Medical Policy

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***Current Policy Effective Date: 1/1/12**

Title: Acupuncture

Description / Background

Acupuncture is the practice of piercing the skin with needles at specific body sites to induce anesthesia, to relieve pain to alleviate withdrawal symptoms of substance abusers, or to treat various non-painful disorders. The placement of needles into the skin is dictated by the location of meridians. These meridians are thought to mark patterns of energy flow throughout the human body. Acupuncture has 4 components:

- The acupuncture needle(s
- The target location defined by traditional Chinese medicine
- The depth of insertion
- The stimulation of the inserted needle

Acupuncture may be performed with or without electrical stimulation. Acupuncture is a traditional form of Chinese medical treatment that has been practiced for over 3,000 years.

The U.S. Food and Drug Administration (FDA) cleared acupuncture needles for marketing. The needles used in acupuncture, when intended for general use in “the performance of acupuncture,” have been classified by the FDA as Class II devices (*The Gray Sheet,* April 8, 1996).

Medical Policy Statement

Acupuncture is experimental and investigational for all indications. While it may be considered safe and effective for treatment of nausea for selected patients, it has not been demonstrated to be more effective than conventional treatment.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

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:

N/A

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

97810	97811	97813	97814

****Note: Code(s) 97810-97814 may be covered by some contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.***

Regulatory Status:

The U.S. Food and Drug Administration (FDA) cleared acupuncture needles for marketing. The needles used in acupuncture, when intended for general use in “the performance of acupuncture,” have been classified by the FDA as Class II devices (*The Gray Sheet,* April 8, 1996).

Rationale

This policy was originally based on a 1996 TEC Assessment (1) of acupuncture for the treatment of pain. The evidence did not clearly show that the effects of acupuncture exceed placebo effects.

The following study selection criteria were used in the 1996 TEC Assessment:

- The study included a control group that was given a treatment intended to serve as a placebo control, and was compared with active acupuncture treatment.
- The study selected a clinical sample, not healthy volunteers.

Various control treatments were used in the studies reviewed in the 1996 TEC Assessment. Some performed acupuncture outside the traditional meridians; these studies generally did not find an advantage of acupuncture performed by the prescribed method. Other studies used low- or no-needle insertion, and still others used low stimulation. These studies provided mixed results, but it was unclear whether studies using better quality methods consistently found active acupuncture to produce better results than control acupuncture.

In November 1997, a National Institutes of Health Consensus Development Panel (NIHCDP) met to discuss acupuncture. The Consensus Statement (2) concluded that evidence clearly shows that needle acupuncture is efficacious in treating nausea secondary to surgery or chemotherapy in adults and probably effective for nausea of pregnancy as well. The document also states that there is evidence of efficacy for postoperative dental pain. The Panel made a more equivocal statement that acupuncture "may be useful" in the following conditions: addiction, stroke rehabilitation, headache, menstrual cramps, lateral elbow pain, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma. The consensus statement has not been updated and is no longer available on the NIH Web site.

Policy updates since the 1996 TEC Assessment have followed TEC in that they are based on studies that include a control group that received a placebo treatment and studies that used a clinical sample, not healthy volunteers. The current update is based on a literature search through May 2009. Studies of non-traditional or variants of acupuncture were not considered nor were studies comparing acupuncture with treatments not considered standard care in the United States.

The Cochrane Library lists 24 Cochrane Reviews on the use of acupuncture for the following conditions: low back pain, idiopathic headache, lateral elbow pain, rheumatoid arthritis, induction of labor, asthma, acute stroke, Bell's palsy, chronic asthma, depression, dysphagia in acute stroke, epilepsy, glaucoma, insomnia, migraine prophylaxis, neck pain, restless legs syndrome, schizophrenia, shoulder pain, stroke rehabilitation, tension-type headache, irritable bowel syndrome, vascular dementia, assisted conception, chemotherapy-induced nausea or vomiting, and smoking cessation. For conditions not represented in Cochrane Reviews, randomized controlled trials (RCTs) and systematic reviews were reviewed. RCTs with at least 20 subjects published after the latest Cochrane review or update were also included in this update. With respect to systematic reviews of the literature on acupuncture for pain, reviews limited to a specific type of pain were preferred over those that included a variety of conditions.

Nausea Due to Surgery, Chemotherapy and Labor

Systematic reviews have been published that confirm the NIHCDP conclusions on nausea due to surgery, chemotherapy and labor. In 1996, Vickers (3) identified 33 controlled trials of acupuncture for antiemesis. Four studies found that acupuncture was no more effective than control when performed during anesthesia, while 27 of the other 29 studies found acupuncture to be more effective than control. Higher quality studies also consistently found acupuncture to have an antiemetic effect. A later meta-analysis of postoperative nausea and vomiting (4) concluded that acupuncture could be offered as an alternative to antiemetic drugs. Later publications have arrived at conflicting conclusions. A randomized study by Streitberger and colleagues of patients with postoperative nausea and vomiting reported that acupuncture provided no additional benefit compared to sham acupuncture. (5)

Pain

The NIHCDP report concluded that acupuncture may be helpful for the following pain conditions: menstrual cramps, fibromyalgia, myofascial pain, osteoarthritis and carpal tunnel syndrome. Two meta-analyses of acupuncture for chronic pain were cited in the NIHCDP report (6, 7), both of which stated that the evidence did not support conclusions about the efficacy of acupuncture, relative to placebo, for chronic pain. Systematic reviews make the same observation on the use of acupuncture for general chronic pain, (8, 9) knee osteoarthritis, (10) fibromyalgia, (11) and myofascial pain. (12).

Dental Pain

Two studies were cited in the NIHCDP report of acupuncture for postoperative dental pain. Sung et al (13) included 40 patients assigned to 4 groups receiving both an analgesic and acupuncture, each in either active or placebo forms. Codeine plus active acupuncture was superior in pain relief to all other conditions, but placebo drug plus active acupuncture did not differ from both placebo conditions. These findings have not been replicated. Lao et al (14) compared active and placebo acupuncture in 19 subjects, finding longer duration of anesthesia in the active group. These authors published another study on a slightly larger sample (15), but independent replication of these findings has not been published yet. Machalek-Sauberer et al (2007) evaluated the impact of auricular electroacupuncture (AE) on pain and analgesic consumption in a placebo-controlled double-blind RCT with 149 patients having third molar tooth

extraction under local anesthesia. (16) Patients were randomized to auricular acupuncture with or without electrical stimulation (AE and AA respectively), sham AE, or no-needle, and concluded that neither AE nor AA alone reduced pain intensity or analgesic consumption. The available evidence on postoperative dental pain is insufficient to permit conclusions about whether the effects of acupuncture exceed those of placebo.

Fibromyalgia

In a study of 100 patients with fibromyalgia, Assefi reported no difference in pain scores for patients who received acupuncture compared to those who received various sham acupuncture treatments. (17) In a second partially blinded small (N=51) study in patients with fibromyalgia, investigators found that fatigue and anxiety were the most improved symptoms with treatment, but that activity and physical function levels did not change for acupuncture compared with simulated acupuncture. (18) Given these conflicting results, larger controlled studies are needed to explore the impact of treatment on various outcomes.

Headache

In a 2002 Cochrane review, Melchart et al (19) selected 26 controlled trials of acupuncture for idiopathic headache. Sixteen studies compared active and sham acupuncture. The authors noted that the majority of studies had methodologic and/or reporting flaws. They concluded that the quality and quantity of evidence are not fully convincing.

For its 2009 update of its review of acupuncture for migraine prophylaxis, the Cochrane panel considered RCTs with a post-randomization period of at least 8 weeks. (20) Of the 18 included trials, 14 compared true acupuncture with a variety of sham interventions. There was considerable variation in the results of single trials, and pooled analyses did not show a statistically significant superiority for true acupuncture for any outcome in any of the time frames reported. In the 4 trials that compared acupuncture with prophylactic drug treatment, slightly better outcomes and fewer adverse effects were reported for acupuncture. Two trials of low quality comparing acupuncture with relaxation alone or relaxation combined with massage could not be interpreted reliably. The authors found no evidence for an effect of true acupuncture over sham interventions. However, they suggest, “exact point location could be of limited importance.”

RCTs with at least 8 weeks of follow-up were included in the 2009 Cochrane review of acupuncture for treatment of tension-type headache. (21) Eleven trials were considered; 6 of them included patients who received sham interventions. Overall, these trials found slightly better effects in the patients receiving the true acupuncture; 50% of patients who received true acupuncture reported a decrease in the number of headache days of at least 50% versus 41% of the patients who received sham acupuncture. Outcomes were not reported at all time points in all 6 studies. Only the largest of the studies (n=409) demonstrated significant differences in response (at least 50% reduction in the number of headaches) and number of headache days in 4 weeks at the first 3 time points after randomization (up to 8 weeks, 5 to 6 months, and >6 months with 4 studies reporting this outcome). A significant difference in headache intensity was found only at 5 months after randomization (4 studies reporting). The authors report that “there was little statistical heterogeneity; however, these analyses have limited power. In the time window 3 to 4 months after randomization, the pooled responder rate ratio (main outcome measure) was 1.24 (95% confidence interval 1.05 to 1.46; I2 = 0%; 50% responders in acupuncture groups compared to 41% in the sham groups), and the weighted mean difference in headache days per 4 weeks was 1.92 days (0.72 to 3.15; I2 = 0%).” Pooling of data from the 3 trials reporting on frequency of medication use demonstrated a small significant effect favoring acupuncture over sham intervention. While pooled results of these studies suggest that acupuncture is more effective than sham acupuncture, variation in treatment protocols (e.g.,

placement of needles, treatment schedules) and outcome measurements suggest caution when interpreting results.

Davis and colleagues at the Dartmouth Institute for Health Policy and Clinical Practice conducted a systematic review and meta-analysis of RCTs of acupuncture for tension-type headache and reviewed 8 trials of which 5 were included in the meta-analysis. (22) The primary outcome was headache days per month and data were assessed during treatment and at long-term follow-up (20–25 weeks). The acupuncture group averaged 8.95 headaches per month during treatment compared with 10.5 in the sham group and 8.21 per month during follow-up versus 9.54 in the sham group. The authors conclude that acupuncture has limited efficacy for reduction of tension-type headache frequency and note the lack of standardization of acupuncture point selection and treatment course among RCTs.

Lateral Elbow Pain

Green et al (23) reviewed the use of acupuncture for lateral elbow pain. Reviewers found 4 small, randomized trials that had study design flaws. The report concluded that the evidence is insufficient to either support or refute the use of acupuncture for this condition. A study postdating the last update to Cochrane Review on this use of acupuncture was published by Fink et al. (24) The study found that, compared with placebo acupuncture, active acupuncture achieved better results in pain and function at 2 weeks, but only function was still better at 2 months. The study included only 22 patients and is insufficient to overcome the overall methodologic flaws and inconsistent results of the whole evidence base.

Arm Pain

Goldman et al (2008) conducted an RTC comparing the effectiveness of true and sham acupuncture on pain and function in patients with arm pain attributed to repetitive use. (25) Eight treatments were given over 4 weeks, and intensity of pain on a 10-point scale (main outcome), arm symptoms and function, and grip strength were measured during and 1 month after treatment. Arm pain improved in both groups but improvement was significantly greater in the sham group. The difference disappeared by 1 month after treatment. True acupuncture patients experienced more side effects, mainly mild pain at time of treatments.

Low Back Pain

A 1999 Cochrane Review on acupuncture for low back pain was completed by van Tulder et al. (26) It included 11 randomized trials, only 2 of which were of high methodologic quality. The paper concluded that evidence was limited that acupuncture is more effective than placebo. A meta-analysis by Ernst and White (27) found that evidence is insufficient to state whether acupuncture is superior to placebo. Two trials appearing since these analyses report conflicting results. Carlsson and Sjolund (28) found better outcomes in patients receiving active acupuncture compared with placebo, while Leibing et al (29) found no difference between active and placebo acupuncture. A systematic review published in 2008 included 23 trials and grouped them according to control interventions: no treatment, sham intervention, conventional therapy, and acupuncture in addition to conventional therapy. (30) The authors concluded that there is moderate evidence that acupuncture is more effective than no treatment and strong evidence of no significant difference between acupuncture and sham acupuncture for short-term pain relief. Results of a recent double-blind RCT with 1,162 patients by Haake et al are consistent with these observations. (31) Patients were randomized to acupuncture (n=387), sham acupuncture (superficial needling at non-acupuncture points; n=387), or conventional therapy (n=388). Primary outcome was response after 6 months defined as 33% or more improvement on three pain-related items on the Von Korff Chronic Pain Grade Scale or 12% or better improvement on the back-specific Hanover Functional Ability Questionnaire. Patients who were unblinded or who

used concomitant therapies were counted as nonresponders. At 6 months, response rate was 47.6% in the acupuncture group, 44.2% in the sham acupuncture group, and 10.3% in the conventional therapy group.

Neck Disorders

A 2006 Cochrane Review focused on acupuncture for chronic (>3 months) neck disorders. (32) While the review concluded that there was moderate evidence to support the use of acupuncture in these patients, the data to support this indication seem limited. Because the total review involved only 661 participants, because there were methodological concerns with most studies, and because outcomes for this chronic condition were just measured at the end of treatment, additional studies are needed. Witt and colleagues reported on use of acupuncture for patients with chronic neck pain. (33) While improvement was seen compared to the control group receiving usual care, the lack of a sham acupuncture comparison group raises questions about these results.

Osteoarthritis

Berman and colleagues reported on a study of 570 patients with osteoarthritis. (34) Patients were randomized to receive a 26-week course of gradually tapering true acupuncture or the same schedule of sham acupuncture. An additional group received educational sessions, consisting of two 6-hour group sessions. The primary outcome measures were WOMAC pain and function scores at 8 and 26 weeks. On follow-up, those in the true acupuncture group experienced greater improvement in WOMAC function scores at 8 weeks compared to the sham group, but pain score was only significantly better at 14 and 26 weeks. However, the major limitation in this study was the large number of dropouts: 25.3% for true acupuncture, 23.0% for sham acupuncture, and 37.9% for the education group. The Technology Evaluation Center, in applying study quality criteria developed by the U.S. Preventive Services Task Force considers any study with a >20% dropout rate to be of “poor” quality. In addition, the published study does not provide adequate detail to determine the impact of the missing data on the reported outcomes. The authors state that they performed a multiple data imputation analysis using 5 randomly drawn imputations. The details of this process are not described, but the authors conclude that the results of the multiple imputation analysis were very similar to those that used nonimputed data. A more informative approach would be to perform sensitivity analyses using different assumptions about the missing data. For example, a rigorous test of sensitivity would be to assume that all the dropouts in the active treatment group were failures, while all the dropouts in the control groups were successes. Vas and colleagues reported on the results of a trial that randomized 97 patients with osteoarthritis of the knee to receive either acupuncture or placebo acupuncture with diclofenac. (35) Patients were treated for 12 weeks, when the final assessment was made. Nine patients dropped out of the study. The primary outcome measure was changes in the WOMAC index and pain levels, using an intent-to-treat analysis, assigning the 1 dropout in the treatment group the worst score for the treatment group as a whole, while the 8 dropouts in the control group were assigned the best scores for the control group. There was a greater reduction in the WOMAC index in the treatment group compared to the control (mean difference between the 2 groups = 23.9%). The study is limited in that there was no attempt to determine the success of the blinding and the short-term follow-up of 12 weeks.

Scharf and colleagues found that compared with physiotherapy and as-needed anti-inflammatory drugs, the addition of traditional Chinese acupuncture (TCA) or sham acupuncture (10 to 15 treatments) to the conservative regimen led to greater improvement in WOMAC scores at 26 weeks among 1,007 patients with chronic osteoarthritis of the knee. (36) Approximately one half of the two “acupuncture” groups had at least a 36% improvement in their WOMAC score. No statistically significant difference was observed between TCA and sham acupuncture groups. In contrast, Witt and colleagues found that acupuncture (12 treatments over 8 weeks) was superior

to both sham acupuncture and no treatment when measured at 8 weeks in a group of 294 patients with osteoarthritis of the knee. (37) At 52 weeks, the difference between acupuncture and sham acupuncture was not statistically significant.
Jubb and colleagues (2008) randomized 68 patients with symptomatic and radiological evidence of osteoarthritis of the knee to acupuncture or non-penetrating sham acupuncture using a sheathed needle. (38) Both manual and electrical stimulation were used. The primary outcome measure was change in WOMAC pain score of osteoarthritis of the knee after the course of treatment; other measures were self-reported pain scale, the EuroQol score, and plasma beta-endorphin. The mean between group difference on WOMAC score was 60 (p=.035) in favor of acupuncture and improvement in pain was significant in the acupuncture group, but not in the sham group (baseline 294, mean change 95 vs. baseline 261, mean change 35, p=.12). Between-group differences were not seen on other measures. One month after treatment the between group difference was lost, although the acupuncture group continued to benefit compared to baseline. Of the acupuncture patients, 41% correctly guessed their treatment group versus 44% in the control group. Plasma beta-endorphin levels were not affected in either group.

A large multicenter RCT including 352 patients with osteoarthritis at 37 centers was conducted in the United Kingdom and published in 2007. (39) Patients were randomized to advice and exercise with true or sham acupuncture, or to advice and exercise alone. The primary outcome was change in WOMAC score at 6 months. Between group differences were non-significant at all time points up to and including 6 months. The authors observe that small benefits in pain intensity and unpleasantness in both acupuncture groups observed make it unlikely that this was due to acupuncture needling effects.

Pelvic Girdle Pain
A double-blinded RCT (2008) evaluating acupuncture for treatment of pregnant women with pelvic girdle pain was conducted in Sweden. (40) A total of 115 women with a diagnosis of PGP who scored at least 50 on a visual analogue scale (VAS) were randomized to standard treatment plus acupuncture or standard treatment plus non-penetrating sham acupuncture for 8 weeks. The main outcome was pain, and secondary outcomes were frequency of sick leave, functional status, discomfort of pelvic girdle pain, health-related quality of life and recovery from severity of pelvic girdle pain as assessed by the independent examiner. After treatment, median pain score on VAS decreased from 66 to 36 in the acupuncture group and from 69 to 41 in the sham treatment group. Differences in sick leave were not significant. The acupuncture group was more able to perform daily activities (44 vs. 55 on disability index, p=.001). There were no significant differences in quality of life, discomfort of pelvic girdle pain, and recovery from severity of pelvic girdle pain between groups. The authors state that “the data imply that needle penetration contributes to a limited extent to the previously reported beneficial effects of acupuncture.”

Lupus Erythematosus
In a 2008 paper, Greco et al report on a pilot study of acupuncture to reduce pain and fatigue associated with systemic lupus erythematosus. (41) Twenty-four patients were randomized to receive 10 sessions of either acupuncture, minimal needling, or usual care. Of the 22 patients who completed the study, 40% of the acupuncture or minimal needling had >/= 30% improvement in pain with similar results in acupuncture and minimal needling groups. No usual care patients showed improvement in pain.

Postoperative Pain
In 2008, Usichenko et al performed a systematic review of controlled trials to evaluate the evidence of efficacy of auricular acupuncture for postoperative pain control. (42) Nine RCTs were included in the review. Study quality was evaluated using the Jadad scale with 7 RCTs scoring 3

or more points but none reaching the maximum of 5 points. Pain intensity and analgesic requirements were considered the primary outcome measures. Heterogeneity of the studies precluded meta-analysis. Auricular acupuncture was superior to control conditions in 8 trials. The authors conclude that the evidence that auricular acupuncture reduces postoperative pain is promising but not compelling.

Usichenko and colleagues (2008) randomized 120 patients undergoing ambulatory arthroscopic knee surgery under general anesthetic to receive either auricular acupuncture (n=61) or a control procedure (n-59). Indwelling needles were placed before surgery and fixed with tape. (43) Needles were placed at non-acupuncture points in the control group patients. Boluses of piritramide, an opioid agonist, were administered in the recovery room to keep patients' reported pain intensity at <40 mm on 100 mm VAS. Patients were encouraged to stimulate the needles every time they experienced more pain than on discharge from the recovery room and instructed to take single doses of ibuprofen, 200 mg, at intervals of at least 1 hour up to a maximum of 1400 mg until the follow-up examination. If the patient still had more pain than on discharge, tramadol at 1-hour intervals to a total of 200 mg was allowed. All needles were removed the morning after surgery, and tablet counts were reported by the patient. Pain scores were not significantly different between groups after surgery, on discharge from recovery room, or the morning after surgery. Acupuncture patients, however, reported requiring less ibuprofen to achieve a VAS score of <40 (mean 200 mg, range 0–600) than the control patients (mean 600 mg, range (200–800) (p=.012). There were no significant differences on other outcome measures including the number of patients needing tramadol, piritramide dose, discharge time from recovery room, hours of sleep the night after surgery, the number of arousals night after surgery, nausea, or vomiting.

Tsang et al (2007) compared effects of acupuncture with sham acupuncture, when added to standard postoperative physiotherapy, on knee pain, range of motion, and ambulation in patients undergoing bilateral total knee arthroplasty. (44) Thirty-six patients were recruited and 30 were included in the final analysis, 3 having dropped out of each group. Primary outcomes were pain on numeric pain rating scale at rest and at maximum after exercise. Beginning on postoperative day 4, acupuncture and sham acupuncture were provided by three physiotherapists who held diplomas in acupuncture, who had 2 to 3 years of experience in acupuncture, and who did not participate in the postoperative therapy. The Chinese version of an 11-point numeric pain rating scale was used to measure average pain level in both legs at rest before the start of acupuncture and the exercise program and pain that was maximally experienced during exercise on postoperative days 4–8 and 11–15. Active and passive range of motion was measured using a goniometer and ambulation assessed by timed up-and-go test on days 4, 8, and 15. Analgesic usage was recorded daily to day 15. Overall averages (SD) of mean pain scores were 2.2 (1.4) and 2.6 (1.2) at rest, and 6.5 (1.5) and 5.7 (1.7) at maximum from day 4 to 15 in the acupuncture group and sham group, respectively. No significant differences in overall averages of mean pain scores at rest (p=.43) and at maximum (p=.177) were found. The mean number of analgesic tablets consumed (SD) was 28.3 (11.6) in the acupuncture group and 24.7 (13.8) in the sham group (p=.447). There were no significant differences in active and passive ranges of motion and timed up-and-go test. The success of blinding and patients' expectations regarding benefit from acupuncture were not assessed in this study.

Rheumatoid Arthritis

Casimiro et al performed the 2002 Cochrane Review on acupuncture for rheumatoid arthritis. (45) Only 2 controlled trials were found, using different acupuncture methods. One study found acupuncture no more effective than placebo, while the other reported an advantage in knee pain for acupuncture at 24 hours. A 2008 systematic review of acupuncture for pain relief in patients with rheumatoid arthritis by Wang et al found 4 active-controlled and 4 placebo-controlled RCTs

that met criteria for review (using Jadad score) and, although there were some favorable results in active-controlled trials, conflicting results were seen in placebo-controlled trials, suggesting that rigorous, well-controlled RCTs are required. (46) In another 2008 systematic review including 7 RCTS, Lee et al concluded that penetrating or non-penetrating sham-controlled RCTs failed to show specific effects of acupuncture for pain control in patients with rheumatoid arthritis. (47) A pilot RCT with 40 patients with rheumatoid arthritis compared acupuncture or superficial acupuncture at non-acupuncture points. (48) The primary endpoint was a 20% improvement on the American College of Rheumatology (ACR) 20 criteria after 5 and 10 treatments and after 1 month of follow-up. There was not a significant difference in the number of patients reaching ACR20 at the end of treatment (p=.479), however, after 1 month of follow-up, there was a trend in favor the acupuncture group.

Acupuncture for conditions other than nausea, vomiting and pain

Allergic Rhinitis

Roberts et al published a systematic review of acupuncture for allergic rhinitis in 2008 and found 7 relevant RCTs. All but 2 trials were of poor quality, as assessed by a modified Jadad scale. A meta-analysis failed to show any summary benefits of acupuncture for symptom severity scores or serum immunoglobulin E measures that could not be accounted for by chance alone. The authors conclude that the evidence is insufficient to support or refute the use of acupuncture for these patients. (49) Xue et al investigated the effectiveness and safety of acupuncture in persistent allergic rhinitis in a single-blind RCT with 80 patients randomized to true or sham acupuncture given twice weekly for 8 weeks and followed for 12 more weeks. (50) Outcome measures were nasal obstruction, sneezing, rhinorrhea, and nasal itch, each on a 5-point scale logged daily by the patients. Scores were aggregated weekly, and the sum of symptom scores (total nasal symptom score [TNSS]) was determined. Use of relief medication was a secondary outcome. After 8 weeks of treatment, the weekly mean difference in TNSS from baseline was greater with real (-17.2; 95% CI, -24.6 to -9.8) than with sham acupuncture (-4.2; 95% CI, -11.0 to 2.7) (P =.01), and the decrease in individual symptom score was also greater with real acupuncture for rhinorrhea (P <.01) but not the other symptoms. The difference in TNSS from baseline in the real acupuncture group was still apparent: real, -21.0 (95% CI, -29.1 to -12.9) versus sham, - 2.3 (95% CI, -10.2 to 5.6) (P = .001) at the end of follow-up. The differences from baseline in all 4 individual symptom scores were greater for the real than for the sham acupuncture (P <.05). Fifteen of 42 in the true acupuncture group and 15 of 38 in the sham group dropped out before the end of the study; however, though not stated it appears that intention to treat analysis was applied. The mean difference in relief medication scores between real and sham groups from baseline was not significant either at the end of treatment (real: -3.2; 95% CI, -4.9 to -1.5; sham: -0.8; 95% CI, -2.6 to 1.0; t = -1.96, P =.053), or at the end of the 12-week follow-up (real: -2.6; 95% CI, -4.8 to -0.4; sham: 0.3; 95% CI, -2.4 to 3.1; t = -1.69, P =.09). However, within-group comparisons of relief medication scores revealed a significant decline in the use of medication in the real acupuncture group between baseline (7.2; 95% CI, 4.8–9.7) and week 8 of treatment (4.1; 95% CI, 2.2–5.9; P =.001), and the reduction was still apparent at the end of follow-up (4.6; 95% CI, 2.6–6.7; P =.02). There was no such reduction in use of relief medication in the sham group: baseline, 4.4 (95% CI, 1.9–6.9); week 8, 3.6 (95% CI, 1.9–5.4; P =.40); and week 20 follow-up, 4.7 (95% CI, 2.4–7.1; P =.80). This may have been explained by non-significant between group differences at baseline.

Chronic Asthma

Linde et al (51) reviewed use of acupuncture for chronic asthma in a 2002 Cochrane Review. Study selection criteria were met by 7 trials. The reviewers concluded that no statistically significant or clinically relevant effects have been found in comparisons of active and sham

acupuncture. They stated further that evidence is insufficient to make recommendations about the value of acupuncture in asthma treatment. The literature search identified 2 randomized trials published since the most recent update to the Cochrane Review. Both studies found that active acupuncture did not differ from placebo acupuncture. (52, 53) The Cochrane Web site indicates that the review was assessed as up-to-date in August 2008.

Epilepsy

A 2006 Cochrane Review of use of acupuncture in patients with epilepsy found only 3 small randomized trials of varying methodological quality and short follow-up. (54) The authors concluded that current evidence does not support acupuncture as a treatment for epilepsy. A 2008 update considered 11 trials all from non-U.S. centers. (55) All had methodological weaknesses including small sample size and short follow-up, and the panel again concluded that the current evidence does not support acupuncture as a treatment for epilepsy.

Reproduction

Most of the recent literature on the role of acupuncture in treatment of infertility focuses on its use as an adjuvant to conventional in vitro fertilization procedures. A 2008 Cochrane review was conducted to determine the impact of acupuncture on the outcomes of assisted reproductive treatment (ART). (56) RCTs comparing acupuncture alone or acupuncture with concurrent ART versus no treatment, placebo, or sham acupuncture plus ART for treatment of primary and secondary infertility were selected. Thirteen trials were included in the review. Outcome measures were live birth rate, clinical ongoing pregnancy rate, miscarriage rate, and any reported side effects of treatment. There was considerable heterogeneity among the trials in terms of type of sham control used and placement of needles. Meta-analysis suggested a benefit on live birth rate when performed on the day of embryo transfer (odds ratio 1.89, 95% CI 0.93 to 3.44); however, the authors conclude, “with the present evidence, this could be attributed to placebo effect and the small number of women included in the trials. There was no evidence of benefit on pregnancy outcomes when acupuncture was performed around the time of oocyte retrieval. The authors caution that “studies in this area should focus on the use of standardized acupuncture methods so that reasonable comparisons can be made; live birth rate should be used as the primary outcome; and the use of ’placebo needles’ can enhance the quality of the studies performed.” They advise against use of acupuncture in the luteal phase “until further evidence is available from properly powered RCTs concerning the possible associations between luteal phase acupuncture and miscarriage.”

El-Toukhy and colleagues (2008) performed a systematic review of 13 trials in which a total of 2,500 woman undergoing in vitro fertilization (IVF)-intracytoplasmic sperm injection treatment were randomized to acupuncture or sham acupuncture. (57) Meta-analysis of 5 trials (n=877) of in vitro fertilization (IVF) outcome when acupuncture was performed around the time of transvaginal oocyte retrieval and 8 trials (n=1623) of IVF outcome when it was performed around the time of embryo transfer, demonstrated no difference in clinical pregnancy rates. Five trials of acupuncture around the time of embryo transfer provided live birth data; meta-analysis did not show a significant increase in live birth rate with acupuncture.

In a third 2008 meta-analysis, Manheimer et al included 7 trials with 1,366 women and obtained data from authors that was not published in the original articles (such as live births). (58) Their analysis found that acupuncture provided within one day of embryo transfer was associated with significant and clinically relevant improvements in clinical pregnancy (odds ratio 1.65, 95% confidence interval 1.27-2.14; 7 trials), on-going pregnancy (1.87, 1.40 to 2.49, 5 trials), and live birth (1.91, 1.39 to 264; 4 trials). A prespecified subgroup analysis restricted to the three trials with the higher rates of clinical pregnancy in the control group suggested a smaller non-

significant benefit of acupuncture (odds ratio 1.24 to 0.86 to 1.77). The authors conclude that these data provide preliminary evidence that acupuncture with embryo transfer improves rates of pregnancy and live births in women undergoing in vitro fertilization.
The effects of acupuncture on uterine and ovarian blood flow, endocrine and metabolic disturbances, and sperm count and motility have also been studied. A 2008 systematic review by Ng et al notes that there are not enough RCTs to validate that acupuncture can help restore ovulation in patients with polycystic ovary syndrome, and that there is insufficient evidence supporting the role of acupuncture in male subfertility, as most studies are case reports and case series with small sample sizes. (59) Dieterle and colleagues have since reported a single-blind, placebo-controlled trial of 57 men with sperm concentrations <1 million sperm/ml. (60) Patients received treatments twice weekly for 6 weeks; the control group received non-penetrating acupuncture. Five patients dropped out, leaving 24 in the acupuncture group and 28 controls. Semen volumes and sperm concentrations and motility were assessed after liquefaction, at 5 months, </=5 months, and <3 months before intervention; <2 months and </=3 months after intervention. Motility was categorized by World Health Organization categories, e.g., A=rapid linear progressive, B=slow or nonlinear progressive, C=nonprogressive, and D=immotile. The primary outcome measure was sperm motility, and secondary outcomes were sperm concentration and semen volume before and after acupuncture. There was a significant effect of acupuncture on the percentage of total motile sperm (motility A–C before acupuncture: 24.2+17.0 before vs. 33.8+18.2 after, p=.35%), but no significant differences in each category before and after acupuncture. There were no significant differences in motility in the placebo group before and after treatment. There was a significant decrease in sperm concentration after acupuncture (4.2ml before and 3.7 ml after, p=.041) and a significant increase in sperm concentration after placebo acupuncture but not after acupuncture (0.016 +0.085 million/ml before and 0.468+1.712 million/ml, p=.0180 for placebo. More evidence is required before the effectiveness of acupuncture in male infertility can be evaluated.

Induction of Labor
A 2001 Cochrane Review on acupuncture for the induction of labor conducted by Smith and Crowther found no randomized trials meeting study quality standards comparing acupuncture with placebo, no treatment, or alternative treatments. (61) The review remained up to date as of January 1, 2008. Crowther, Smith, and others published a RCT in late 2008 comparing 2 sessions of either acupuncture or sham acupuncture 2 days before planned induction in 364 women with singleton pregnancy and cephalic presentation. (62) Outcomes measured were the need for induction methods and time from administration of the intervention to delivery. There were no differences between groups on need for induction methods. Median time from acupuncture to delivery was 68.6 hours in the acupuncture group versus 65 hours in the sham treatment group.

Hot Flashes
Avis et al (2008) randomized 56 peri- and postmenopausal women who reported having at least 4 hot flashes per day to receive usual care, or twice weekly sham acupuncture or traditional acupuncture twice weekly for 8 weeks. (63) All groups experienced a significant decrease in mean frequency of hot flashes between weeks 1 and 8 (p=.01). The two acupuncture groups showed a greater improvement than the usual care group (p=.05) but did not differ from each other. There were no significant effects for changes in hot flash interference, sleep, mood, health-related quality of life, or psychological well-being. The authors conclude that either there is a strong placebo effect or that both traditional and sham acupuncture significantly reduce hot flash frequency. In another RCT (2007), 72 women with breast cancer and at least 3 hot flashes per day were assigned to true or sham acupuncture treatments twice weekly for weeks and got flash frequency measured at baseline, 6 weeks, and 6 months after initiation of treatment. (64) Hot

flash frequency was reduced in both groups but not significantly, and the between group difference was not statistically significant.

Smoking Cessation

Acupuncture for smoking cessation was reviewed by White et al in 2002. (65) The authors found 22 randomized trials. Of these, none found active acupuncture to be superior to placebo acupuncture at any time interval. An RCT of 131 patients was reported by Wu in 2007. (66) Patients were randomized to 8 weeks of auricular acupuncture in Shen Men, Sympathetic, Mouth and Lung points or sham acupuncture and followed up for 6 more months. At the end of treatment, cigarette consumption had decreased significantly in both groups, but only the treatment group showed a significant decrease in withdrawal symptom score. There was no significant difference in smoking cessation rate between groups at the end of treatment or at the end of follow-up.

Other Addictions

The NIHCDP report cites 3 studies on addictions other than tobacco. One study published initial pilot results and 6-month follow-up for a comparison of active and sham acupuncture in 80 severe recidivist alcoholics. (67, 68) Control patients had higher rates of drinking episodes and admissions to detoxification centers than patients treated with active acupuncture. This was a single-blind study that has not been replicated. A study of 321 patients entered in an outpatient substance abuse program was cited in the NIHCDP report, but it did not include a placebo acupuncture group (69). A study of cocaine dependence also had no placebo acupuncture group. (70) A study comparing active and sham acupuncture for both inpatient and outpatient treatment of cocaine abuse failed to find significant effects favoring active acupuncture. (71)

Stroke Rehabilitation

The NIHCDP report cited only 1 study comparing active and sham acupuncture for stroke rehabilitation. (72) Response to active treatment was rated as good in 4 of 10 patients, compared with 0 of 6 placebo group patients. A study by Johansson et al (73) compared acupuncture with low-intensity control electrostimulation and found no significant effects favoring acupuncture in functional outcome or quality of life. A 2006 Cochrane Review was to assess the efficacy and safety of acupuncture for patients with stroke in the subacute or chronic stages. (74) Five randomized clinical trials were found through November 2005: however, the methodological quality was considered inadequate in all. The authors concluded that there is currently no clear evidence on the effects of acupuncture on subacute or chronic stroke. The Cochrane panel published a review in 2008 of acupuncture for dysphagia in acute stroke and concluded that there is insufficient evidence to draw any conclusion about a therapeutic effect for this indication. (75) Hopwood et al (2008) investigated the efficacy of acupuncture versus placebo (mock transcutaneous electrical stimulation) on stroke recovery in 92 patients. (76) The primary outcome was the Barthel Index (activities of daily living, bowel and bladder function), and secondary outcomes were Motricity Index, mood, Nottingham Health Profile, and treatment credibility. There were no significant differences between the two interventions at 12 and 52 weeks, but an apparently accelerated improvement in Motricity Index at 3 weeks in the acupuncture group.

The Cochrane panel has also published reviews on acupuncture for Bell’s palsy (2006), glaucoma (2007), insomnia (2007), restless legs syndrome (2008), and vascular dementia (2007). (77-81) In all of these, either no support for the use of acupuncture was found or the lack of high-quality clinical evidence prevented drawing conclusions about its efficacy. Other systematic reviews, all published since 2007, of acupuncture for lowering blood pressure, treatment of cardiac arrhythmias, Parkinson’s disease, treatment of dysmenorrhea, and

chemotherapy-induced leukopenia found that most studies were of low methodological quality and concluded that the evidence was inconclusive. (82-86) A systematic review of 8 trials of acupuncture for depression concludes that the treatment can reduce the severity of depression, but acknowledges the low quality of the studies. (87) Small pilot studies of acupuncture for patients with diabetes and symptoms of gastroparesis have also been published.
In summary, the available evidence indicates that acupuncture can reduce nausea and vomiting associated with surgery, chemotherapy, and pregnancy. Its use as a complementary treatment in the setting of currently available drug therapies, however, is not clear. (88) There is limited evidence that acupuncture provides a modest benefit in the treatment of pain associated with osteoarthritis and headache and for improving pregnancy rates in assisted reproductive treatment. The studies do not address patient characteristics that identify patients who may benefit from acupuncture. Heterogeneity of treatment protocols and the variety of sham acupuncture treatments used in studies prevent pooling data with confidence. The absence of a plausible mechanism of action for acupuncture and questions about the significance of placement of needles raised by repeated observations of similar outcomes from true and sham acupuncture treatment also make interpretation of studies difficult.

Technology Assessments, Guidelines and Position Statements
National Institutes of Health Consensus Development Panel
A 1997 Consensus Statement concluded that evidence clearly shows that needle acupuncture is efficacious in treating nausea secondary to surgery or chemotherapy in adults and probably effective for nausea of pregnancy as well. The document also states that there is evidence of efficacy for postoperative dental pain. The Panel made a more equivocal statement that acupuncture "may be useful" in the following conditions: addiction, stroke rehabilitation, headache, menstrual cramps, lateral elbow pain, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma.

Medicare Coverage Policy Position
The Center for Medicare and Medicaid Services (CMS) currently does not cover acupuncture under any condition, and issued a national noncoverage determination for acupuncture in May 1980. In April 2004, CMS issued noncoverage decisions for acupuncture for pain relief in fibromyalgia and osteoarthritis. (89, 90) Citing study design flaws, CMS concluded there is no convincing evidence that acupuncture is useful in improving health outcomes. Therefore, CMS affirmed acupuncture is not reasonable and necessary for pain relief in fibromyalgia or osteoarthritis. No change in the CMS decision was found during the 2009 review.

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 9/15/11, 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.

Next Review Date: 4th Qtr, 2012

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:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	Not covered.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.
BlueCaid	Not covered.

II. Administrative Guidelines:

N/A