Acupuncture

POLICY

GEHA provides coverage for up to 20 treatments per calendar year for the treatment of pain and anesthesia only, where each modality used is considered a treatment. The practitioner must be licensed by the state they in which they are providing service. Treatments are limited to the following acupuncture codes: 97810-14. In the United States, the American Board of Medical Acupuncture (ABMA) certifies clinician acupuncturists while the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) certifies non-clinician acupuncturists. Certifications require passing a standardized exam and demonstration of adequate training. The standard for an acupuncturist is usually between 2000 and 3000 hours of training in a three- or four-year program that is independently accredited\(^1\).

SCOPE OF PRACTICE

Over its long history and dissemination, acupuncture has diversified and encompasses a large array of styles and techniques. Common styles include Traditional Chinese, Japanese, Korean, Vietnamese, and French acupuncture, as well as specialized forms such as hand, auricular, and scalp acupuncture. Acupuncture also refers to a family of procedures used to stimulate anatomical points. Aside from needles, acupuncturists can incorporate manual pressure, electrical stimulation, magnets, low-power lasers, heat, and ultrasound. Despite this diversity, the techniques most frequently used and studied are manual manipulation and/or electrical stimulation of thin, solid, metallic needles inserted into skin. Unless otherwise stated, "acupuncture" in this topic refers to these two most common procedures.

Injection Therapy

Some states have licensed acupuncturists to perform “injection therapy” after a prescribed training certified training program. This certification allows the use of hollow hypodermic needles rather than the traditional solid acupuncture needles. Various solutions have been utilized for this type of injection.

The GEHA acupuncture benefit refers specifically to traditional acupuncture therapy as defined above. It does not encompass injection therapy even when the practitioner is licensed for this service. Furthermore, any drug or solution used for this purpose must be shown to be effective and safe in the peer reviewed medical literature. This is the same policy to apply to any drug or procedure in reviews of allopathic medicine. The FDA does not “approve” non-prescription products for injection, such Traumeel. The FDA lists this compound as “unproven” meaning it has not been investigated by the FDA. For this specific product, the few studies done have been of poor quality and have not established safe and effective outcomes. The FDA oversees labeling and safe manufacturing of this solutions, not their clinical usefulness. The Homeopathic US Pharmacopeia also monitors the contents of these solutions but does not ascertain their effectiveness. The FDA does not require a prescription for homeopathic products, including injectable. However, some manufacturers of these products will only dispense them to licensed practitioners, including acupuncturists licensed to perform injection therapy.

RATIONALE

Acupuncture’s early development coincided with the rise and prominence of two major Chinese philosophies, Confucianism and Taoism. As a result, acupuncture theory is largely grounded in these philosophies\(^2\). One notable, early influence of these philosophies was the recognition that one’s observation and experience were sufficient to explain the human condition \([12]\). This was a significant departure from primordial Chinese healing arts which usually ascribed illness to some superstitious force or moral punishment\(^1\). The two philosophies, particularly Taoism, emphasized the importance of understanding the laws of nature and for humans to integrate and abide by these laws rather than resist them. The human body was regarded as a microcosmic reflection of the macrocosm of the universe. For this reason, concepts used to explain nature, such as yin/yang and Five Elements, became central to acupuncture theory\(^3\). The goal of the clinician was to maintain the body’s harmonious balance both internally and in relation to the external environment.

Acupuncture treatments are therefore usually individualized, and two patients with the same symptoms often do not get the same treatment. The same patient also may not receive the same treatment on subsequent visits.

The major concepts in acupuncture revolve around the concept of qi, yin/yang, and Five Elements.

Qi is frequently translated as “vital energy”. It is felt to permeate all things, may assume different forms, and travels through meridians located on the body. It can be described as stagnant, depleted, collapsed, or rebellious. Whether qi is a quantitative force or a metaphor for the way people experience and depict connections and interconnections is not clear. It likely provides a rationale for explaining change and linking phenomena.

Yin and yang are felt to be complementary opposites and are used to describe all things in nature. Yin is used to represent more material, dense states of matter while yang represents more immaterial, rarefied states of matter\(^4\). The interplay between the two opposites is dynamic and cyclical. To the acupuncturist, health is a constant state of dynamic balance and one must employ a series of qualitative assessments to establish a patient’s present disposition. The evaluation is more complex than merely designating a patient as "more yin" or "more yang." An intricate set of qualitative measures, examination tools, and symptom evaluations are used.

Five Elements along with yin/yang theory form the basis of Chinese medical theory. The Five Elements are wood, water, fire, earth, and metal. These elements are not basic constituents of nature but represent different basic processes, qualities, or phases of a cycle.\(^4\) each element can generate or counteract another element. Most vital organs, acupuncture meridians, emotions, and other health-related variable are assigned an element, thus providing a global description of the balancing dynamics seen in each person.

\(^3\) Kaptchuk T. The Web That Has No Weaver: Understanding Chinese Medicine, ed, McGraw-Hill, Lincolnwood, IL 2000
Multiple physiologic models have been proposed to explain the effects of acupuncture. Various models have implicated cytokines, hormones (e.g., cortisol and oxytocin), biomechanical effects, electromagnetic effects, the immune system, and the autonomic and somatic nervous systems. For many proposed models, the data have been either too inconsistent or inadequate to draw significant conclusions.

Endorphins have been proposed as another mechanism activated by acupuncture. The most thoroughly studied application of acupuncture is for pain relief. Studies performed in the 1970s and 1980s have contributed tremendously to our present understanding of acupuncture's analgesic effects.

According to this theory, acupuncture stimulation is associated with neurotransmitter effects such as endorphin release at both the spinal and supraspinal levels. In support of this theory, there is evidence that opioid antagonists block the analgesic effects of acupuncture. In contrast to this theory, however, the endorphin effects appear to be short-term, only lasting 10 to 20 minutes and possibly up to several days, while many acupuncture clinical trials have documented longer effects. Additionally, endorphin release can be induced by strongly stimulating any free nerve ending or muscle afferents. The specificity of acupuncture point location and the rationale for needling certain points in various conditions remain unexplained.

For these and other reasons, researchers have acknowledged the limitations of the endorphin-related mechanism.

Functional MRI studies have demonstrated physiologic effects with acupuncture. In one study, needling Bladder Points located on the foot (purported to treat visual disorders) was associated with changes in MRI signals at the visual cortex. Multiple other acupuncture-MRI studies have also shown another theory is that acupuncture points are associated with anatomic locations of loose connective tissue.

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8. Han JS, Fei H, Zhou ZF. Met-enkephalin-Arg6-Phe7-like immunoreactive substances mediate electroacupuncture analgesia in the periaqueductal gray of the rabbit. Brain Res 1984; 322:289

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13. Change in the medical science of acupuncture. World Federation of Acupuncture and Moxibustion Societies, Kyoto 1993
study that looked at points and meridians in the arm concluded that such an association was present. It is possible that such an association might relate to the concept of "grasp" noted by practitioners.

Conditions for which acupuncture has been studied and appears to have possible efficacy (whether or not it has greater efficacy than sham acupuncture) include:

- Chronic pain
- Postoperative nausea and vomiting
- Chemotherapy induced nausea
- Acute pain including dental pain
- Headache
- Hypertension
- Chronic obstructive pulmonary disease (COPD)
- Seasonal allergic rhinitis
- Menopausal hot flashes

Acupuncture has been studied for many other conditions including stroke, depression, fibromyalgia, functional dyspepsia, schizophrenia, and tobacco use, but the evidence is insufficient to recommend the use of acupuncture for these conditions.

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15. Langevin HM, Yandow JA. Relationship of acupuncture points and meridians to connective tissue planes. Anat Rec 2002; 269:257
CLINICAL EVIDENCE

Some of the problems encountered with acupuncture randomized trials are shared by trials in many domains: inadequate sample size, lack of follow up, imprecise outcomes, improper statistical analysis, and others. Some problems, however, are particular to acupuncture research. Issues include:

Identifying an acupuncture treatment for a biomedically defined disease can be difficult. One disease in biomedicine can be many "patterns" within the Eastern medicine classification schema. As an example, diabetes can have Eastern medical diagnoses of "stomach fire," "kidney fire," or "lung fire".

Individualized treatments seen in acupuncture run counter to the standardized treatments used in randomized trials. Researchers have tried to deal with this by performing pragmatic trials (where acupuncturists are given full freedom) or trials using semi-standardized treatment (where acupuncturists are assigned mandatory points but given additional individualized options). Whether this latter approach approximates real acupuncture treatments is uncertain, as few studies have reported on the acupuncturists' perceptions of whether their treatments were constrained.

Acupuncture entails many different styles and techniques. In the United States alone, at least eight different styles of acupuncture are taught in the various accredited schools. Differences exist on what points are to be needled, how the needle should be manipulated, how long the needle should be kept in, and what is the appropriate response elicited from the patient. Thus it is difficult to know whether the results of a trial of single type of acupuncture can be generalized to other types.

Due to the heterogeneity of acupuncture, an optimal control for one style may not be ideal for another. It is difficult to perform a double-blind acupuncture study. Acupuncturists are typically able to distinguish real treatment from sham treatment. Delivering acupuncture is not as simple as administering pills, and much like psychotherapy and surgery, experience may play a critical role in determining outcome.

Despite these difficulties a number of trials have compared active acupuncture with a sham control procedure that allows evaluation of the efficacy of acupuncture compared with placebo.

Well-designed clinical trials have found that both acupuncture and sham acupuncture are more effective than control interventions for low back pain. In a systematic review of six randomized trials for chronic non-specific low back pain, acupuncture was found to have a small beneficial effect in reducing pain and improving functional status compared with sham, placebo, or other passive modalities at short-term (one month) and intermediate-term follow-up (three and/or six months). Similarly, in five randomized trials, the combination of acupuncture plus an intervention was found to have a small beneficial effect in

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reducing pain and improving functional status compared with the intervention alone (physiotherapy, exercise, or standard medical care) at short- and intermediate-term follow-up. A subsequent randomized trial in 638 adults with chronic low back pain compared acupuncture treatment individualized to the patient, acupuncture treatment standardized for low back pain, sham acupuncture, and usual care. At eight weeks, back dysfunction scores improved by similar amounts in the individualized, standardized, and sham acupuncture groups and more than in the usual care group.

Knee osteoarthritis — A multicenter randomized trial compared 10 sessions of acupuncture, sham acupuncture, or clinician visits in 1007 patients with chronic knee osteoarthritis who were also being treated with physical therapy and anti-inflammatory medications as needed. Acupuncture treatments were semi-standardized: practitioners were instructed in certain points that were to be needled and could then choose individually to needle additional points. Sham acupuncture involved the use of points not deemed to be useful in the treatment of knee osteoarthritis administered at minimal needling depths. The researcher assessing endpoints was blinded to treatment assignment. Patient blinding between acupuncture and sham acupuncture was successful, with about half of patients who thought they knew which treatment they were receiving guessing incorrectly. Rates of success were similar for acupuncture and sham acupuncture and greater than with conservative therapy.

Two other high-quality randomized trials that compared acupuncture with sham acupuncture found some added benefit with acupuncture; however, some blinding breakdown appears to have occurred in these trials. A meta-analysis of randomized trials of acupuncture for knee osteoarthritis concluded that acupuncture may have had some additional measurable benefits compared with sham acupuncture but that the differences were too small to be clinically relevant.

Relatively small improvements in pain with acupuncture, laser acupuncture, and sham laser acupuncture were also seen in a randomized trial in 282 patients with chronic knee pain. A concern with trials of acupuncture is that the large improvements seen may, in part, reflect the recruitment of patients who expect acupuncture to work. This trial used an unusual design to try to minimize this effect by randomizing patients before they were aware of the intervention arms of the trial. This may explain the smaller benefits seen in both the active and sham arms of the trial; however, the design may also have diluted measured benefits by including outcomes of patients who ultimately refused to be assigned to an intervention arm of the trial.

A meta-analysis of 22 randomized trials (including 4985 participants) evaluated the efficacy of acupuncture in preventing episodic migraines compared with no acupuncture, sham acupuncture, or prophylactic drug treatments. For comparisons with no acupuncture (acute abortive treatment only or “routine” care), acupuncture demonstrated a “moderate” reduction of headache frequency at study end.

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completion. Approximately 40 percent of participants in the acupuncture groups noted ≥50 percent reduction in headache frequency compared with 17 percent in the no-acupuncture groups. Compared with the sham acupuncture, acupuncture was associated with a small reduction in headache frequency at both study completion and at follow-up. This diminished difference in response, compared with no acupuncture, is consistent with findings from other studies that sham acupuncture is associated with clinical improvements. Acupuncture reduced migraine frequency more than prophylactic drug treatment at study completion. A similar pattern was noted for the secondary outcome of dichotomized treatment response. Trial participants receiving acupuncture were less likely to report adverse effects than participants receiving the prophylactic drug treatment.

Based on this meta-analysis, acupuncture is associated with moderate reduction in migraine episodes at study completion (and possibly sustained till a six-month post-randomization follow-up) when compared with no-acupuncture groups. This difference is smaller yet statistically significant when compared with both sham acupuncture and prophylactic drug treatment at completion of treatment. Acupuncture is associated with fewer adverse outcomes relative to prophylactic drug treatment.

Failure to effectively blind the subjects for no-acupuncture and drug treatment comparisons and failure to blind the acupuncturists for all intervention comparisons were noted as limitations for these included studies. Furthermore, the substantial heterogeneity in acupuncture treatments (five trials with standardized approach, seven with semi-standardized treatments, and 10 with individualized treatments) makes the generalization of these results difficult for all acupuncture approaches.

A randomized trial compared acupuncture with sham acupuncture (device that did not puncture the skin applied in locations not normally used for acupuncture) in 327 women with menopausal hot flashes. Ten treatments were administered over eight weeks, and the primary outcome was the hot flash score (a validated measure) at the end of eight weeks. Both the acupuncture and sham acupuncture groups showed an approximately 40 percent reduction in symptoms after treatment. The mean hot flash score (where higher values reflect more severe or more frequent symptoms, and where a difference of four points between the groups was felt to be clinically meaningful a priori) was similar between the two groups. Acupuncture was not superior to sham acupuncture for treating menopausal hot flashes.

In summary, these studies suggest that there is little difference in the effects on pain between acupuncture and sham acupuncture. A meta-analysis of randomized controlled trials of acupuncture for pain that included both sham acupuncture and no treatment arms (three-armed trials) found that the

superiority of acupuncture over sham acupuncture, if real, appeared to be too small to be clinically important\textsuperscript{35 36}.

A 2012 individual patient data meta-analysis concluded that acupuncture was somewhat more effective than sham therapy for back and neck pain, osteoarthritis, and chronic headache\textsuperscript{37}, but the sham therapies in this meta-analysis were heterogeneous and included no-acupuncture sham devices such as deactivated electrical stimulation and detuned lasers. Additionally, the clinical significance of these results is unclear, since the differences between true and sham acupuncture were modest overall and difficult to extrapolate given the incorporation of different clinical outcome measures.

One likely explanation for the results seen in high-quality randomized trials is that both acupuncture and sham acupuncture moderate pain through a strong placebo effect. An alternate possibility is that sham needling at non-acupuncture points to minimal depths has physiologic effects on pain. Against this latter possibility is the result of a randomized trial that examined the effects of acupuncture and sham acupuncture on postoperative nausea and vomiting\textsuperscript{38}; this trial used a sham device that did not penetrate the skin and still found similar effects with acupuncture and sham acupuncture.

It is difficult to know whether acupuncture constrained by the requirements of a clinical trial has the same efficacy as when it is performed according to the practitioner’s preferences. However the marked superiority of acupuncture and sham acupuncture over untreated controls demonstrates the strong effects of treatment seen even under study conditions.

\textsuperscript{35} Madsen MV, Gøtzsche PC, Hróbjartsson A. Acupuncture treatment for pain: systematic review of randomized clinical trials with acupuncture, placebo acupuncture, and no acupuncture groups. BMJ 2009; 338:a3115