

Clinical UM Guideline

Subject: Acupuncture
Guideline #: CG-ANC-03
Status: Reviewed

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Description

This document addresses the use of acupuncture, which is the practice of stimulating specific points on the body using needles for the purpose of treating various health conditions. Manual manipulation or electrical stimulation of the needles may or may not be incorporated into therapy.

Note: For additional information regarding the use of auricular electroacupuncture, please see:

- DME.00011 Electrical Stimulation as a Treatment for Pain and Other Conditions: Surface and Percutaneous Devices

Clinical Indications

Medically Necessary:

The use of acupuncture is considered **medically necessary** for the treatment of nausea and vomiting associated with surgery, chemotherapy, or pregnancy.

The use of acupuncture is considered **medically necessary** for treatment of painful chronic osteoarthritis of the knee or of the hip that is significantly affecting daily activity.

Not Medically Necessary:

Acupuncture is considered **not medically necessary** when the criteria above are not met, and for any other indication.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

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97810	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97811	Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)
97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)

ICD-10 Procedure

8E0H30Z Acupuncture

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met, for the following procedure code, or when the code describes a procedure designated in the Clinical Indications section as not medically necessary.

ICD-10 Procedure

8E0H300 Acupuncture using anesthesia

ICD-10 Diagnosis

All diagnoses

Discussion/General Information

Acupuncture is one of the oldest, most commonly used medical procedures in the world. Acupuncture has become a very popular form of complementary and alternative therapy in the United States (U.S.), with an estimated 3.5 million adults or approximately 1.5% of the population, undergoing treatment annually (Zia, 2017).

The core procedure in acupuncture involves stimulation of specific points on the body, acupoints, by insertion of fine needles. Typical treatments involve insertion of 5 to 20 needles at various depths. Traditional acupuncturists judge the effectiveness of their insertion by looking for a physiologic reaction called “de qi.” This is perceived as an aching or throbbing by the recipient and by a tightening of tissue around the needle point felt by the therapist. Needles are typically left in for less than 1 hour. Acupuncturists may increase the stimulation by manipulating the needles (periodically twirling the needles) or by applying heat or electrical stimulation to the needles. An alternative technique includes using laser rather than needles to stimulate acupoints.

The exact mechanism by which acupuncture works is unknown. Traditional Chinese acupuncture theory is based on the premise that a form of energy called “qi” travels along prescribed pathways or meridians within the body. This theory proposes that qi is responsible for maintaining good health by providing homeostatic regulation of vital body

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function. Excess or deficiency in the flow of qi is thought to result in disease. Stimulation of specific acupoints along the body's meridians can restore balance in the qi and return the individual to health.

Scientists have studied acupuncture for decades and have proposed other theories more in keeping with biomedical concepts. Studies in the 1970s and 1980s suggest that acupuncture may work by modifying nerve function at the spinal and supraspinal levels. Roles have been suggested for cytokines, endorphins, and neurotransmitters but the physiologic mechanism of action is not known. It has also been proposed that acupuncture stimulates a variety of central and peripheral physiological effects, although the relationship between these mechanisms and the observed responses are not understood at this time (Zia, 2017).

There is objective evidence that acupuncture stimulation results in specific identifiable patterns in brain activity. Yan and colleagues (2005) performed functional MRI of the brain while stimulating real versus sham acupoints in the Liv3 and Liv4 vicinity. Stimulation at the acupoints resulted in activation and deactivation in specific brain areas in distinct response patterns. Stimulation of the acupoints showed a greater activation and deactivation response than stimulation of sham points. The authors noted these results were consistent with previously reported results.

A central point of debate regarding the efficacy of acupuncture is related to the results of many trials which include sham acupuncture controls and do not report significant differences between real acupuncture and sham acupuncture. Sham acupuncture control groups are frequently incorporated into studies to account for a strong placebo effect observed in many pain studies. There are several sham techniques used, including non-penetrating needles, sites not recognized as valid acupuncture sites, or sham devices such as nonfunctioning laser or electrical stimulation devices. Other studies have used needles on valid acupuncture sites at superficial depths or eliminated manipulation of the needles. The wide variation of methods used as controls may account for or contribute to the conflicting results associated with many acupuncture studies.

Some authors have proposed that these sham acupuncture controls are not inert and may produce some therapeutic benefits (Furlan, 2012; Linde, 2009; Lund, 2006; Moffet, 2009; Zia, 2017). Alternatively, Linde and colleagues (2009) proposed that sham acupuncture may exhibit a larger than usual placebo effect or biases may exist which researchers have not accounted for. The 2010 Agency for Healthcare Research and Quality (AHRQ) Evidence Report/Technology Assessment on complementary and alternative therapies for back pain noted that trials using sham acupuncture tended to produce results that were negative or statistically non-significant compared to those using other types of placebo. The authors noted it appears that different types of controls result in different effects. Other studies have also supported the concept that sham acupuncture may produce additional benefits over other controls (Hrobjartsson, 2010; Kaptchuk, 2006).

Linde and colleagues (2010) conducted a meta-analysis evaluating potential non-specific effects associated with acupuncture or sham acupuncture treatment. This review included 32 trials and 5754 individuals. In a comparison of sham acupuncture to no acupuncture, the authors reported an additional moderate, nonspecific effect in the sham acupuncture group over the no acupuncture group. However, the authors did note that trials with a large sample size and a low risk of bias showed less positive results.

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The diversity of sham acupuncture techniques is only one of the inherent issues related to evaluation of acupuncture in clinical trials. Acupuncture therapy is not standardized, and techniques can include traditional Chinese or western style ideologies. Some studies required practitioners to deliver a standardized protocol, while others allow practitioners to develop individualized plans based upon presenting symptoms. Trials used different devices, including needles, laser, manual stimulation or electrical stimulation. There are no standards such as duration of therapy or number of treatments. In most cases, while participants and assessors may be blinded, it is difficult to blind the practitioner. Also, the concept of acupuncture may elicit strong reactions among study populations, either positive or negative. Finally, outcomes primarily rely on subjective, self-reported data. All of these variables, coupled with the relatively unknown mechanism of action of acupuncture make the interpretation of the evidence challenging.

The National Center for Complementary and Integrative Health (NCCIH, 2014) notes that millions of Americans use acupuncture every year, and that studies suggest acupuncture may be beneficial for chronic pain such as low back or neck pain, osteoarthritis (OA), or to reduce frequency of tension type headaches or migraines. However, other factors, such as expectation and beliefs may play a role in the positive outcomes of acupuncture treatment for pain.

Cervical Spine and Neck Pain

The 2010 AHRQ Evidence Report/Technology Assessment on complementary and alternative therapies for back pain noted that six trials included an acupuncture arm. The majority of studies which were specific to acupuncture evaluated neck pain that had been present for greater than 3 months. Acupuncture for the treatment of neck pain not associated with whiplash-associated disorders was categorized as “likely helpful or worth considering,” along with commonly used modalities such as manipulation, mobilization, supervised exercises, massage, low level laser therapy and analgesics. The authors noted that none of the modalities appeared to be superior in the short or long-term. There was inconsistent evidence that acupuncture was superior to sham.

Trinh and colleagues (2016) included 27 trials on a variety of chronic neck pain conditions including myofascial neck pain, pain due to arthritic changes, non-specific neck pain, radicular neck pain and mechanical neck pain. Studies evaluating whiplash-associated disorders (acute and chronic) were also included. The authors concluded there was moderate quality evidence that acupuncture was more effective than some sham therapies or delayed therapy. There was limited evidence that acupuncture is more effective than sham acupuncture or inactive treatment in the short-term. The authors reported the effect does not appear to be sustainable in the long term. The authors noted that while quality of the studies is improved over the last review, there were few large trials which provided high-quality evidence.

A systematic review and meta-analysis by Fu and colleagues (2009) identified 14 studies for inclusion in an assessment of the effectiveness and efficacy of acupuncture to treat neck pain. A total of nine separate meta-analyses were performed. Meta-analysis was completed only when statistically significant heterogeneity was absent. A majority of the meta-analyses (7/9) reported statistically significant results favoring acupuncture over other interventions. These favorable results included short-term effectiveness, effectiveness of acupuncture on range of motion (ROM), long-term effectiveness, short-term effectiveness of acupuncture based on dichotomous data, comparison with sham acupuncture, comparison with sham TENS and comparison with sham laser. In

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addition to the meta-analysis, a systematic review was completed. The majority of the studies (9/14) reported a positive result. Several studies (4/14) were reported as showing a negative result and one study was mixed. Studies were defined as positive when acupuncture resulted in a statistically better outcome than control in the primary outcome. Studies were defined as negative in all other cases (acupuncture was similar to or worse than control, or acupuncture was better but result was statistically insignificant). Quality seemed to be a factor in the outcomes of the studies. Of the nine studies reporting positive outcomes, eight of those studies were considered high quality. Among the four studies reporting negative outcomes, two of them were considered low quality. The authors noted the evidence supporting the effectiveness was stronger than the evidence against acupuncture's effectiveness.

Furlan and associates (2012) performed a meta-analysis and systematic review of studies of common complementary and alternative medicine (CAM) treatments of neck and low back pain, published between 1978 and 2009. Out of the 147 randomized and 5 nonrandomized studies included in the report, 24 were specific to neck pain and acupuncture. The authors reported that there was no significant difference between acupuncture and sham based upon two meta-analyses. In addition, there was inconsistent evidence comparing acupuncture to pain medication, no treatment, or spinal manipulation. Acupuncture was found to be significantly better than massage. Due to the wide variety of controls, there were a limited number of trials included in each category. Similar to previous reviews, the authors report that the level of evidence was low to moderate.

A single-blinded, two-arm pilot randomized controlled trial (RCT) by Liang and colleagues (2011) compared acupuncture to sham acupuncture in 190 individuals with recurrent or chronic neck pain or stiffness. Both groups received treatment 3 times a week for 2 weeks. Both therapies were similar with the exception of the sham therapy using needles 1 cm lateral to recognized acupuncture points at minimal depths and no manipulation. Outcomes were evaluated using both a clinical-reported outcome (CRO) determined by physicians and a patient-reported outcome (PRO). Both groups improved significantly from baseline in the PRO assessment with the acupuncture group significantly improved over sham. The CRO assessment also reported acupuncture significantly favored over sham during the intervention and the 3 month follow-up period. The results of this study are inconsistent with previous studies which generally found little difference between acupuncture and sham.

In a study comparing electroacupuncture and sham electroacupuncture, Cameron and colleagues (2013) included 124 individuals with chronic or subacute whiplash injuries. Both groups showed an improvement in pain intensity at 3 months; this improvement was not sustained at 6 months in the sham group. At both 3 and 6 months, the acupuncture group showed significant improvements over sham in the visual analogue score (VAS).

Other conservative therapies typically used to treat neck pain include muscle relaxants, manual therapy, physical therapy, behavioral therapy, traction, cervical collar, electromagnetic therapy, massage or proprioceptive exercises. There has been limited, high quality evidence that support the effectiveness of these modalities as well (Borenstein, 2007, Hurwitz, 2009, Trinh, 2006). In general, studies evaluating conservative treatments of neck pain have shown little or no clinical benefit from these therapies, even in those considered to have substantive benefits. This reinforces the concept that chronic pain is a complex condition which requires a multifaceted treatment plan. While the evidence may be promising, further studies are needed to support that acupuncture is a valid, effective treatment of cervical spine/neck pain.

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Low Back Pain (LBP)

Back pain can be classified in several different ways, including location and symptom duration. Acute LBP is typically limited to pain lasting less than 4 weeks. Subacute LBP can last from 4 to 12 weeks while LBP lasting longer than 12 weeks is defined as chronic (Qaseem, 2017). While acute back pain only lasts a few days or weeks and resolves spontaneously, chronic LBP may require additional treatment. A fact sheet developed by the National Institute of Neurological Disorders and Stroke notes that while the evidence regarding potential benefits of acupuncture to treat acute LBP is conflicting, acupuncture is moderately effective in the treatment of chronic LBP. Multiple studies assessing the utility of acupuncture to treat chronic LBP using a variety of modalities as comparators have been published. Much like studies evaluating acupuncture for other types of pain, the results have varied.

Cherkin and colleagues (2009) conducted a four-arm RCT comparing acupuncture to usual care for lower back pain. A total of 638 individuals with mechanical LBP were randomized to receive individualized acupuncture, standardized acupuncture, simulated acupuncture or usual care. At 8 weeks, all acupuncture groups were significantly improved in dysfunction and pain bothersomeness scores compared to the usual care group ($p < 0.001$), although there were no significant differences between the acupuncture groups. These significant differences were sustained for the dysfunction score in the individualized and standardized acupuncture groups throughout the 52 week follow-up.

In a single-blinded multicenter RCT, Cho and colleagues (2013) compared acupuncture to non-penetrating sham acupuncture in 130 subjects with chronic LBP. While both groups showed improvement in the visual analogue score (VAS) for bothersomeness, the acupuncture group reported significantly improved scores compared to the sham group (3.36 vs. 2.27) at 8 weeks. The authors note that this study appears to be the first study for LBP performed using non-penetrating needles as sham. Further studies using this sham technique would be helpful to support these findings.

Several systemic reviews and meta-analysis comparing acupuncture to a variety of other treatments, including sham, placebo, no treatment or other active treatments, concluded that acupuncture is more effective than no treatment or provides additional benefit when combined with usual care for LBP. However, in general, the evidence regarding the other controls was conflicting and inconclusive (Furlan, 2005; Hutchinson, 2012; Kong, 2020; Lam, 2013; Manheimer, 2005; Rubinstein, 2010; Yuan, 2015).

A 2017 clinical practice guideline on LBP developed by the American College of Physicians (ACP) includes new recommendations regarding acute and chronic LBP. Although the ACP has graded these as strong recommendations, these recommendations are based upon low or moderate quality evidence. These recommendations note:

Given that most patients with acute or subacute low back pain improve over time regardless of treatment, clinicians and patients should select nonpharmacologic treatment with superficial heat (moderate-quality evidence), massage, acupuncture, or spinal manipulation (low-quality evidence). If pharmacologic treatment is desired, clinicians and patients should select nonsteroidal anti-

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inflammatory drugs or skeletal muscle relaxants (moderate-quality evidence). (Grade: strong recommendation).

For patients with chronic low back pain, clinicians and patients should initially select nonpharmacologic treatment with exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction (moderate-quality evidence), tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, or spinal manipulation (low-quality evidence). (Grade: strong recommendation).

The 2010 AHRQ Evidence Report/Technology Assessment on complementary and alternative therapies for back pain notes there was low to moderate-grade evidence that acupuncture was better than sham acupuncture in improved outcomes immediately following treatment for LBP. There was moderate evidence that acupuncture for LBP was better than no treatment for pain, disability, function, range of motion, and well-being. In comparison to other therapies, acupuncture did not differ from pain medication, but was better than physical therapy for pain and disability in the immediate treatment phase.

In a double-blind RCT, Glazov and associates (2014) compared two levels of laser acupuncture (low and high) to sham laser acupuncture in 144 individuals with chronic LBP. While all groups reported reductions in pain at all assessment points, there was no significant difference between any of the groups. Weiss and colleagues (2013) reported on the results of a multicenter, double-blind RCT comparing acupuncture to sham acupuncture using non-penetrating needles. A total of 143 participants being treated in an inpatient rehabilitation program for LBP lasting more than 6 months were randomized to receive either usual treatment only or usual treatment with acupuncture throughout the 21 day program. The results were mixed; while there were significant differences favoring acupuncture while sitting or carrying heavier loads, there was no difference or a non-significant difference while carrying lighter loads or walking.

There have been a myriad of studies evaluating the effect of acupuncture on LBP. The results of these studies, and the studies themselves have been disappointing. Overall, the evidence for the use of acupuncture to treat LBP is conflicting and weak to moderate. As the quality of studies improves, the results may provide better quality evidence on acupuncture as a treatment of lower back pain.

Headaches/Migraines

There have been numerous acupuncture trials involving individuals with headaches and migraines. In a large RCT, Jena and colleagues (2008) assessed the efficacy of acupuncture in individuals with a non-specific diagnosis of headache. Of the 15,056 individuals enrolled in this study, 47.8% of the subjects were categorized as having tension-type headaches and 46.3% were categorized as having migraines. The remainder did not fall into either category. Individuals were randomized to either the treatment group who immediately received to up to 15 sessions of acupuncture over 3 months (n=1613) or to the control group who did not receive acupuncture treatment for the first 3 months (n=1569). The study also included a large nonrandomized arm comprised of individuals who declined randomization (n=11,874). These individuals received acupuncture immediately. The treatment group included both the randomized and nonrandomized groups who received acupuncture

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immediately. At 3 months, there was a significant decrease in the number of days with headache per month favoring the treatment group versus control (8.4 ± 7.2 to 4.7 ± 5.6 and 8.1 ± 6.8 to 7.5 ± 6.3 , respectively). The proportion of responders, those who reported at least a 50% reduction in headache frequency, significantly favored the treatment group (44.9% migraine; 46.7% tension-type) versus control (19.6% migraine; 17.5% tension-type). At 6 months, the migraines and tension-type headaches were not reported separately; however, the combined data indicates the improvement noted at 3 months was sustained. After 3 months, the group that initially received no treatment was treated with acupuncture. At 6 months, this group then showed improved headache frequency and there were no significant differences between the control group and the treatment group. While the results of this study were promising, there was a considerable potential for bias. The study was not blinded and participants were allowed to self-select treatments. In addition, rather than use headache diaries, individuals responded to monthly questionnaires about the number of headaches in the last month, which could result in inaccuracies from faulty memory.

Sun and Gan (2008) published the results of a meta-analysis conducted to assess the efficacy of acupuncture in treating chronic headaches. The meta-analysis included 31 clinical trials; 10 studies for tension-type headaches, 17 studies for migraines and 4 studies with mixed (chronic) headaches. The authors used the response rate, defined as at least a 33% improvement in headache symptoms, as the primary outcome. In a comparison of 14 acupuncture-versus-sham trials, 53% (510/961) of acupuncture and 45% (373/829) of sham individuals were classified as responders. A subgroup analysis showed there was a significant difference in the tension-type group compared to control, but not a significant difference for migraine versus control. In an analysis of seven trials comparing acupuncture and medication, the acupuncture group showed a significantly higher response rate than the medication group (62% and 45%, respectively). This significant difference remained at 1-year follow-up. The authors noted that the medication group had a higher dropout rate than the acupuncture group and theorized this could have been related to medication side effects. Heterogeneity in control groups did not allow for meta-analysis amongst the four trials comparing acupuncture to other non-pharmacological modalities, but the study results showed the other modalities, including physiotherapy and massage, were significantly better than acupuncture in the treatment of chronic headaches and migraines. In the two studies which included a waiting list arm, the acupuncture groups reported better outcomes for headache frequency and intensity outcomes. In addition, the quality of the trials was an issue; many studies had inadequate blinding and variables such as outcomes and observation periods were not defined. This is consistent with other reviews which have noted that the quality of older studies was low.

In an updated Cochrane review, Linde and colleagues (2016a) evaluated 22 migraine trials ($n=4985$). These trials included sham acupuncture, prophylactic drug treatment and no prophylactic treatment or routine care only as controls for acupuncture. The authors note that the evidence does suggest there is a small effect of acupuncture over sham acupuncture. This particular comparison included 12 trials ($n=1646$) and moderate quality evidence with considerable heterogeneity. In addition, the authors noted that in the three largest trials which were described as unambiguously adequately blinded trials, the effects of acupuncture over sham were significantly smaller. In addition, the authors concluded that acupuncture is non-inferior to prophylactic drug treatment. This comparison included five trials, four of these trials were unblinded and two of the trials reported relevant attrition in the drug treatment group. Due to additional concerns regarding study interventions or data reliability, only three studies were included in the meta-analysis. The authors noted that further studies are needed stating “it is unclear to what extent the effects of acupuncture are mainly mediated by context variables and generalized (i.e. not specific to traditional

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points) needling effects, and what contribution correct point location makes.” In addition, the establishment of standards regarding the reporting of outcome data would be beneficial in facilitating future analysis.

Several trials have focused on evaluating the use of acupuncture to treat migraines. Similar to previous studies, the results are generally mixed. In a 2017 RCT by Zhao and associates, 249 individuals with migraines without aura were randomized to receive true acupuncture (TA), sham acupuncture (SA) or be placed on a waiting list (WL) to receive acupuncture following the 24 weeks study period. Individuals received either true or sham acupuncture 5 days a week for 4 weeks and were then followed for an additional 20 weeks. At the primary endpoint, the change in frequency of migraine attacks at 16 weeks after randomization, the frequency decreased by 3.2 in the TA group, 2.1 in the SA group and 1.4 in the WL group. The differences between both the TA group compared to the SA group (1.1 attacks, 95% confidence interval [CI], 0.4-1.9; $p=0.002$) and the TA group compared to the WL group (1.8 attacks, 95% CI, 1.1 to 2.5, $p<0.001$) were significant. There were several limitations to this study including no comparison to standard migraine prophylaxis, substandard acupoint treatment and lack of blinding in the WL group. The authors noted further pragmatic studies are needed.

In 2011, Wang and colleagues reported on a multicenter, double-dummy, single-blinded RCT comparing acupuncture plus drug placebo to sham plus flunarizine in 140 individuals with migraines. Both groups reported a significant improvement in all outcome measurements from baseline through the 4 month follow-up period. There was a significant difference favoring acupuncture in the primary outcome of responder rates after 4 weeks and 16 weeks. A larger study by Li and colleagues (2012) included 476 individuals with migraines who were randomized into 1 of 4 arms, real acupuncture (3 arms) or sham acupuncture (using penetrating needles at non acupuncture recognized sites). While all 3 acupuncture groups showed significant improvements in the primary outcome (number of days with migraine) from baseline through follow-up, there were no significant differences between the groups. When the acupuncture groups were compared to the sham group, there were significant differences beginning at week 4 and continuing through week 16. The authors note this effect was clinically minor. In both studies, sham acupuncture consisted of penetrating needles at non-recognized acupuncture sites. These studies provided evidence supporting that acupuncture is superior to sham. However, since these studies did not include an arm with other controls, such as no treatment, it is unclear whether both acupuncture and sham provided therapeutic benefits.

A prospective RCT by Facco and colleagues (2013) compared acupuncture to a prophylactic dosage of valproic acid ($n=100$) in those with a diagnosis of migraines. Both groups reported significant improvements throughout the 6 month study period in the Midas Index score. There were no significant differences between the groups. However, 47.8% of the valproic acid group reported adverse events versus no reported adverse events in the acupuncture group.

A three-arm, partially blinded trial by Melchart and colleagues (2005) involving 270 participants with episodic or chronic tension type headaches randomized participants to acupuncture, minimal acupuncture or waiting list groups. The minimal acupuncture intervention consisted of the same treatment as acupuncture except for the use of fewer needles and the elimination of needle manipulation. Researchers labeled minimal acupuncture as a sham intervention, although they noted it is likely not a physiologically inert placebo. Both the acupuncture and the minimal acupuncture groups received 12 sessions over 8 weeks while the waiting list group received acupuncture at the end of 3 months. At 12 weeks, there was a significant improvement in the number of headache days per

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month from baseline in both acupuncture groups; this improvement persisted throughout the 6 month follow-up period. There was no significant difference between the acupuncture groups. At 6 months, improvement in number of headache days in the waiting list group who received delayed acupuncture treatment after 3 months was similar to the acupuncture groups. The authors noted that the overall current body of evidence regarding acupuncture and tension headaches was conflicting.

Endres and colleagues (2007) compared acupuncture to sham acupuncture in the prophylactic treatment of tension type headaches in 409 individuals. At 6 months follow-up, both groups reported improvement in the response rate (defined as the number of individuals with a greater than 50% reduction in number of headaches per 4 weeks). The acupuncture group reported a higher non-significant response rate compared to sham, 33% compared to 27%. It was noted that the researchers did categorize a group of individuals as non-responders, regardless of reported response, if certain study criteria were not followed; the exact number of these individuals was not reported. An additional analysis was done based solely on individuals reported response. Based upon this analysis, there was a significant difference in the response rate favoring acupuncture (66% vs. 55%, respectively).

A 2008 meta-analysis of RCTs by Davis and colleagues used the data from eight studies to evaluate the efficacy and safety of acupuncture in treating tension-type headaches. In a pooled analysis of four trials, the acupuncture group reported significantly improved outcomes in headache days per month compared to sham in long-term follow-up (8.21 vs. 9.5; $p=0.003$). The acupuncture group also reported a significant reduction in headache intensity compared to sham in long-term follow-up (weighted mean difference [WMD] -3.64; 95% CI, -6.55 to -0.73; $p=0.01$). The authors concluded that acupuncture has a small effect on headache days per month and headache intensity compared to sham.

A Cochrane review by Linde and colleagues (2016b) evaluated 12 trials with a total of 2349 participants with episodic or chronic tension-type headaches. Of the 12 trials included, two trials compared acupuncture to routine care or treatment of acute headaches, seven trials compared acupuncture to sham acupuncture, and four trials compared acupuncture with other interventions. The proportion of individuals who reported at least a 50% decrease in headache frequency was higher in the acupuncture group versus the routine care or treatment of acute headaches group (48% versus 19%). The proportion of individuals who reported at least a 50% decrease in headache frequency was also higher in the acupuncture group (51% versus 43%). Acupuncture was not found to be superior in those trials which compared other therapies and was found to be inferior for some outcomes. The authors noted that while the results suggest acupuncture may be an effective treatment of frequent episodic or chronic tension-type headaches, further studies are needed.

Hao and colleagues (2013) acknowledged the conflicting outcomes associated with acupuncture studies for tension-type headaches and attempted to find an explanation for this. The authors included five studies considered of high methodological quality, which used a variety of acupuncture techniques. A meta-analysis of the five studies did not show a statistically significant difference between real and sham acupuncture outcomes for headache days; however, high heterogeneity was noted. Subgroup analysis of specific features of the treatments revealed some significant differences between sham and real acupuncture when heterogeneity was reduced by removing trials which had drastically different clinical features. Following subgroup analysis, the authors identified mode of acupuncture stimulation, duration of needle retention, and frequency of treatment as potential contributing factors to results showing a lack of difference between sham and real acupuncture. The authors noted that adequacy of

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acupuncture treatment is equally as important as methodological quality, and recommended that a standard acupuncture treatment plan is developed and accepted. This study appears to be one of the first of its kind, and additional research is needed in this area to confirm the author's findings. Since that time, there appears to be no additional studies published on the use of acupuncture for tension headaches to confirm or contradict this study.

The evidence for acupuncture in the treatment of tension headaches is promising, but studies have been small and of limited quality. Further high quality studies would be helpful to clarify potential benefits. In addition, the development of treatment standards and clinical trial standards would allow for the maximization of treatment.

Nausea and vomiting

In November 1997, a National Institutes of Health Consensus Development Panel (NIHCDP) addressed the use of acupuncture in a consensus statement. The authors concluded that the evidence in adults clearly showed that needle acupuncture is efficacious in treating nausea secondary to surgery or chemotherapy, and likely effective for nausea of pregnancy as well. There have been several studies which support the use of acupuncture to treat nausea and vomiting (Liodden, 2011; Rithirangsiroj, 2015).

Osteoarthritis

The American College of Rheumatology Recommendations for Management of Osteoarthritis of the Hand, Hip, and Knee (2019) note that the use of acupuncture is conditionally recommended for individuals with OA of the knee, hip or hand, commenting:

Although a large number of trials have addressed the use of acupuncture for OA, its efficacy remains a subject of controversy. Issues related to the use of appropriate blinding, the validity of sham controls, sample size, effect size, and prior expectations have arisen with regard to this literature.

The American College of Rheumatology Recommendations for the Use of Nonpharmacologic and Pharmacologic Therapies in Osteoarthritis of the Hand, Hip, and Knee (2012) note that the use of traditional Chinese acupuncture for individuals with OA of the knee is a conditional recommendation, and commented:

These modalities are conditionally recommended only when the patient with knee osteoarthritis (OA) has chronic moderate to severe pain and is a candidate for total knee arthroplasty but either is unwilling to undergo the procedure, has comorbid medical conditions, or is taking concomitant medications that lead to a relative or absolute contraindication to surgery or a decision by the surgeon not to recommend the procedure.

A large meta-analysis of acupuncture and other physical treatments for the relief of pain due to OA of the knee was conducted by Corbett (2013). This study found that in a sensitivity analysis of satisfactory and good quality studies, most studies were of acupuncture (11 trials) or muscle-strengthening exercise (9 trials); both interventions were statistically significantly better than standard care, with acupuncture being statistically significantly better than muscle-strengthening exercise (standardized mean difference: 0.49, 95% credible interval 0.00-0.98). The authors concluded that their meta-analysis indicated that acupuncture can be considered as one of the more effective physical treatments for alleviating OA knee pain in the short-term.

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Stener-Victorin and colleagues (2004) conducted a study of 45 subjects with hip OA awaiting hip replacement surgery that were randomized to receive hydrotherapy, electro-acupuncture, or education. While positive results of both electroacupuncture and hydrotherapy were reported compared to no changes in the education group, the small numbers in each group (n=15) require confirmation in larger studies. Nevertheless, this study provides well-designed, if limited, evidence of the safety and efficacy of acupuncture for this indication.

A large meta-analysis conducted by Vickers and colleagues (2012) addressed the use of acupuncture for a variety of chronic pain conditions, including headache, shoulder, musculoskeletal pain, and osteoarthritis. The analysis included data from 17,922 individuals from 31 RCTs for which the authors could determine sufficient blinding. The report describes a large variation across trials with regard to the type of sham acupuncture used, as well as in other treatments subjects were allowed to have. Nonetheless, the authors report that acupuncture was significantly better compared to controls for all analyses. The authors conclude that acupuncture has a significant benefit, but that aspects of treatment traditionally considered crucial to treatment (such as correct location and depth of insertion) were not vital in outcomes. In 2014, Vickers and Linde updated the evidence search and concluded that the additional 7 published studies are very small or results are similar to the meta-analytic estimates and would not change the previously reported findings. In 2018, Vickers and associates updated their meta-analysis to include 10 recently published studies. A total of 39 trials with 20,827 individuals were included in the review which evaluated four separate areas: chronic headache, nonspecific musculoskeletal pain, osteoarthritis and shoulder pain. Outcome measurements varied from one month to 24 months. The meta-analysis continues to be marked by a large amount of heterogeneity, which the authors noted was larger than would be expected by chance.

Cancer

The National Comprehensive Cancer Network® (NCCN) Clinical Practice Guideline (CPG) in Oncology (NCCN Guidelines®, 2021) recommends acupuncture along with pharmacologic therapy as needed. Acupuncture can be used as part of a comprehensive, integrative approach to treating cancer related pain. This recommendation is based on 2A category of evidence and uniform consensus. One small RCT (n=58) reporting on acupuncture for pain control and dysfunction following neck dissection was cited for this recommendation. In general, there is a lack of high-quality RCTs supporting the efficacy of acupuncture in treating cancer pain.

In 2018, Hershman and colleagues reported on the results of a multi-center RCT which evaluated the effectiveness of acupuncture in reducing aromatase inhibitor-related joint pain. Women with early-stage breast cancer taking a third-generation aromatase inhibitor for more than 30 days with the intent to continue for at least one additional year and reported a score of 3 or greater on the Brief Pain Inventory-Short Form (BPI-SF) which started or increased since aromatase inhibitor therapy was initiated were included. Participants were randomized to three groups: true acupuncture (n=226), sham acupuncture (n=59), or a wait list control group (n=57). Treatment in the sham acupuncture group consisted of minimally invasive shallow needles inserted at non-acupuncture points. Both true and sham acupuncture received treatment twice per week for 6 weeks followed by one session per week for 6 additional weeks. The waitlist group received no acupuncture or other intervention for 24 weeks. The primary endpoint was the BPI worst pain (BPI WP) score at 6 weeks of treatment, with a clinically meaningful change of 2 points on the scale. The BPI WP at 6 weeks was 2.05 points lower in the true acupuncture group, 1.07 points lower in the sham acupuncture group, and 0.99 points lower for the waitlist control group. The differences

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in scores between the true acupuncture group compared to either the sham acupuncture group or the waitlist group were significant. At 12 weeks, the true acupuncture group still had a significant improvement in the BPI WP score over the waitlist group, but reported statistically significant scores in only the average pain component of the BPI WP score. However, there was no significant improvement in worst pain, pain interference, pain severity, or worst stiffness. Individuals in the true acupuncture group were more likely to believe they were receiving true acupuncture when compared to those in the sham acupuncture group, but the intervention effect for BPI WP did not differ between those who believed compared to those who did not believe they were receiving true acupuncture. However, this finding does raise concerns regarding the effectiveness of the masking procedure. While this study reported reduced pain in women receiving acupuncture treatment while being treated with third-generation aromatase inhibitors in the short term, additional studies of longer duration would be needed to evaluate the clinical importance of this finding.

Other indications

The American Academy of Otolaryngology- Head and Neck Surgery (AAO-HNS) released clinical practice guidelines on allergic rhinitis (2015) and tinnitus (2014) which include references to acupuncture. The allergic rhinitis (AR) clinical practice guideline notes “Clinicians may offer acupuncture, or refer to a clinician who can offer acupuncture, for patients with AR who are interested in nonpharmacologic therapy.” This recommendation is rated as an option and is not based upon strong evidence, but rather on RCTs with limitations, and observational studies.

The clinical practice guideline for tinnitus notes “No recommendation can be made regarding the effect of acupuncture in patients with persistent bothersome tinnitus.” This recommendation is based upon the poor quality trials available and acupuncture’s anticipated benefit and harm balance.

The Cochrane Library includes numerous reviews on the use of acupuncture for treatment of the following conditions: epilepsy, insomnia, restless leg syndrome, asthma, depression, stroke, uterine fibroids, smoking cessation, traumatic brain injury, and other indications (Chen, 2010; Cheong, 2013; Law, 2013; Li, 2011; Lim, 2016; Manheimer, 2012; Paley, 2011; Smith, 2018, 2011; Walshe, 2012; Wei, 2011; White, 2014; Wong, 2013; Zhang, 2010; Zhu, 2011). The majority of these reviews concluded there was inadequate scientific data to determine whether acupuncture was superior to placebo.

Zhao and associates (2019) evaluated the efficacy of acupuncture as an adjunct to antianginal therapy in the treatment of chronic stable angina in multicenter RCT conducted in China. Individuals were randomized to 4 groups: acupoints on the disease-affected meridian (DAM), acupuncture on the acupoints on the non-affected meridian (NAM), sham acupuncture (SA), and no acupuncture (wait list [WL]). Individuals with at least a 3 month history of stable angina with attacks occurring at least twice a week were included. Treatment in the DAM group (n=99) consisted of bilateral acupoints considered in a relevant area along with the induction of *deqi* as well as electrical stimulation. Individuals in the NAM group (n=99) received the same treatment on bilateral acupoints considered to be non- relevant. The SA group (n=101) consisted of insertion of needles at sham points as well as electrical stimulation, however, without the induction of *deqi* sensation. All active group participants received acupuncture treatments three times a week for 4 weeks. The WL group (n=99) did not receive acupuncture. All participants received antianginal therapy for 16 weeks. The primary outcome was change in frequency of angina

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attacks from baseline to 16 weeks as self-reported in diaries. The frequency of angina attacks was significantly lower in the DAM group compared to the other groups at each evaluation from week 4 through week 16. The frequency decreased by 7.96 attacks in the DAM group, 3.89 attacks in the NAM group, by 2.78 attacks in the SA group, and by 2.33 attacks in the WL group (baseline 13.31). While the results of this study are promising, studies which evaluate the efficacy of acupuncture in decreasing angina pain in the longer term would be relevant for a chronic disease. In addition, the literature does not indicate that the effectiveness of the masking process was assessed. Individual beliefs regarding what type of treatment they were receiving (sham vs true) may have an impact regarding their perceptions of efficacy, particularly in a population which may have higher expectations of relief from acupuncture treatment than might be found in the United States.

In the past, experts were concerned that the use of acupuncture with or without electrical stimulation may interfere with the function of medical devices that are highly sensitive to disruptions in the body's electrical field. However, no peer-reviewed publications regarding safety concerns related to the use of acupuncture in those with electrical sensing devices were located after a comprehensive review of the literature. In the 2005 American College of Cardiology (ACC) Expert Consensus Document on the role of complementary medicine combined with cardiovascular medicine, the authors report that the overall risk of adverse events is small and they do not voice any specific concerns about devices which are sensitive to electrical activity in the heart, such as pacemakers or automatic implantable cardiac defibrillators (AICDs). In addition, for individuals with a bleeding disorder, acupuncture may pose a bleeding risk. Use of acupuncture in this population should be used with caution.

Overall, the use of RCTs to evaluate the potential benefit of acupuncture has increased over the years. The quality of many of the studies generally remains low or moderate. This is based on multiple factors including high levels of heterogeneity, risk of bias and lack of blinding (Kobler, 2021; Li, 2020; Mu, 2020; Su, 2020). In a meta-analysis comprised of RCTs evaluating pharmacologic and non-pharmacologic treatments of chronic low back pain, Kobler and associates (2021) noted that the benefit of acupuncture disappeared with higher-quality studies.

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History

Status	Date	Action
Reviewed	08/12/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion and References sections.
Reviewed	08/13/2020	MPTAC review. Updated Discussion and References sections. Reformatted Coding section.
Reviewed	08/22/2019	MPTAC review. Updated Discussion and References sections.
Reviewed	09/13/2018	MPTAC review. Updated Rationale, Discussion and References sections.
	05/02/2018	The document header wording updated from “Current Effective Date” to “Publish Date.”
Reviewed	08/03/2017	MPTAC review. Updated Discussion and References sections.
Reviewed	11/03/2016	MPTAC review. Updated Discussion and References sections.
Revised	11/05/2015	MPTAC review. Removed criteria regarding pacemaker or automatic implantable cardioverter-defibrillator (AICD) from the Clinical Indications for nausea and vomiting and osteoarthritis of the hip or knee. Removed criteria regarding

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		radiographic evidence and absence of other causes of arthritis from the Clinical Indications for osteoarthritis of the hip or knee. Updated Description, Discussion, References and Index sections. Removed ICD-9 codes from Coding section.
Reviewed	08/06/2015	MPTAC review. Updated References section.
Reviewed	08/14/2014	MPTAC review. Updated References section.
Reviewed	08/08/2013	MPTAC review.
Reviewed	08/09/2012	MPTAC review. Updated Rationale and References sections. Updated Coding section to remove revenue codes 0374 and 2101.
Reviewed	08/18/2011	MPTAC review. Updated Coding, Rationale and References sections.
Reviewed	08/19/2010	MPTAC review.
Revised	08/27/2009	MPTAC review. Deleted “bleeding disorders” from medically necessary position statements. Updated Background and References sections. Updated Coding section with 10/01/2009 ICD-9 changes.
Reviewed	08/28/2008	MPTAC review.
Reviewed	08/23/2007	MPTAC review. Clarified position statement regarding the use of acupuncture in the presence of bleeding disorders, AICDs, or pacemakers. Updated Coding and References sections.
New	09/14/2006	MPTAC review. Transferred content from ANC.00002 Acupuncture to new Clinical Guideline CG-ANC-03 Acupuncture. Not Medically Necessary indications in new guideline previously considered Investigational/Not Medically Necessary. Coding updated; removed CPT 97780, 97781 deleted 12/31/04.
Revised	06/08/2006	MPTAC review. Added limits to use of acupuncture for individuals with pacemakers, AICDs, or bleeding disorders; added the use of acupuncture for the treatment of chronic osteoarthritis of the hip and knee as medically necessary; revised Rationale and References sections.
	11/17/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	09/22/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc. WellPoint Health Networks, Inc.	06/17/2003	ANC.00002 No prior document	Acupuncture

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