Care Solutions, LLC; ACN Group IPA of New York, Inc.; ACN Group IPA of California, Inc. d/b/a OptumHealth Physical Health of California; Managed Physical Network, Inc.; and OrthoNet Holdings, Inc. which includes OrthoNet New York IPA, Inc., OrthoNet West, Inc., OrthoNet, LLC, OrthoNet of the South, Inc.
04/27/2023	Annual review and approval completed; no significant changes made to the document. Updated contact email from <u>policy.inquiry@optumhealth.com</u> to <u>phpolicy_inquiry@optum.com</u> .
01/10/2024	Annual review; no substantive changes to clinical content. Document content transitioned to new policy template. Approved by Optum Clinical Guideline Advisory Committee.
04/25/2024	Annual review and approval by Optum Quality Improvement Committee.
01/08/2025	Annual review with no substantive changes. Approved by Optum Clinical Guideline Advisory Committee.
04/24/2025	Approved by Optum Quality Improvement Committee.