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## Medical Policy



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**\*Current Policy Effective Date: 7/1/23**  
(See policy history boxes for previous effective dates)

### **Title: Acupuncture**

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#### **Description/Background**

Acupuncture describes a group of procedures intended to stimulate anatomical points with the goal of inducing physiologic changes. Acupuncture has been proposed for the treatment of pain of various etiologies as well as other non-pain disorders, including the alleviation of opioid dependence withdrawal symptoms.

Acupuncture is a traditional form of Chinese medical treatment that has been practiced for over 2000 years. It involves piercing the skin with needles at specific body sites. The placement of needles into the skin is dictated by the location of “meridians” or channels, which are thought to represent patterns of energy, called Qi (Chi) that flow through the human body. According to traditional Chinese philosophy, illness occurs when the energy flow is blocked or unbalanced, and acupuncture is a way to influence chi and restore balance. Another tenet of this philosophy is that all disorders are associated with specific points on the body, on or below the skin surface.

Proposed physiologic explanations of acupuncture’s mechanism of action include an analgesic effect from the release of endorphins or hormones (e.g., cortisol, oxytocin), a biomechanical effect, and/or an electromagnetic effect.

There are 361 classical acupuncture points located along 14 meridians.(1) Different points are stimulated depending on the condition treated. In addition to traditional Chinese acupuncture, there are a number of more modern styles of acupuncture, including Korean and Japanese acupuncture. Modern acupuncture techniques can involve stimulation of additional non-meridian acupuncture points. Acupuncture is sometimes used along with manual pressure, heat (moxibustion), or electrical stimulation (electroacupuncture). Acupuncture treatment can vary by style and by practitioner and is personalized to the patient. Thus, patients with the same condition may be treated at different acupuncture points.

Scientific study of acupuncture is challenging due to the multifactorial nature of the intervention, variability in practice, and individualization of treatment. There has been much discussion in the literature on the ideal control condition for studying acupuncture. Ideally, any control condition should be able to help distinguish between specific effects of the treatment and nonspecific placebo effects related to factors such as patient expectations and beliefs and patient-provider therapeutic relationships. A complicating factor in the selection of a control treatment is that it is not clear whether all four components (i.e., the acupuncture needles, the target location defined by traditional Chinese medicine, the depth of insertion, and the stimulation by the inserted needle) are necessary for efficacy. Sham acupuncture interventions vary; they can involve, superficial insertion of needles or insertion of needles at the “wrong” points, for example. A consensus recommendation on clinical trials of acupuncture, published by White et al (2002), recommends distinguishing between a penetrating and a nonpenetrating sham control.(2)

Dry needling refers to a procedure in which a fine needle is inserted into the skin and muscle at a site of myofascial pain. See “Dry Needling of Trigger Points for Myofascial Pain” for more information.

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## Regulatory Status

The U.S. Food and Drug Administration (FDA) cleared acupuncture needles for marketing but does not regulate the practice of acupuncture.(3)

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## Medical Policy Statement

The safety and effectiveness of acupuncture has been established for a narrow range of medical conditions. It may be considered a useful therapeutic option when specific indications are met.

Other uses of acupuncture are considered experimental/investigational. While acupuncture may be considered safe, it has not been demonstrated to be more effective than conventional treatment for these other (multiple) proposed uses.

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## Inclusionary and Exclusionary Guidelines

### **Inclusions:**

Acupuncture (manual or electroacupuncture) may be considered medically necessary when an individual has been referred by their treating physician to a licensed acupuncturist for the treatment of any of the following:

- Chronic<sup>a</sup> non-specific low back pain
- Chronic<sup>a</sup> neck pain
- Episodic migraines
- Tension-type headaches
- Prevention of chemotherapy associated nausea and vomiting
- Pregnancy induced nausea or vomiting

<sup>a</sup> *Unresolved pain which has been persistent for at least 12 weeks*

**Exclusions:**

- Acupuncture point injection
  - Dry needling
  - Acupuncture for/when:
    - Opioid reduction or cessation in opiate users
    - Maintenance care (therapeutic goals of the treatment program have been reached)
    - No further significant progress has been achieved or is reasonably expected to occur
    - Other uses not mentioned in inclusions
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**CPT/HCPCS Level II Codes** *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

**Established codes:**

97810	97811	97813	97814	99201	99202
99203	99204	99211	99212	99213	99214

**Other codes (investigational, not medically necessary, etc.):**

20560	20561
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*\*Note: Code(s) may be covered by some contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.*

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**Rationale**

Anecdotal experience suggests that many individuals have a beneficial response to acupuncture. However, clinical outcomes research suggests that a larger proportion of individuals may not respond. The NIH has issued a consensus statement that discussed the efficacy and role of acupuncture in the treatment of various conditions, the biologic effects of acupuncture, the issues that need to be addressed so that acupuncture is appropriately incorporated into the health care system, and the directions for future research. The report notes that high-quality research in which acupuncture is compared with placebo or sham acupuncture is scant. The consensus statement calls attention to the recommendation that safeguards be in place to protect patients. Although adverse events are rare, they do occur, and some have been life-threatening. If a patient is receiving care from a physician and an acupuncturist, both practitioners should be informed. Communication between physicians and acupuncturists is emphasized. Panelists determined that numerous rigorous, randomized, controlled trials are needed for a variety of conditions regarding patterns of use, the efficacy of acupuncture, whether different theoretical bases for acupuncture result in different treatment outcomes, and, in the absence of scientific proof that meridians or acupuncture points exist, fixed acupuncture points should be investigated.(47)

**Clinical Context and Test Purpose**

The purpose of acupuncture is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with:

- Episodic migraines

- Tension type headaches
- Pain involving:
  - Low Back (chronic)
  - Neck (chronic)
  - Shoulder
  - Lateral elbow
  - Spinal cord injury (chronic)
  - Endometriosis
  - Rheumatoid arthritis
  - Non-cancer
- Nausea and vomiting including:
  - Hyperemesis gravidarum
  - Chemotherapy induced
  - Post op
- Opioid dependence
- Opiate addiction

The use of acupuncture point injection therapy.

The questions addressed in this evidence review are:

- Does the use of acupuncture improve the net health outcome for individuals with the diagnosis/symptoms being reviewed.
- Does acupuncture point injection therapy improve the net health outcomes of individuals.

The following PICO's were used to select literature to inform this review.

### **Populations**

The relevant population of interest are individuals with the diagnosis/symptoms/modality being discussed.

### **Interventions**

The therapies being considered are acupuncture and acupuncture point injection therapy.

### **Comparators**

Therapies that are currently being used to treat the diagnosis/symptoms/modality being discussed such as: medication therapy and other conservative therapies.

### **Outcomes**

The general outcomes of interest are symptoms, functional outcomes, medication use, tapering, counseling, other replacement therapies, and treatment-related morbidity including:

- Pain reduction in:
  - Migraine frequency
  - Tension-type headaches
  - Chronic low back pain
  - Chronic neck pain
  - Shoulder pain
  - Lateral elbow pain
  - Chronic pain in pts with spinal cord injuries
  - Endometriosis pain
  - Rheumatoid arthritis pain

- Non-cancer pain
- Reduction in nausea and vomiting related to:
  - Hyperemesis gravidarum
  - Chemotherapy induced n/v
  - Post-op n/v
- Opioid dependence
- Opioid addiction
- Added benefit/lack thereof regarding use of acupuncture point injection therapy

Follow-up over months is of interest to relevant outcomes for each diagnosis/modality.

### **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

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

## **PAIN RELATED CONDITIONS**

### ***Episodic Migraine***

#### **Review of Evidence**

##### **Systematic Reviews**

A Cochrane review by Linde et al (2016) included RCTs at least 8 weeks in duration that compared acupuncture with sham acupuncture, prophylactic medication treatment, and/or no acupuncture in patients with episodic migraines.(4) Trials focusing on chronic migraine were excluded. The primary efficacy outcome was headache frequency, and the secondary outcome was the proportion of responders (at least 50% reduction in migraine frequency). Twenty-one RCTs met reviewers' selection criteria; all were parallel-group trials. Fifteen trials included a sham acupuncture control group, five had a prophylactic medication group, and five had a no acupuncture group (several trials had >2 arms). Acupuncture interventions were heterogeneous (e.g., number of sessions, length of sessions, standardized vs individualized placement of needles). Risk of bias was assessed in 13 sham-controlled trials; all attempted blinding and the overall risk of bias was considered to be low. None of the three trials comparing acupuncture and prophylactic medication that were included in meta-analyses were blinded, and dropout rates were high in two; overall, these trials were considered at considerable risk of bias. Key outcomes for the acupuncture vs sham acupuncture and acupuncture vs prophylactic medication analyses are shown in Table 1.

**Table 1. Key Outcomes for Episodic Migraine**

Outcomes	Follow-Up	No. Trials	Results		
			Treatment Effect	95% CI	p
<b>Acupuncture vs sham</b>					
Reduction in headache frequency	End of treatment	12	SMD = -0.18	-0.28 to -0.08	<0.001
	End of follow-up	10	SMD = -0.19	-0.30 to -0.09	<0.001
Response <sup>a</sup>	End of treatment	14	RR=1.24	1.11 to 1.36	<0.001
	End of follow-up	11	RR=1.25	1.13 to 1.39	0.004
<b>Acupuncture vs prophylactic medication</b>					
Reduction in headache frequency	End of treatment	3	SMD = -0.25	-0.39 to -0.10	0.001
	End of follow-up	3	SMD = -0.13	-0.28 to 0.01	0.08
Response	End of treatment	3	RR=1.24	1.08 to 1.44	0.003
	End of follow-up	3	RR=1.11	0.97 to 1.26	0.12

CI: confidence interval; RR: relative risk ratio; SMD: standardized mean difference.

<sup>a</sup>At least a 50% reduction in headache frequency.

In a pooled analysis comparing acupuncture with sham acupuncture, acupuncture had statistically significant effects on reduction of headache frequency and on response rates at both follow-ups. Reviewers considered the differences between groups to be small but clinically relevant. Fewer trials compared acupuncture and prophylactic medication. There was a significantly greater effect of acupuncture on reduction in headache frequency and response rates at the end of treatment but not at the end of follow-up.

Giovanardi et al (2020) completed a more recent systematic review and meta-analysis that evaluated the efficacy and safety of acupuncture versus pharmacological prophylaxis of migraine.(5) The review included 9 RCTs, the majority of which were discussed in the Cochrane review by Linde et al (2016). Results were similar with the authors concluding that acupuncture is mildly more effective and much safer than medication for the prophylaxis of migraine.

### Randomized Controlled Trials

Zhao et al (2017) conducted an RCT in three clinical centers in China to investigate the long-term effects of true acupuncture for migraine prophylaxis compared with sham acupuncture and being placed in a waiting-list control group.(6) Adults (18-65 years) with migraines without aura (n=245) were recruited from hospital outpatient departments and randomized to true acupuncture (n=83), sham acupuncture (n=80), and waiting-list (n=82) groups. Participants in the true acupuncture and sham acupuncture groups were blinded and received treatment five days a week for 4 weeks for a total of 20 sessions. Participants in the waiting-list group did not receive acupuncture but were informed that 20 sessions of acupuncture would be provided free of charge at the end of the trial. The change in the frequency of migraine attacks from baseline to week 16, as recorded inpatient diaries, was the primary outcome of the study. Secondary outcome measures included the number of migraine days, average headache severity, and medication intake every four weeks within 24 weeks. The mean change in frequency of migraine attacks differed significantly among the 3 groups at 16 weeks after randomization (p<0.001); the mean (standard deviation) frequency of attacks decreased in the true acupuncture group by 3.2 (2.1), in the sham acupuncture group by 2.1 (2.5), and the

waiting-list group by 1.4 (2.5); a greater reduction was observed in the true acupuncture than in the sham acupuncture group (difference of 1.1 attacks; 95% confidence interval [CI], 0.4 to 1.9;  $p=0.002$ ) and in the acupuncture vs waiting-list group (difference of 1.8 attacks; 95%CI, 1.1 to 2.5;  $p<0.001$ ). Sham acupuncture did not differ statistically from the waiting-list group (difference of 0.7 attacks; 95%CI, -0.1 to 1.4;  $p=0.07$ ).

### **Nonrandomized Comparative Studies**

Tastan et al (2018) published a comparative study of 3 treatments for migraines.(7) Ninety patients were included in the study and assigned to the acupuncture group (n=30), hypnotherapy group (n=30), or pharmacotherapy group (n=30; acetaminophen 650 mg or 1300 mg was used). Visual analog scale (VAS) and Migraine Disability Assessment scores decreased significantly for all 3 groups after three months ( $p<0.001$ ). For acupuncture and hypnotherapy, the percentage reduction in the VAS score was significantly higher than pharmacotherapy at 3 months ( $p<0.001$ ). Also, the percentage reduction for the Migraine Disability Assessment score was significantly higher for acupuncture and hypnotherapy than pharmacotherapy ( $p=0.007$  and  $p=0.002$ , respectively). The study was limited by its short follow-up time, lack of blinding, and lack of assessment of patients' demographic characteristics.

### **Section Summary: Episodic Migraine**

Pooled analyses of 15 sham-controlled trials on episodic migraine in a Cochrane review found significantly better outcomes with acupuncture. The magnitude of difference between acupuncture and sham acupuncture was small but considered clinically relevant. Similar findings were observed in a more recent RCT. A limitation of the sham-controlled literature is the variability in intervention protocols, which makes it difficult to draw conclusions about any specific approach to acupuncture. Pooled analyses of trials on acupuncture vs medication found a significant benefit of acupuncture at the end of treatment but not at the end of the follow-up period.

### **Tension-Type Headache**

#### **Systematic Reviews**

Another Cochrane review by Linde et al (2016) included RCTs at least 8 weeks in duration that compared acupuncture with sham acupuncture, standard care, or another comparator intervention in adults with episodic or chronic tension-type headache.(8) Interventions had to include at least six acupuncture sessions given at least once a week. The primary outcome measure was treatment response (at least 50% reduction in headache frequency) three to four months after randomization. Outcomes at eight weeks or less, five to six months, and more than six months after randomization were reviewed. Secondary outcomes included number of headache days, headache intensity, frequency of analgesic use, and headache scores.

Twelve RCTs met reviewers' inclusion criteria; all were parallel-group trials. Seven RCTs included a sham control group, and all were blinded. Control groups in other trials were physical therapy (3 studies), relaxation or massage (2 studies), and delayed acupuncture treatment (similar to a no treatment group). One study had more than 2 arms. The trials that did not use a sham control were considered at major risk of bias. Key outcomes are shown in Table 2.

**Table 2. Key Outcomes for Tension-Type Headache**

Outcomes	Follow-Up	No. Trials	Results
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			<i>Treatment Effect</i>	<i>95% CI</i>	<i>p</i>
<b>Acupuncture vs sham</b>					
Response <sup>a</sup>	Up to 2 mo after randomization	4	RR=1.26	1.10 to 1.45	<0.001
	3-4 mo after randomization	4	RR=1.27	1.00 to 1.48	0.003
	5-6 mo after randomization	4	RR=1.17	1.02 to 1.35	0.02
No. headache days	Up to 2 mo after randomization	4	MD = -1.49	-2.58 to -0.39	0.008
	3-4 mo after randomization	4	MD = -1.62	-2.69 to -0.54	0.003
	5-6 mo after randomization	4	MD = -1.51	-2.59 to -0.43	0.006

CI: confidence interval; MD: mean difference; RR: relative risk ratio.

<sup>a</sup> At least a 50% reduction in headache frequency.

In a pooled analysis comparing acupuncture with sham acupuncture, acupuncture has statistically significant effects on treatment response (the primary outcome) and the number of headache days at all time points for which data were available. There were insufficient data for pooling on other secondary outcome measures. Cochrane reviewers did not comment on whether the differences between groups in pooled analyses were clinically significant.

Kolokotsios et al (2021) conducted a systematic review and meta-analysis of 15 trials (N=1267) that evaluated the effectiveness of acupuncture on headache intensity and frequency in patients with tension-type headache.(9) Of the included studies, only 4 met the inclusion criteria for the meta-analysis (n=557). The average number of acupuncture sessions per patient in these studies was 9 and the average duration of treatment was 5.5 weeks. Results revealed that headache frequency after the last treatment was not significantly lower in the acupuncture group versus the placebo/sham group (mean difference, -1.53; 95% CI, -4.73 to 1.67); however, there was a trend toward improvement in the frequency of headaches in the long term (p=.06). Additionally, the VAS score was slightly reduced in the acupuncture group as compared with control after the last treatment (mean difference, -0.29; 95% CI, -1.21 to 0.62; p=.53). Long term, acupuncture was associated with a significant reduction in VAS (mean difference, -0.41; 95% CI, -0.72 to -0.10; p=.009).

### **Section Summary: Tension-Type Headache**

Pooled analyses in a Cochrane review on acupuncture for tension-type headache consistently found statistically significant benefits of acupuncture compared with sham acupuncture. These findings were specific to 5 to 6 months of follow-up; there were insufficient data to conduct analyses of longer-term follow-up (i.e., > 6 months). Reviewers did not comment on the clinical significance of the findings.

### **Chronic Low Back Pain**

Lam et al (2013) conducted a meta-analysis of random control trials to evaluate the effectiveness of acupuncture on non-specific chronic low back pain.(10) Thirty-two studies were included in the systematic review, of which 25 studies presented relevant data for the meta-analysis. Acupuncture had a clinically meaningful reduction in levels of self-reported pain (mean difference =-16.76 [95% confidence interval, -33.33 to -0.19], P = 0.05, I = 90%) when compared with sham, and improved function (standard mean difference =-0.94 [95% confidence interval, -1.41 to -0.47], P < 0.00, I = 78%) when compared with no treatment immediately postintervention. Levels of function also clinically improved when acupuncture in addition to usual care, or electroacupuncture was compared with usual care alone. When acupuncture was compared with medications (NSAIDs, muscle relaxants, and analgesics) and usual care, there were statistically significant differences between the control and the



intervention groups. This systematic review demonstrated that acupuncture may have a favorable effect on self-reported pain and functional limitations on nonspecific chronic low back pain.

Xu et al (2013) performed a meta-analysis comparing acupuncture with sham acupuncture and other treatments.(11) Overall, 2678 patients were identified from thirteen randomized controlled trials. Clinical outcomes were evaluated by pain intensity, disability, spinal flexion, and quality of life. Compared with no treatment, acupuncture achieved better outcomes in terms of pain relief, disability recovery and better quality of life.

Manheimer et al (2005) performed a meta-analysis to assess the effectiveness of acupuncture in the treatment of low back pain.(12) Thirty-three randomized control trials comparing needle acupuncture with sham acupuncture, other sham treatments, no additional treatment or another active treatment for patients with low back pain were identified. For the primary outcome of short-term relief of chronic pain, the meta-analyses showed that acupuncture is significantly more effective than sham treatment (standardized mean difference, 0.54 [95% CI, 0.35 to 0.73]; 7 trials) and no additional treatment (standardized mean difference, 0.69 [CI, 0.40 to 0.98]; 8 trials). For patients with acute low back pain, data are sparse and inconclusive.

Liu et al (2019) investigated the impact of acupuncture in the treatment of sciatica.(13) Fifty-seven patients with sciatica, aged 35-70 years, were recruited and screened. Thirty-one participants were randomly assigned to receive "low-dose" manual acupuncture (MAL) (n= 15) or "high-dose" manual acupuncture (MAH) (n=16). The acupuncture treatment was administered twice weekly for four weeks. The primary outcome was the visual analog scale (VAS) score at baseline and after four weeks of acupuncture treatment. Secondary outcomes included the Roland Disability Questionnaire for Sciatica (RDQS), the Sciatica Bothersomeness Index (SBI), and the World Health Organization Quality of Life in the Brief Edition (WHOQOL-BREF) scores at baseline and after 4 weeks of acupuncture treatment. Thirty patients completed the study. For all patients, acupuncture achieved significant improvement in the VAS ( $5.48 \pm 2.0$ ,  $p < 0.001$ ), RDQS ( $3.18 \pm 2.83$ ,  $p = 0.004$ ), and SBI ( $2.85 \pm 3.23$ ,  $p = 0.008$ ) scores, but not in the WHOQOL-BREF scores. In the between-group analysis, the assessed scales showed no significant differences between the MAL and MAH groups. However, based on the level of chronicity, the MAH group demonstrated greater improvement in the outcomes and a significant benefit in the physical subscale of the WHOQOL-BREF ( $p < 0.05$ ). Results of this pilot study indicate that acupuncture is safe and may effectively relieve symptoms and disability in patients with non-acute sciatica.

The American College of Physicians (ACP) reported on a systematic review (2017) of noninvasive pharmacologic and nonpharmacologic treatments for low back pain.(48) The review included randomized controlled trials and systematic reviews published through April 2015. As a result, the ACP released guidelines (based on moderate quality evidence) which encouraged patients to work with their providers to select nonpharmacological modalities including acupuncture.

### ***Section Summary: Chronic Low Back Pain***

Three meta-analyses and a consensus guideline have been identified which support the use of acupuncture for chronic low back pain. Acupuncture has been found to be more effective for pain relief and functional improvement in chronic low-back pain than no treatment or sham treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

### **Chronic Neck Pain**

Vickers et al (2012) conducted a systematic meta-analysis of random control trials (RCTs) of acupuncture for chronic pain which included back and neck pain. Twenty-nine RCTs (n=17,922) were used to determine efficacy. Acupuncture was found to be superior to both sham and no-acupuncture control for each pain condition (P < .001 for all comparisons). Patients receiving acupuncture had less pain, with a score of 0.23 (95% CI, 0.13-0.33) standard deviations lower than the sham control for back and neck pain. The effect size in comparison to the no-acupuncture control was 0.55 (95% CI, 0.51-0.58) standard deviation. Authors concluded that acupuncture is effective for the treatment of chronic neck pain and is therefore a reasonable referral option. Significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo. However, these differences are relatively modest. However, acupuncture is an important contributor to effective pain management.(49)

Trinh et al (2006) evaluated the effects of acupuncture for chronic neck pain. Ten trials were found that examined acupuncture treatments for chronic neck pain. Authors concluded that for chronic mechanical neck disorders, there was moderate evidence that acupuncture was more effective for pain relief than some types of sham controls and limited evidence that acupuncture was more effective than massage at short-term follow-up. For chronic neck disorders with radicular symptoms, there was moderate evidence that acupuncture was more effective than a wait-list control at short-term follow-up.(56)

### **Pain-Related Conditions: Other Pain-Related Conditions**

Increasingly acupuncture is being used for overall wellness across a spectrum of disease processes. Most of the existing research on acupuncture is directed toward pain management which relies on subjective evidence to determine outcomes. The National Institutes of Health (2007) indicate that although acupuncture may be a reasonable option for people with chronic pain to consider, clinical guidelines are inconsistent in recommendations about acupuncture.(50) A literature search indicated that clinical studies of acupuncture are often inconclusive (51) and high quality research (acupuncture compared to placebo or sham) is scant.(47) Clinical trials were found to differ in terms of technique, the number for (1) acupuncture points, (2) sessions, and (3) duration of the sessions. Debates were prominent regarding the use of acupuncture due to multiple barriers which included: the difficulty involved in designing the trials (double blinding is almost impossible); many studies lacked controls, randomization and/or consistent outcome measures; or reported a small population. No standardized method was used for sham acupuncture (e.g., no consensus on needle placement, number of needles, length of session). Multiple sham vs acupuncture studies showed no difference in outcomes, indicating that a placebo effect may have been occurring when placing needles under the semblance of acupuncture.

### **Systematic Reviews**

Various Cochrane reviews have found insufficient evidence to demonstrate that acupuncture is effective for treating shoulder pain,(14) lateral elbow pain,(15) carpal tunnel syndrome,(16,17), hip osteoarthritis,(18) cancer pain in adults,(19) chronic pain in patients with spinal cord injury,(20) pain in endometriosis,(21) and pain in rheumatoid arthritis.(22) These reviews identified few RCTs, low quality RCTs, and/or lack of significantly better outcomes with acupuncture than with control conditions.

He et al (2020) published an additional systematic review and meta-analysis on acupuncture for cancer pain.(23) Seven sham-controlled trials were identified, and a meta-analysis of data from these trials found that true acupuncture reduced pain more than sham acupuncture (mean difference, -1.38 points; 95% CI, -2.13 to -0.64). However, heterogeneity was high ( $I^2 = 81\%$ ), and the clinical significance of the difference between groups is uncertain. No analyses were performed to compare true acupuncture to other active interventions.

Huang et al (2021) conducted a systematic review and meta-analysis that analyzed the efficacy and safety of acupuncture for the treatment of chronic spinal pain.(24) The review included 22 RCTs with 2588 patients who had chronic neck pain, chronic low back pain, or sciatica for more than 3 months. Any type of acupuncture therapy was included in the systematic review/meta-analysis such as traditional acupuncture, electro-acupuncture, fire needling, auricular acupuncture, abdominal acupuncture, warm acupuncture, and bee venom acupuncture. Control interventions included usual care, no treatment, sham acupuncture, placebo, or pharmacologic therapies. The primary outcome was pain intensity. Overall, standard acupuncture was utilized in 16 studies, the duration of interventions ranged from 1 treatment to 8 weeks of treatment, and follow-up ranged from 2 weeks to 1 year after the final treatment. A pooled analysis revealed acupuncture to significantly improve chronic spinal pain as compared to sham acupuncture (weighted mean difference [WMD], -12.05; 95%CI, -15.86 to -8.24), usual care (WMD, -9.57; 95% CI, -13.48 to -9.44), and no treatment (WMD, -17.1; 95% CI, -24.83 to -9.37). Acupuncture was also associated with improvement in physical functioning at short-, intermediate-, and long-term follow-up. Of note, the meta-analysis had significant heterogeneity, which may have been due to the differing forms of acupuncture utilized and quality of included studies. Additionally, the majority of included trials had only short- and intermediate-term follow-up data and a relatively small sample size. Blinding of treatment was also difficult due to the nature of acupuncture therapy.

### **Randomized Controlled Trials**

Bahrami-Taghanaki et al (2020) performed an RCT in 49 patients comparing acupuncture to celecoxib treatment for carpal tunnel syndrome.(25) Although patients receiving acupuncture had lower pain and symptom scores than patients receiving celecoxib both immediately postintervention and at the 3-month follow-up visit, these differences were unlikely to be clinically significant. Additionally, the trial was unblinded, so outcomes may have been influenced by knowledge of group assignment.

### ***Section Summary: Other Pain-Related Conditions***

One meta-analysis of 7 RCTs in cancer pain found better pain reduction with true acupuncture versus sham acupuncture, but heterogeneity was high and the difference between groups was of questionable clinical significance. Another meta-analysis of 22 RCTs in patients with chronic spinal pain found acupuncture therapy to significantly improve pain as compared to sham acupuncture, usual care, or no treatment; however, included studies were of small sample size, had significant heterogeneity, and had blinding concerns. One RCT in carpal tunnel syndrome reported that patients receiving acupuncture had lower pain and symptom scores than patients receiving celecoxib both immediately postintervention and at the 3-month follow-up visit; however, these differences were unlikely to be clinically significant. Additionally, the trial was unblinded, so outcomes may have been influenced by knowledge of group assignment.

## **NAUSEA AND VOMITING**

## Review of Evidence

### *Hyperemesis Gravidarum and Pregnancy Induced Nausea and Vomiting*

#### **Systematic Reviews**

A Cochrane review by Boelig et al (2018) assessed interventions including metoclopramide, ondansetron, vitamin B6, acupuncture, promethazine, corticosteroids, and placebo for treating hyperemesis gravidarum. In comparing the efficacy of pharmaceuticals, vitamin B6, and acupuncture, no clear superiority was proven for one modality over another. In a study of 81 participants, acupuncture proved to be as efficient as metoclopramide regarding symptom relief of nausea and vomiting. Authors concluded that other factors such as side effects, modality safety and health care costs should be considered when selecting an intervention.(52)

A publication in the American Family Physician Clinical Evidence Handbook (2015) pointed out that the efficacy of acupuncture versus sham acupuncture and antiemetics (i.e., prochlorperazine, promethazine, metoclopramide) versus placebo for pregnancy induced nausea or vomiting remain unknown. Existing trials which investigate the various treatment modalities for efficacy, related to nausea or vomiting in pregnancy, are small and of limited quality. The author concluded that there is a need for other large high-quality trials on this condition with consistent outcomes.(53)

Boelig et al (2016) published a Cochrane review of various interventions for treating hyperemesis gravidarum (severe nausea and vomiting during pregnancy [morning sickness]).(26) Reviewers did not identify any studies comparing acupuncture with a placebo intervention. One RCT comparing acupuncture with medication (metoclopramide) did not find a significant difference between groups in the rate of symptom reduction (relative risk [RR], 1.40; 95% CI, 0.79 to 2.49) or cessation of symptoms (RR=1.51; 95% CI, 0.92 to 2.48).

Smith et al (2002) conducted a randomized controlled trial to evaluate the efficacy of acupuncture in early pregnancy. Five hundred and ninety-three women less than 14 weeks pregnant with nausea or vomiting were randomized into 4 groups: traditional acupuncture, pericardium 6 acupuncture, sham acupuncture, or no acupuncture (control). Women receiving traditional acupuncture reported less nausea ( $p < 0.01$ ) throughout the trial and less dry retching ( $p < 0.01$ ) from the second week compared with women in the no acupuncture control group. Women who received p6 acupuncture ( $p < 0.05$ ) reported less nausea from the second week of the trial, and less dry retching ( $p < 0.001$ ) from the third week compared with women in the no acupuncture control group. Women in the sham acupuncture group ( $p < 0.01$ ) reported less nausea and dry retching ( $p < 0.001$ ) from the third week compared with women in the no acupuncture group. No differences in vomiting were found among the groups at any time. Authors concluded that acupuncture is an effective treatment for women who experience nausea and dry retching in early pregnancy.(54)

## ***Chemotherapy-Induced Nausea and Vomiting***

### **Systematic Reviews**

A Cochrane review by Ezzo et al (2006) addressed various types of acupuncture point stimulation (i.e., needles, magnetic, acupressure, electrical stimulation) for reducing nausea and vomiting associated with chemotherapy.(27) Primary outcomes were acute vomiting, acute nausea, delayed vomiting, and delayed nausea. Reviewers included RCTs (11 trials and over 1200 patients) with any comparison group, and sensitivity analyses were conducted on sham-controlled vs non-sham-controlled trials. In addition, sub analyses were conducted on each method of acupuncture point stimulation. Eleven trials and over 1200 patients were included in the meta-analysis.

Electroacupuncture was found to be beneficial for first-day vomiting. Acupressure was effective for first-day nausea but not vomiting. Wristwatch-like electrical devices were not effective for any outcome. A pooled analysis of 4 trials using either manual acupuncture or electroacupuncture found a statistically significant reduction in the incidence of acute vomiting during the next 24 hours in the acupuncture group vs the control group (RR=0.74; 95% CI, 0.58 to 0.94; p=0.01). Authors concluded that P6 stimulation may be beneficial for various conditions involving nausea and vomiting. The added value to modern antiemetics remains unclear. In patients on chemotherapy, future research should focus on patients for whom the problems are refractory. The next steps in research should include investigating whether acupuncture points added to P6 or individualizing treatment based on a Traditional Chinese Medicine diagnosis increases treatment effectiveness.

### **Randomized Controlled Trials**

Li et al (2020) reported an additional single-blind RCT in 134 patients undergoing chemotherapy.(28) Patients were randomized to receive true acupuncture (n=68) or sham acupuncture (n=66) in addition to antiemetics. Interventions were administered twice on day 1 of chemotherapy, then daily for the next 4 days. The rates of complete response of nausea or vomiting did not differ significantly between groups at any time point during the 21-day follow-up period, except at day 21, where the true acupuncture group exhibited a higher complete response rate for nausea (83.9% vs. 67.2%, p=.033).

### **Society Support**

Multiple societies have released consensus guidelines which support the use of acupuncture to aid in chemotherapy induced nausea and vomiting (Refer to Supplemental section below).

## ***Postoperative Nausea and Vomiting***

### **Systematic Reviews**

A Cochrane review by Lee et al (2015) evaluated 10 interventions for stimulating the wrist acupuncture point PC6 for the prevention of postoperative nausea and vomiting (PONV).(29) Reviewers identified 59 trials; a plurality of them addressed acupressure, which can be self-administered. Because there were no analyses specific to acupuncture, its effect on PONV could not be determined. Because there were no analyses specific to acupuncture, its effect on PONV could not be determined.

Zheng et al (2021) performed a systematic review and meta-analysis involving 10 trials (9 RCTs and 1 prospective cohort) that evaluated the effectiveness of acupuncture therapy on PONV after gynecologic surgery.(30) A total of 1075 women who had undergone gynecologic

surgery with general anesthesia were included. Included studies evaluated the use of acupuncture and its derived techniques (e.g., transcutaneous acupoint electrical stimulation, acupressure, and acupoint application) versus placebo or sham acupuncture. Primary outcomes of the analysis included the incidence of postoperative nausea and the incidence of postoperative vomiting. Results revealed that acupuncture therapy was associated with a significant reduction in the risk of developing postoperative nausea and postoperative vomiting by 48% (RR, 0.52; 95% CI, 0.44 to 0.61;  $p < .00001$ ) and 42% (RR, 0.58; 95% CI, 0.49 to 0.68;  $p < .00001$ ), respectively. There were no significant differences between groups with regard to the incidence of adverse effects (e.g., bleeding and needle pain;  $p = .54$ ). Acupuncture therapy was also significantly associated with a reduced rate of rescue antiemetic usage ( $p < .00001$ ) and an increased degree of satisfaction with postoperative recovery ( $p < .0001$ ). The authors concluded that acupuncture therapy is effective and safe for PONV prophylaxis in patients undergoing gynecologic surgery; however, a large, multicenter study is still required to compare the effects of acupuncture on preventing PONV with other noninvasive acupoint stimulation techniques.

### **Section Summary: Nausea and Vomiting**

Given the high prevalence of nausea and vomiting in early pregnancy and the associated physical, social and psychological effects on the women who experience these symptoms, many are turning to alternative therapies. Acupuncture is used as a fundamental treatment in traditional Chinese Medicine; however, this approach has only become popular in the United States in the last few decades. Limited, low-quality studies regarding the efficacy of acupuncture for pregnancy induced nausea and vomiting is not the same as saying that the interventions are ineffective. Many pharmacologic interventions are noted to have adverse effects and acupuncture has minimal to no side effects

Multiple societies and a meta-analysis support the use of acupuncture for treating chemotherapy induced nausea and vomiting. Debates continue regarding the added value of acupuncture to modern antiemetics. In patients on chemotherapy, future research should focus on patients for whom the problems are refractory.

A 2015 Cochrane review assessed 10 interventions for stimulation of the wrist acupuncture point PC6 to prevent or delay PONV. Conclusions could not be drawn it on acupuncture for PONV because only a few studies evaluated acupuncture and findings were not stratified by intervention.

## **OPIOID DEPENDENCE**

### **Study Selection Criteria**

Methodologically credible studies were selected using the principles outlined above.

### ***Non-Cancer Pain***

### **Systematic Reviews**

Eccleston et al (2017) published a Cochrane review of interventions for reducing prescribed opioid use in patients with chronic non-cancer pain who had a treatment goal of reduction or cessation of opioid use.(31) Selection criteria included RCTs comparing interventions with sham, active control, or usual care. One RCT on acupuncture was identified. It compared 6 weeks of electroacupuncture (n=17) with sham electroacupuncture (n=18). At the end of

treatment, 64% of the electroacupuncture group and 46% of the sham group had reduced opioid consumption; the difference between groups was not statistically significant. At the 20-week follow-up, patients in the electroacupuncture group, but not the sham group, had significantly increased opioid use from their posttreatment level.

## ***Opiate Addiction***

### **Systematic Reviews**

Other than the Eccleston et al (2017) review,(31) no Cochrane reviews were identified on acupuncture in opioid users. A 2012 systematic review by Lin et al (2012) addressed acupuncture for treating opiate addiction.(32) Reviewers searched for RCTs of individuals who met criteria for opiate or heroin addiction; trials could be blinded or unblinded. Ten trials met these inclusion criteria. None mentioned blinding. Four studies used acupuncture with manual stimulation, 4 used auricular acupuncture, 1 used electroacupuncture, and another used a Chinese acupoint stimulating device (Han's acupoint nerve stimulator). Reviewers rated 8 trials as low quality and 2 as higher quality. The 2 studies rated higher quality both examined auricular acupuncture, and both reported that this treatment did not have a significant effect on outcomes when used as an adjunct to standard methadone treatment services. Reviewers did not pool study findings. They concluded that there was insufficient evidence to draw conclusions on the efficacy of acupuncture for treating opiate addiction.

A network meta-analysis by Wen et al (2021) investigated the impact of acupuncture in individuals with opioid dependence receiving methadone maintenance treatment. (33) A total of 20 RCTs (N=1997) evaluating patients with opioid dependence, as diagnosed by the Chinese Classification of Mental Disorders second or third editions or Diagnostic and Statistical Manual of Mental Disorders third or fourth editions, compared methadone maintenance treatment, traditional Chinese medicine (Chinese formulated herbal products), or 4 types of acupuncture (manual acupuncture, electroacupuncture, auricular acupuncture, and transcutaneous electrical acupoint stimulation [TEAS]). Heroin was the most commonly abused opioid across all trials. Treatment duration ranged from 7 to 90 days. A total of 14 studies that covered 8 head-to-head comparisons reported the recovery rate, which was assessed by the proportion of participants who were completely detoxified, nearly detoxified, or partially detoxified from therapy, indicated by varying levels of withdrawal. In the pair-wise meta-analysis, no statistically significant differences were observed in terms of recovery rate between methadone maintenance therapy and the various types of acupuncture. Withdrawal symptom scores measured by the Modified Himmelsbach Opiate Withdrawal Scale (MHOWS) were measured by 9 studies that included 8 direct comparisons of 5 interventions. A significant decrease in MHOWS score was observed with manual acupuncture compared to methadone maintenance therapy (-8.59; 95% CI, -15.96 to -1.23;  $p < .01$ ). A network meta-analysis was also conducted to rank interventions for opioid dependence. In the comparisons for recovery rate, manual acupuncture was the most efficacious intervention for opioid dependence and methadone maintenance therapy was the least efficacious among all interventions; a statistically significant difference was only observed in manual acupuncture versus maintenance methadone therapy (risk ratio, 0.72; 95% CI, 0.50 to 0.95). In terms of withdrawal scores, manual acupuncture demonstrated a significant decrease in MHOWS scores compared to methadone therapy (-5.74; 95% CI, -11.60 to -0.10). While authors concluded that acupuncture may be effective for treating patients receiving methadone maintenance therapy, there were many limitations. All selected trials were conducted in China and no trials were at

low risk of bias. Additionally, methadone maintenance therapy, including doses and frequency, were not well described.

### **Section Summary: Opioid Dependence**

A Cochrane review identified an RCT that did not find a significant benefit from acupuncture in reducing opioid consumption in patients with chronic non-cancer-related pain. A narrative systematic review concluded that there was insufficient evidence from high-quality RCTs to draw conclusions on the efficacy of acupuncture in the treatment of opiate addiction. A more recent network meta-analysis found that acupuncture may be effective in treating patients receiving methadone therapy for opioid dependence, but methadone therapy was not well described and all included trials were conducted in China.

### **Acupuncture Point Injection Therapy**

Also known as acupoint injection therapy or biopuncture, acupuncture point injection therapy is a modified acupuncture technique which emerged in China during the 1950's. A liquid agent (e.g., Chinese herbal extractions, Western medications, vitamins, bee venom, normal saline) is integrated into traditional Chinese acupuncture. The agent is injected into the acupuncture point. The combination therapy is thought to create a synergistic effect through the meridians, thus enhancing the overall benefits.

Sha et al (2016) reported on a meta-analysis which reviewed 61 articles over a 5-year period (2010-2015).<sup>(55)</sup> Acupuncture point injection therapy was found to be used to treat multiple diseases in different systems. Clinical evidence was found to be considerably weak. Adverse events included extrapulmonary mycobacterium tuberculosis, retrosternal abscess, pneumothorax, cardiac tamponade, epileptic seizure, and vasovagal responses. Standardization of acupoint injection was found to be lacking. Authors determined that acupuncture point injection therapy has poor clinical evidence and further studies remain necessary. With the reported adverse effects of acupuncture point injection, the need to standardize the procedure has become urgent.

### **Section Summary: Acupuncture Point Injection Therapy**

There is insufficient evidence in the peer-reviewed published scientific literature to support safety and efficacy of acupuncture point injection therapy. Data comparing the effectiveness of different products, methods of stimulation and overall clinical utility is lacking.

## **SUMMARY OF EVIDENCE**

### **Pain-Related Conditions**

For individuals who have episodic migraines who receive acupuncture, the evidence includes randomized controlled trials (RCTs), a nonrandomized comparative study, and systematic reviews. Relevant outcomes include symptoms, functional outcomes, medication use, and treatment-related morbidity. Pooled analyses of 15 sham-controlled trials on episodic migraine in a Cochrane review found significantly better outcomes with acupuncture, which were considered to be clinically significant. Pooled analyses of trials on acupuncture vs medication found a significant benefit of acupuncture at the end of treatment but not at the end of the follow-up period. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have tension-type headaches who receive acupuncture, the evidence includes RCTs and systematic reviews. Relevant outcomes include symptoms, functional



outcomes, medication use, and treatment-related morbidity. Pooled analyses in a Cochrane review on acupuncture for tension-type headaches consistently found statistically significant benefits of acupuncture compared with sham up to 5 to 6 months. The clinical significance of the findings was not assessed. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have low back pain who receive acupuncture, the evidence includes multiple meta-analyses and a consensus statement. Relevant outcomes include symptoms, functional outcomes, medication use, and treatment-related morbidity. Pooled analyses of sham-controlled randomized trials on chronic low back pain in different meta-analyses found improvements in pain. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have other pain-related conditions who receive acupuncture, the evidence includes a few RCTs and systematic reviews. Relevant outcomes include symptoms, functional outcomes, medication use, and treatment-related morbidity. The RCTs were of low quality and/or lacked significantly better outcomes with acupuncture than with control conditions. Clinical guidelines are inconsistent, and studies are often inconclusive or of low quality. Clinical trials were found to differ in terms of technique and reported barriers. Debates continue regarding use of acupuncture in a variety of conditions and standardization is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **Nausea and Vomiting**

For individuals who have nausea or vomiting or are at high risk of nausea or vomiting who receive acupuncture during pregnancy or for post-operative issues, the evidence includes RCTs and meta-analyses. Relevant outcomes include symptoms, functional outcomes, medication use, and treatment-related morbidity. Two Cochrane reviews addressed acupuncture for treating nausea and vomiting in pregnancy. The few RCTs identified did not find significant differences in outcomes between acupuncture and sham acupuncture. Conclusions about acupuncture could not be drawn from this review because only a small number of studies assessed acupuncture and review findings were not stratified by intervention. This is not the same as saying that the modality is ineffective. Given that pharmaceuticals are known to have side effects and acupuncture has limited to no side effects, there may be value in utilizing acupuncture in lieu of medications for pregnancy induced nausea.

For individuals who are at risk of chemotherapy induced nausea and vomiting the evidence includes an RCT, a meta-analysis and consensus guidelines which support the use of acupuncture. Two societies recommend the use of acupuncture as an adjunct to standard of care for nausea and vomiting and 1 indicates that prevention is key, listing acupuncture as an early measure for anticipatory emesis.

### **Opioid Dependence**

For individuals who have opioid dependence who receive acupuncture, the evidence includes RCTs and systematic reviews. Relevant outcomes include symptoms, functional outcomes, medication use, and treatment-related morbidity. A Cochrane review identified a single RCT, which did not find a significant benefit from acupuncture in reducing opioid consumption in patients with chronic non-cancer-related pain. A narrative systematic review concluded that there is insufficient evidence from high-quality RCTs to draw conclusions about the efficacy of

acupuncture in the treatment of opiate addiction. A more recent network meta-analysis found that acupuncture may be effective in treating patients receiving methadone therapy for opioid dependence, but methadone therapy was not well described and all included trials were conducted in China. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **Chronic Low Back Pain**

For individuals who have chronic, non-specific low back pain who receive acupuncture, the evidence includes RCTs and systematic reviews. Relevant outcomes include pain relief, functional outcomes, and overall quality of life. Multiple meta-analyses indicated that patients with chronic non-specific low back pain who received acupuncture treatments reported better outcomes than the sham groups. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

### **Chronic Neck Pain**

For individuals who have chronic neck pain who receive acupuncture, the evidence includes systematic reviews and meta-analyses. Relevant outcomes include pain relief, functional outcomes, and overall quality of life. Meta-analyses indicated that patients with chronic neck pain who received acupuncture treatments reported better outcomes than the sham groups. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

### **Acupuncture Point Injection Therapy**

Evidence in the peer-reviewed published scientific literature to support safety and efficacy of acupuncture point injection therapy is lacking. Further studies are needed to set standardization.

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## **Supplemental Information**

### **PRACTICE GUIDELINES AND POSITION STATEMENTS**

#### **American College of Chest Physicians**

The American College of Chest Physicians (2013) issued guidelines which support use of acupuncture as an adjunct treatment in patients who are having nausea and vomiting from either chemotherapy or radiation therapy.(56)

#### **American College of Physicians**

The American College of Physicians (2017) guidelines for the treatment of low back pain recommend that physicians and patients initially select non-drug therapies that have the fewest harms and costs. The list of alternative therapies included acupuncture.(35)

#### **American College of Rheumatology**

The guidelines from the American College of Rheumatology (2019) on the treatment of osteoarthritis conditionally recommend acupuncture for patients with hip, knee, and/or hand osteoarthritis.(34) Guideline authors note that the evidence for efficacy of acupuncture in osteoarthritis remains a subject of controversy. The greatest number of positive trials with the largest effect sizes have been in patients with knee osteoarthritis. The authors conclude: "While the 'true' magnitude of effect is difficult to discern, the risk of harm is minor, resulting in the Voting Panel providing a conditional recommendation."

The 2012 guidelines from the American College of Rheumatology on the treatment of osteoarthritis (OA) with acupuncture recommended the following:

“Treatment with traditional Chinese acupuncture or instruction in the use of transcutaneous electrical stimulation are conditionally recommended only when the patient with knee 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....”(57)

### **Department of Veterans Affairs/Department of Defense**

The Department of Veterans Affairs/Department of Defense (2020) guideline on the primary care management of headache found insufficient evidence to recommend for or against acupuncture for the treatment of headache.(36) According to guideline authors, "evidence suggests small or inconsistent benefits for migraine and tension-type headache in comparison to sham acupuncture."

The Department of Veterans Affairs/Department of Defense (2020) guideline on the non-surgical management of hip and knee osteoarthritis found insufficient evidence to recommend for or against the use of acupuncture in this setting.(37)

The Department of Veterans Affairs/Department of Defense (2017; updated 2022) guideline on the treatment of low back pain suggests offering acupuncture to patients with chronic low back pain.(38) The authors state: "Acupuncture appears to have a small benefit for the reduction of pain for those with chronic LBP [low back pain] in the intermediate-term (3 to 12 months). The evidence from two SRs [systematic reviews] and 1 small RCT [randomized controlled trial] favored acupuncture over sham for the critical outcome of pain intensity.

### **National Comprehensive Cancer Network**

The National Comprehensive Cancer Network updated its Antiemesis guidelines in 2023. Acupuncture is listed as a key prevention technique to combat anticipatory chemotherapy induced nausea and vomiting.(58)

### **National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (2012) guidance, updated in 2021, on the diagnosis and management of headaches in those over 12 years of age recommended a course of up to 10 sessions of acupuncture over 5 to 8 weeks for prophylactic treatment of chronic tension-type headaches.(39)

For migraines, the guidance recommended a course of up to 10 sessions of acupuncture over 5 to 8 weeks for prophylactic treatment if both topiramate and propranolol were unsuitable or ineffective.(39)

The NICE (2020) guidance on the assessment and management of low back pain and sciatica in those over 16 years of age recommended not offering acupuncture for low back pain with or without sciatica.(40)

### **North American Spine Society**

The North American Spine Society (2020) guideline on low back pain states that "in patients with low back pain, there is conflicting evidence that acupuncture provides improvements in pain and function as compared to sham acupuncture."(41) However, the guideline recommends acupuncture in addition to usual care in patients with chronic low back pain, stating that "addition of acupuncture to usual care is recommended for short-term improvement of pain and function compared to usual care alone."

**Society for Integrative Oncology**

The Society for Integrative Oncology (2018) produced a guideline endorsed by the American Society of Clinical Oncology. The guideline indicates that "Electroacupuncture can be considered as an addition to antiemetic drugs to control vomiting during chemotherapy". This was a grade B recommendation, indicating that there was high certainty of a moderate net benefit, or moderate certainty of a moderate to substantial net benefit. For grade B recommendations, the modality should be offered/provided.(59)

**Society for Integrative Oncology and American Society of Clinical Oncology**

The Society for Integrative Oncology and the American Society of Clinical Oncology (ASCO) released joint guidance in 2022 on integrative approaches to managing pain in adults with cancer.(42) The recommendations provided related to acupuncture are below:

"Acupuncture should be offered to patients experiencing aromatase inhibitor-related joint pain in breast cancer (Evidence based, benefits outweigh harms; Evidence quality: Intermediate; Strength of recommendation: Moderate).

Acupuncture may be offered to patients experiencing general pain or musculoskeletal pain from cancer (Evidence based, benefits outweigh harms; Evidence quality: Intermediate; Strength of recommendation: Moderate).

Acupuncture may be offered to patients experiencing chemotherapy-induced peripheral neuropathy from cancer treatment (Evidence based-informal consensus, benefits outweigh harms; Evidence quality: Low; Strength of recommendation: Weak).

Acupuncture or acupressure may be offered to patients undergoing cancer surgery or other cancer-related procedures such as bone marrow biopsy (Evidence based-informal consensus, benefits outweigh harms; Evidence quality: Low; Strength of recommendation: Weak)."

**U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS**

No U.S. Preventive Services Task Force recommendations on acupuncture have been identified.

**Ongoing and Unpublished Clinical Trials**

Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

**Table 3. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
NCT04866121	The Comparison of P6+ST36 Combination Acupuncture Therapy with P6 Alone Acupuncture and Standard Treatment in Postoperative Nausea and Vomiting	105	May 2022

NCT04982315	Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults	789	Nov 2023
NCT04553562	Efficacy of Acupuncture for Female with Non-cyclic Chronic Pelvic Pain: a Three-armed Randomized Controlled Trial	150	Aug 2022
NCT04185259	Efficacy of Acupuncture vs Sham Acupuncture or Waitlist Control for Patients with Chronic Planter Fasciitis: Study Protocol for a 2-center Randomized Controlled Trial	120	Mar 2022
<b>Unpublished</b>			
NCT04401384	Effectiveness of Acupuncture and Doxylamine/Pyridoxine for Moderate to Severe Nausea and Vomiting in Pregnancy: A Randomized Controlled Two-by-two Factorial Trial	352	Jan 2022

## Government Regulations

### National:

**Acupuncture** - Pub 100-03; Section 30-3 Effective date: 1/21/20; Implantation date: 6/24/20

#### A. General

ACUPUNCTURE is the selection and manipulation of specific ACUPUNCTURE points by a variety of needling and non-needling techniques.

#### Indications and Limitations of Coverage

#### B. Nationally Covered Indications

Effective for claims with dates of service on and after January 21, 2020, ACUPUNCTURE is only covered for chronic low back pain under section 1862(a)(1)(A) of the Social Security Act (the Act). See National Coverage Determination section 30.3.3 for specific coverage criteria.

#### C. Nationally Non-Covered Indications

Medicare reimbursement for ACUPUNCTURE, as an anesthetic, or as an analgesic or for other therapeutic purposes, may not be made unless the specific indication is excepted. All indications for ACUPUNCTURE outside of NCD section 30.3.3 remain non-covered.

**Acupuncture for Chronic Low Back Pain**; Pub 100-03; Sec 30.3.3 Effective date: 1/21/20; Implementation Date: 6/24/20

#### A. General

Acupuncture is the selection and manipulation of specific acupuncture points by a variety of needling and non-needling techniques.

#### Indications and Limitations of Coverage

#### B. Nationally Covered Indications

Effective for services performed on or after January 21, 2020, CMS will cover acupuncture for Medicare patients with chronic Lower Back Pain (cLBP). Up to 12 visits in 90 days are covered for Medicare beneficiaries under the following circumstance:

- For the purpose of this decision, cLBP is defined as:
  - Lasting 12 weeks or longer;
  - nonspecific, in that it has no identifiable systemic cause (i.e., not associated with metastatic, inflammatory, infectious, etc. disease);
  - not associated with surgery; and,
  - not associated with pregnancy.

- An additional 8 sessions will be covered for those patients demonstrating an improvement.
  - No more than 20 acupuncture treatments may be administered annually
- Treatment must be discontinued if the patient is not improving or is regressing.

Physicians (as defined in 1861(r)(1) of the Social Security Act (the Act) may furnish acupuncture in accordance with applicable state requirements.

Physician assistants (PAs), nurse practitioners (NPs)/clinical nurse specialists (CNSs) (as identified in 1861(aa)(5) of the Act), and auxiliary personnel may furnish acupuncture if they meet all applicable state requirements and have:

- a masters or doctoral level degree in acupuncture or Oriental Medicine from a school accredited by the Accreditation Commission on acupuncture and Oriental Medicine (ACAOM); and,
- a current, full, active, and unrestricted license to practice acupuncture in a State, Territory, or Commonwealth (i.e. Puerto Rico) of the United States, or District of Columbia.

Auxiliary personnel furnishing acupuncture must be under the appropriate level of supervision of a physician, PA, or NP/CNS required by our regulations at 42 CFR §§ 410.26 and 410.27.

### **C. Nationally Non-Covered Indications**

All types of acupuncture including dry needling for any condition other than cLBP are non-covered by Medicare.

**Acupuncture for Fibromyalgia** - Pub 100-03; Section 30.3.1; Effective date: 1/21/20; Implementation Date: 6/24/20

After careful reconsideration of its initial noncoverage determination for acupuncture, CMS concludes that there is no convincing evidence for the use of acupuncture for pain relief in patients with fibromyalgia. Study design flaws presently prohibit assessing acupuncture's utility for improving health outcomes. Accordingly, CMS determines that acupuncture is not considered reasonable and necessary for the treatment of fibromyalgia within the meaning of §1862(a)(1) of the Social Security Act, and the national noncoverage determination for acupuncture continues.

**Acupuncture for Osteoarthritis** – Pub 100-3; Section 30.3.2; Effective date: 1/21/20; Implementation Date: 6/24/20

After careful reconsideration of its initial noncoverage determination for acupuncture, CMS concludes that there is no convincing evidence for the use of acupuncture for pain relief in patients with osteoarthritis. Study design flaws presently prohibit assessing acupuncture's utility for improving health outcomes. Accordingly, CMS determines that acupuncture is not considered reasonable and necessary for the treatment of osteoarthritis within the meaning of §1862(a)(1) of the Social Security Act, and the national noncoverage determination for acupuncture continues.

**Inpatient Hospital Pain Rehabilitation Programs (10.3)** – Pub 100-3; Version 1; Section 10.3. Longstanding NCD – effective date not posted

- **Indications and Limitations of Coverage**

Some pain rehabilitation programs may utilize services and devices which are excluded from coverage, e.g., ACUPUNCTURE...

**Outpatient Hospital Pain Rehabilitation Programs (10.4)** - Pub 100-3, Version 1, Section 10.4; Longstanding NCD – effective date not posted

- **Indications and Limitations of Coverage**

Non-covered services (e.g., ...acupuncture) continue to be excluded from coverage...

## Local:

**Trigger Points, Local Injections** (L34588). Original Effective Date: 10/1/15; Revision Effective Date: 9/30/21

Per national Medicare regulations, acupuncture is not a covered service, even if provided for treatment of established trigger points:

- Use of acupuncture needles and/or the passage of electrical current through these needles is not a covered service whether the service is rendered by an acupuncturist or any other provider;
- providers of acupuncture services should inform the beneficiary that such services will not be covered;

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

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## Related Policies

- Cranial Electrotherapy Stimulation and Auricular Electrostimulation
  - Dry Needling of Trigger Points for Myofascial Pain
  - Temporomandibular Joint Disorder
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*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 1/30/23, the date the research was completed.*

### Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/12/02	3/12/02	3/12/02	Joint medical policy established
1/21/04	1/21/04	3/12/04	Routine maintenance
11/10/04	11/10/04	12/4/04	Routine maintenance
11/11/05	11/11/05	11/11/05	Routine maintenance
7/1/07	5/10/07	3/31/07	Routine maintenance
11/1/08	08/19/08	10/28/08	Routine maintenance
1/1/12	10/11/11	11/9/11	Reformatted policy to mirror BCBSA policy; added additional references. Policy statement unchanged.
3/1/14	12/10/13	1/6/14	Routine maintenance
5/1/15	2/17/15	2/27/15	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
11/1/16	8/16/16	8/16/16	Routine maintenance
11/1/17	8/15/17	8/15/17	Routine maintenance
7/1/22	5/9/22		Moved from Inv to Mixed stance
7/1/23	4/18/23		Routine maintenance (slp) Vendor Managed: N/A

Next Review Date: 2<sup>nd</sup> Qtr, 2024

### Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: N/A	Revised: N/A
BCBSM: 4/1/99	Revised: 9/12/00

**BLUE CARE NETWORK BENEFIT COVERAGE  
POLICY: ACUPUNCTURE**

**I. Coverage Determination:**

<b>Commercial HMO (includes Self-Funded groups unless otherwise specified)</b>	Covered; Criteria apply
<b>BCNA (Medicare Advantage)</b>	Refer to the Medicare information under the Government Regulations section of this policy.
<b>BCN65 (Medicare Complementary)</b>	Coinsurance covered if primary Medicare covers the service.

**II. Administrative Guidelines:**

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.