



MASSACHUSETTS

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MEDICAL POLICY

Policy #: 178

Original policy date: 1/1991
Revised date: 4/4/2012

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Title

Complementary Medicine

- Massage Therapy
- Acupuncture
- Mind-Body Medicine
- Alternative Medicine
- Holistic Medicine
- Naturopathic Medicine and Other Therapies
- Hippotherapy

When services are covered

We cover massage therapy provided by BCBSMA participating providers including physical therapists, chiropractors, psychiatrists, osteopaths, and physicians.

Note: Coverage for massage therapy is determined by the member's subscriber certificate. (BCBSMA does not have participating agreements with massage therapists.).

When services are not covered

We do not cover services provided by health care providers who are not part of our provider network.

Acupuncture

We do not cover acupuncture^{1,2} except for members of accounts who have added a special addition to their subscriber certificate to cover this service. For those members, acupuncture is covered for any diagnosis.

However, the National Institutes of Health (NIH) has concluded that acupuncture is promising for the following conditions:

- adult post-operative nausea³/ vomiting
- chemotherapy nausea³/ vomiting
- post-operative dental pain.

The NIH also concluded that there were other situations for which acupuncture may be useful as an acceptable alternative, or as part of a comprehensive management program:

- nausea of pregnancy³
- addiction (but not for smoking cessation)
- stroke rehabilitation
- headache
- menstrual cramps
- tennis elbow
- fibromyalgia myofascial pain
- osteoarthritis
- low back pain

- carpal tunnel syndrome
- asthma.

We do not cover the following services (which include but are not limited to the following):

- Acupressure
- Antioxidant therapy and nutritional supplements (except vitamin B12 for vitamin B12 deficient patients)
- Aromatherapy
- Ayurvedic Medicine
- Colon Hydrotherapy
- Cupping
- Herbal Therapy
- Holistic Medicine
- Homeopathy
- Hypnotherapy
- Infratonic sound therapy (i.e., Infratonic QGM Machine, Infratonic Qi-Gong Machine)
- Iridology
- Naturopathic Medicine
- On-site massage (in the home or work setting)
- Oxidative Therapy
- Polarity Therapy
- Qi Gong
- Reflexology
- Reiki
- Rolfing.

We do not cover **hippotherapy**⁴ as it is considered investigational and does not meet our Medical Technology Assessment Guidelines, #[350](#).

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

For services already billed	Prior to performance of service
Blue Cross Blue Shield of Massachusetts Provider Appeals PO Box 986065 Boston, MA 02298	Blue Cross Blue Shield of Massachusetts Case Creation/Medical Policy One Enterprise Drive Quincy, MA 02171 Tel: 1-800-327-6716 Fax: 1-888-282-0780

Authorization Information

For Managed Care members:

- No authorization is required for this service; see **Managed Care Guidelines** for additional requirements.

For Indemnity and PPO members:

- No authorization is required for this service; see **Indemnity and PPO Guidelines** for additional requirements.

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Managed Care Guidelines

All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description, however;

- **For Medicare HMO Blue members:** The service must meet the criteria for coverage noted in this policy, be medically necessary, prescribed by a plan physician and provided by a network provider.
- **For Medicare HMO Blue members:** Referrals are required for all visits to a specialist.
- For all other Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
- Authorization is required for an inpatient admission.

Indemnity and PPO Guidelines

All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description, however;

- Authorization is required for an inpatient admission.
- Authorizations are not required for most outpatient services as determined by the individual's subscriber certificate.
- Referrals to a specialist are not required.

Coding information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Acupuncture

CPT codes:

- **97810:** acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
- **97811:** acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)
- **97813:** acupuncture, 1 or more needles; with electrical stimulation initial 15 minutes of personal one-on-one contact with the patient
- **97814:** acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)

The procedures noted below will reject as non-covered, **for commercial products and for Medicare HMO Blue and Medicare PPO Blue products**, leaving **no** patient balance, as these procedures do not meet our Medical Technology Assessment Guidelines, #[350](#).

HCPCS code:

- **S8940:** equestrian/hippotherapy, per session
- **S8930:** electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-to-one contact with the patient

Policy update history

Policy issued 1/91, reviewed 12/95 without coverage change. Updated 9/96 to continue exclusion for acupuncture. Updated 12/97 to include NIH consensus statement on acupuncture. Updated 2/17/98 to include acupuncture codes. Updated 1/2000 to clarify coverage for massage therapy for participating registered physical therapists. Reviewed 2/01, no changes in coverage were made. Updated 10/01 to clarify coverage exclusions for antioxidant therapy and nutritional supplements. Reviewed 3/02, no changes in coverage were made. Reviewed 3/03 MPG Pulmonology, no changes in coverage were made. Reviewed 3/04 MPG Pulmonology, Allergy and ENT/Otolaryngology, no changes in coverage were made. Reviewed 3/05 MPG Pulmonology, Allergy and ENT/Otolaryngology, no changes in coverage were made. Updated 6/05 to clarify coverage exclusion of naturopathic medicine. Updated 8/05 to include the rationale and references from the 2005 BCBSA national policy on acupuncture (footnote #9). Reviewed 3/06 MPG-Pulmonology, Allergy, ENT/Otolaryngology, no changes in coverage were made. Updated 2/07 to exclude coverage for cupping. Reviewed 3/07 MPG- Pulmonology, Allergy and ENT/Otolaryngology, no changes in coverage were made. Updated 6/07 to exclude coverage for infrasonic sound therapy. Updated 3/08, comparison review of BCBSA policy on Hippotherapy; BCBSMA benchmarks the BCBSA policy finding this movement therapy investigational; #178 updated to include this non-coverage information in-line with #400; footnote #11 created to include BCBSA policy rationale and references. Reviewed 3/08 MPG- Pulmonology, Allergy and ENT/Otolaryngology, no changes in coverage were made. Reviewed 3/09 MPG-Pulmonology, Allergy/Asthma/Immunology and ENT/ Otolaryngology, no changes in coverage were made. Updated 4/09, comparison review of BCBSA national medical policy on Hippotherapy; BCBSA's coverage language-investigational unchanged; BCBSMA benchmarks the BCBSA medical policy; footnote 11 edited- references reordered. Updated 9/09 to remove coverage language pertaining to chelation therapy from policy #178, see new policy document #122 Chelation Therapy, effective 9/1/2009. The references to Blue Medicare PFFS PlusRx were removed. Update 5/1/2010 to remove policy statement regarding Biofeedback for Miscellaneous Indications from policy #178, Complementary Medicine. See new policy document #187, Biofeedback for Miscellaneous Indications. Also updated to remove the policy statement regarding Biofeedback as a Treatment of Chronic Pain from policy #178, Complementary Medicine. See new policy document #210, Biofeedback as a Treatment of Chronic Pain. Reviewed 3/2010 MPG – Pulmonology, Allergy/Asthma/Immunology, ENT and Otolaryngology, no changes in coverage were made. Reviewed 3/2011 MPG – Allergy/Asthma/Immunology and ENT/Otolaryngology, no changes in coverage were made. Updated 5/2011 with revised references on hippotherapy, based on updated BCBSA National policy 2/2011. Reviewed 3/2012 MPG – Allergy, Asthma, Immunology and ENT/Otolaryngology, no changes in coverage were made. Updated 4/2012 to add new non-covered HCPCS code S8930.

Scientific background, Rationale and References

¹ Based upon a 9/96 TEC (Technology Evaluation Center) assessment of Chinese Acupuncture for Treatment of Pain, analyzing literature from 8/95-9/96 . Because all pain treatments are subject to placebo effects, efficacy must be demonstrated in randomized placebo-controlled trials. Since pain is subjective, and self-reported, it is likely to influenced by research protocols; careful controls are essential to adequate assessments. In 1992, AHCPR reviewed acupuncture and other treatments, and concluded that “the physical modalities of acupuncture and electroacupuncture also have been evaluated in post-operative patients, with conflicting findings; no clear analgesic effect has been demonstrated.” Acupuncture (AP) is a procedure, therefore not subject to FDA approval. The needles have recently been reclassified from Class III devices to Class II devices. Manufacturers who wish to make disease-specific claims for the needles must submit a 501(K) with evidence from well-controlled prospective studies.

Four different types of controls have been used in studies: needle vs. no needle, correct location vs. wrong location, adequate needle depth vs. inadequate depth, and stimulation vs. no stimulation (“tweeding”). Studies were included if they were randomized trials (RCT) with some form of placebo or control were included.

Needles outside the meridian: 10 RCTs included studies for stable angina (Ballegaard 1986 n=26, 90 n=49), low back pain (Edelist 1976 n=30), osteoarthritis (Gaw 1975 n=40), (Takeda 1994 n=40), rheumatoid arthritis

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(Man 1974 n=20), mixed disorders (Ghia 1976 n=40) (Lee 1975 n=128), musculoskeletal complaints (Godfrey 1978 n=193), dysmenorrhea (Helms 1987 n=43), tension headache (Tavola 1992 n=30). 8 studies reported that acupuncture was no more effective than needles used elsewhere. Of the two studies reporting significant differences, Ballegaard found benefit for AP on cardiac work, but not on pain or exercise. Only Man's study on RA reported consistent findings across various parameters. It is relevant that the two smallest studies reported posttussive findings, while the larger ones were all negative. Generally, larger studies are more able to detect even subtle differences often missed in small studies. In this case, the reverse suggests that bias, rather than true effect, is responsible for the findings.

Low needle insertion: Skin pressure, pricking, or shallow needle insertion was used as controls. Conditions included: tension headache (Hanse 1985 n=18), migraine (Vincent 1989 n=30), oral surgery (Lao 1995 n-19), tennis elbow (Molesberger 1994 n=48), shoulder pain (Moore 1976 n=117, Moore and Berk 1976 n=42), osteoarthritis (Thomas 1991 n=44), low back pain (Mendelson 1983 n=77), and mixed (Junnila 1982 n=44). Molesberger found AP superior to control in pain reduction. Vincent found AP superior to low-insertion control for self-reported pain, but not on more objective outcomes. Junnila reported AP superior to fingernail pressure in terms of self-reported pain. Blinding procedures were not addressed in these reports. 2 studies where needles did not break the skin reported negative findings (Moore, Moore and Berk); this includes the largest study. Thomas found AP superior to a placebo pill, low-insertion AP control was comparable to the AP group. Mendelson's study was also negative. Again, the larger studies yielded negative results.

No or low stimulation: Mao (1980 n=26) varied stimulation in mixed patients, reporting that higher stimulation was associated with greater pain relief than lower levels. High stimulation was also correlated with higher serum levels of serotonin.

Comparison to TENS: 3 studies compared AP with TENS. In two studies, there were no differences. The Lehman study (1983 n=48) found a significant effect, but failed to reproduce these findings 3 years later (Lehman 1986). 7 studies compared AP and sham TENS. 3 found a significant difference, and 4 found no differences. Again, Lehman (1983) was unable to reproduce these findings in the 1986 report. The other studies with positive findings were small. Conditions treated in these studies included: musculoskeletal complaints, headache, low back pain, post-herpetic neuralgia, neck pain, and mixed complaints.

Summary: There is little evidence that acupuncture improves the perception of pain over placebo. The fact that only the smaller studies show positive findings, while larger ones do not, suggest weaknesses or bias in study design, or random differences.

² See the National Institutes of Health Consensus Development Statement, November 3-5, 1997, Revised Draft 11/5/97, NIH Consensus Statement Online 1997 November 3-5; 15(5): in press

ACUPUNCTURE

Conclusions and Recommendations

Acupuncture as a therapeutic intervention is widely practiced in the United States. There have been many studies of its potential usefulness. However, many of these studies provide equivocal results because of design, sample size, and other factors. The issue is further complicated by inherent difficulties in the use of appropriate controls, such as placebo and sham acupuncture groups.

However, promising results have emerged, for example, efficacy of acupuncture in **adult post-operative and chemotherapy nausea and vomiting** and in **post-operative dental pain**. There are other situations such as **addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma** where acupuncture may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program. Further research is likely to uncover additional areas where acupuncture interventions will be useful.

Findings from basic research have begun to elucidate the mechanisms of action of acupuncture, including the release of opioids and other peptides in the central nervous system and the periphery and changes in neuroendocrine function. Although much needs to be accomplished, the emergence of plausible mechanisms for the therapeutic effects of acupuncture is encouraging.

The introduction of acupuncture into the choice of treatment modalities that are readily available to the public is in its early stages. Issues of training, licensure, and reimbursement remain to be clarified. There is sufficient evidence, however, of acupuncture's value to expand its use into conventional medicine and to encourage further studies of its physiology and clinical value.

NIH Consensus Statements are prepared by a non-advocate, non-Federal panel of experts, based on presentations by investigators working in areas relevant to the consensus questions during a 2-day public session; questions and statements from conference attendees during open discussion periods that are part of the public session; and closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the consensus panel and is not a policy statement of the NIH or the Federal Government.

Introduction

Acupuncture can be traced back for at least 2,500 years, and is based on the premise patterns of energy flow [Qi- pronounced "chee"] through the body are essential for health. Disruptions of this flow are believed to be responsible for disease. The acupuncturist can correct imbalances of flow at identifiable points close to the skin. Since President Nixon to China in 1972, there has been an explosion of interest in the United States and Europe in the application of acupuncture to Western medicine.

Acupuncture describes a family of procedures involving stimulation of anatomical locations on the skin by a variety of techniques. The most studied mechanism employs penetration of the skin by thin, solid, metallic needles manipulated manually or by electrical stimulation. The majority of comments in this report are based on data that came from such studies. Stimulation of these areas by moxibustion, pressure, heat, and lasers is used in acupuncture practice, but due to the paucity of studies, these techniques are more difficult to evaluate.

After reviewing the existing body of knowledge, the U.S. Food and Drug Administration recently removed acupuncture needles from the category of "experimental medical devices" and now regulates them just as it does other devices, such as surgical scalpels and hypodermic syringes, under good manufacturing practices and single-use standards of sterility.

The World Health Organization lists a variety of medical conditions that may benefit from the use of acupuncture or moxibustion, including prevention and treatment of nausea and vomiting; treatment of pain and addictions to alcohol, tobacco, and other drugs; treatment of pulmonary problems such as asthma and bronchitis; and rehabilitation from neurological damage such as that caused by stroke.

The consensus statement addressed the following key questions:

- What is the efficacy of acupuncture, compared with placebo or sham acupuncture, in the conditions for which sufficient data are available to evaluate?
- What is the place of acupuncture in the treatment of various conditions for which sufficient data are available, in comparison with or in combination with other interventions (including no intervention)?
- What is known about the biological effects of acupuncture that helps us understand how it works?
- What issues need to be addressed so that acupuncture may be appropriately incorporated into today's health care system?
- What are the directions for future research?

1. What is the efficacy of acupuncture, compared with placebo or sham acupuncture, in the conditions for which sufficient data are available to evaluate?

Acupuncture is a complex intervention that may vary for different patients with similar chief complaints. The number and length of treatments and the specific points used may vary among individuals and during the course of treatment. According to contemporary research standards, there is a paucity of high-quality research assessing efficacy of acupuncture compared with placebo or sham acupuncture. The vast majority of papers studying acupuncture in the biomedical literature consist of case reports, case series, or intervention studies with designs inadequate to assess efficacy. This discussion of efficacy refers to needle acupuncture (manual or electroacupuncture) because the published research is primarily on needle acupuncture and often does not encompass the full breadth of acupuncture techniques and practices. The controlled trials usually have only involved adults and did not involve long-term (i.e., years) acupuncture treatment.

Efficacy of a treatment assesses the differential effect of a treatment when compared with placebo or another treatment modality using a double-blind controlled trial and a rigidly defined protocol. Papers should describe enrollment procedures, eligibility criteria, description of the clinical characteristics of the subjects, methods for diagnosis, and a description of the protocol (i.e., randomization method, specific definition of treatment, and control conditions, including length of treatment, and number of acupuncture sessions). Optimal trials should also use standardized outcomes and appropriate statistical analyses. This assessment of efficacy focuses on high-quality trials comparing acupuncture with sham acupuncture or placebo.

Response Rate. As with other interventions, some individuals are poor responders to specific acupuncture protocols. Both animal and human laboratory and clinical experience suggest that the majority of subjects respond to acupuncture, with a minority not responding. Some of the clinical research outcomes, however, suggest that a larger percentage may not respond. The reason for this paradox is unclear and may reflect the current state of the research.

Efficacy for Specific Disorders. There is clear evidence that needle acupuncture is efficacious for **adult post-operative and chemotherapy nausea and vomiting** and probably for the **nausea of pregnancy**. Much of the research is on various pain problems. There is evidence of efficacy for **post-operative dental pain**. There are reasonable studies (although sometimes only single studies) showing relief of pain with acupuncture on diverse pain conditions such as **menstrual cramps, tennis elbow, and fibromyalgia**. This suggests that acupuncture may have a more general effect on pain. However, there are also studies that do not find efficacy for acupuncture in pain.

There is evidence that acupuncture does **not** demonstrate efficacy for **cessation of smoking** and may not be efficacious for some other conditions. While many other conditions have received some attention in the literature and, in fact, the research suggests some exciting potential areas for the use of acupuncture, the quality or quantity of the research evidence is not sufficient to provide firm evidence of efficacy at this time.

Sham Acupuncture. A commonly used control group is sham acupuncture, using techniques that are not intended to stimulate known acupuncture points. However, there is disagreement on correct needle placement. Also, particularly in the studies on pain, sham acupuncture often seems to have either intermediate effects between the placebo and 'real' acupuncture points or effects similar to those of the 'real' acupuncture points. Placement of a needle in any position elicits a biological response that complicates the interpretation of studies involving sham acupuncture. Thus, there is substantial controversy over the use of sham acupuncture as control groups. This may be less of a problem in studies not involving pain.

2. What is the place of acupuncture in the treatment of various conditions for which sufficient data are available, in comparison with or in combination with other interventions (including no intervention)?

Assessing the usefulness of a medical intervention in practice differs from assessing formal efficacy. In conventional practice, clinicians make decisions based on the characteristics of the patient, clinical experience, potential for harm, and information from colleagues and the medical literature. In addition, when more than one treatment is possible, the clinician may make the choice taking into account the patient's preferences. While it is often thought that there is substantial research evidence to support conventional medical practices;

this is frequently not that case. This does not mean that these treatments are ineffective. The data in support of acupuncture are as strong as those for many accepted Western medical therapies.

One of the advantages of acupuncture is that the incidence of adverse effects is substantially lower than that of many drugs or other accepted medical procedures used for the same conditions. As an example, musculoskeletal conditions, such as fibromyalgia, myofascial pain, and "tennis elbow," or epicondylitis, are conditions for which acupuncture may be beneficial. These painful conditions are often treated with, among other things, anti-inflammatory medications (aspirin, ibuprofen, etc.) or with steroid injections. Both medical interventions have a potential for deleterious side effects, but are still widely used, and are considered acceptable treatment. The evidence supporting these therapies is no better than that for acupuncture.

In addition, ample clinical experience, supported by some research data, suggests that acupuncture may be a reasonable option for a number of clinical conditions. Examples are **postoperative pain** and **myofascial and low back pain**. Examples of disorders for which the research evidence is less convincing but for which there are some positive clinical reports include addiction, **stroke rehabilitation**, **carpal tunnel syndrome**, **osteoarthritis**, and **headache**. Acupuncture treatment for many conditions such as **asthma**, **addiction**, or **smoking cessation** should be part of a comprehensive management program.

3. What is known about the biological effects of acupuncture that helps us understand how it works?

Many studies in animals and humans have demonstrated that acupuncture can cause multiple biological responses. These responses can occur locally, i.e., at or close to the site of application, or at a distance, mediated mainly by sensory neurons to many structures within the central nervous system. This can lead to activation of pathways affecting various physiological systems in the brain as well as in the periphery. A focus of attention has been the role of endogenous opioids in acupuncture analgesia. Considerable evidence supports the claim that opioid peptides are released during acupuncture and that the analgesic effects of acupuncture are at least partially explained by their actions. That opioid antagonists such as naloxone reverse the analgesic effects of acupuncture further strengthens this hypothesis. Stimulation by acupuncture may also activate the hypothalamus and the pituitary gland, resulting in a broad spectrum of systemic effects. Alteration in the secretion of neurotransmitters and neurohormones and changes in the regulation of blood flow, both centrally and peripherally, have been documented. There is also evidence that there are alterations in immune functions produced by acupuncture. Which of these and other physiological changes mediate clinical effects is at present unclear.

Some of the biological effects of acupuncture have also been observed when "sham" acupuncture points are stimulated, highlighting the importance of defining appropriate control groups in assessing biological changes purported to be due to acupuncture. Such findings raise questions regarding the specificity of these biological changes. In addition, similar biological alterations including the release of endogenous opioids and changes in blood pressure have been observed after painful stimuli, vigorous exercise, and/or relaxation training; it is at present unclear to what extent acupuncture shares similar biological mechanisms.

It should be noted also that for any therapeutic intervention, including acupuncture, the so-called "non-specific" effects account for a substantial proportion of its effectiveness, and thus should not be casually discounted. Many factors may profoundly determine therapeutic outcome including the quality of the relationship between the clinician and the patient, the degree of trust, the expectations of the patient, the compatibility of the backgrounds and belief systems of the clinician and the patient, as well as a myriad of factors that together define the therapeutic milieu.

Although much remains unknown regarding the mechanism(s) that might mediate the therapeutic effect of acupuncture, the panel is encouraged that a number of significant acupuncture-related biological changes can be identified and carefully delineated.

4. What issues need to be addressed so that acupuncture may be appropriately incorporated into today's health care system?

Educational standards have been established for training of physician and non-physician acupuncturists. Many acupuncture educational programs are accredited by an agency that is recognized by the U.S. Department of Education. A national credentialing agency exists that is recognized by some of the major professional acupuncture organizations and provides examinations for entry-level competency in the field.

A majority of States provide licensure or **registration for acupuncture** practitioners. Because some acupuncture practitioners have limited English proficiency, credentialing and licensing examinations should be provided in languages other than English where necessary. There is variation in the titles that are conferred through these processes, and the requirements to obtain licensure vary widely. The scope of practice allowed under these State requirements varies as well. While states have the individual prerogative to set standards for licensing professions, harmonization in these areas will provide greater confidence in the qualifications of acupuncture practitioners.

The occurrence of **adverse events** in the practice of acupuncture has been documented to be extremely low. However, these events have occurred in rare occasions, some of which are life threatening (e.g., pneumothorax). Therefore, appropriate safeguards for the protection of patients and consumers need to be in place. Patients should be fully informed of their treatment options, expected prognosis, relative risk, and safety practices to minimize these risks prior to their receipt of acupuncture. Use of acupuncture needles should always follow FDA regulations, including use of sterile, single-use needles. It is noted that these practices are already being done by many acupuncture practitioners; however, these practices should be uniform. Recourse for patient grievance and professional censure are provided through credentialing and licensing procedures and are available through appropriate state jurisdictions.

It has been reported that more than 1 million Americans currently receive acupuncture each year. Continued access to qualified acupuncture professionals for appropriate conditions should be ensured. Because many individuals seek health care treatment from both acupuncturists and physicians, communication between these providers should be strengthened and improved. Care should be taken so that important medical problems are not overlooked. Patients and providers have a responsibility to facilitate this communication.

5. What are the directions for future research?

The incorporation of any new clinical intervention into accepted practice faces more scrutiny now than ever before. The demands of evidence-based medicine, outcomes research, managed care systems of health care delivery, and a plethora of therapeutic choices makes the acceptance of new treatments an arduous process. It is important, therefore, that the evaluation of acupuncture for the treatment of specific conditions be carried out carefully, using designs which can withstand rigorous scrutiny. In order to further the evaluation of the role of acupuncture in the management of various conditions, the following general areas for future research are suggested.

Relatively few high-quality, randomized, controlled trials have been published on the effects of acupuncture. Such studies should be designed in a rigorous manner to allow evaluation of the effectiveness of acupuncture. Such studies should include experienced acupuncture practitioners in order to design and deliver appropriate interventions. Although randomized controlled trials provide a strong basis for inferring causality, other study designs such as used in clinical epidemiology or outcomes research can also provide important insights regarding the usefulness of acupuncture for various conditions. There have been few such studies in the acupuncture literature. Competing theoretical orientations (e.g., Chinese, Japanese, French) currently exist that might predict divergent therapeutic approaches (i.e., the use of different acupuncture points). Research projects should be designed to assess the relative merit of these divergent approaches, as well to compare these systems with treatment programs using fixed acupuncture points.

Mechanisms which provide a Western scientific explanation for some of the effects of acupuncture are beginning to emerge. This is encouraging, and may provide novel insights into neural, endocrine and other physiological processes. Research should be supported to provide a better understanding of the mechanisms involved and such research may lead to improvements in treatment.

³ Based upon the 2005 Blue Cross Blue Shield Association National Policy 7/01.01, Acupuncture. 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 more mixed results, but it was unclear whether studies using better quality methods consistently found active acupuncture to produce better results than control acupuncture.

2002 Update

National Institutes of Health Consensus Development Panel

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.

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.

Two studies were cited in the NIHCDP report of acupuncture for postoperative dental pain. Sung et al (5) 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 (6) 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 (7), but independent replication of these findings has not been published yet. A literature search did not identify additional controlled trials. The available evidence on postoperative dental pain is insufficient to permit conclusions about whether the effects of acupuncture exceed those of placebo.

Cochrane Database of Systematic Reviews Search/MEDLINE Search Update

The Cochrane Library lists 7 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, and smoking cessation. This update addresses those conditions, in addition to chronic pain other than low back pain or headache, stroke rehabilitation, and addictions other than tobacco. For conditions not represented by Cochrane Reviews, studies cited in the NIHCDP report were reviewed in addition to systematic reviews, and studies published since 1996 were sought. Online search updates were performed on the MEDLINE database. The dates covered in the searches were January 1996 through August 2002.

Low Back Pain: A 1999 Cochrane Review on acupuncture for low back pain was completed by van Tulder et al (8). 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 (9) 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 (10) found better outcomes in patients receiving active acupuncture compared with placebo, while Leibing et al (11) found no difference between active and placebo acupuncture.

Idiopathic Headache: Melchart et al (12) 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. Since the most recent update to the Cochrane Review, no additional placebo-controlled trials on the use of acupuncture for headache were identified in the literature search.

Lateral Elbow Pain: Green et al (13) 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. (14) 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.

Rheumatoid Arthritis: Casimiro et al (15) performed the Cochrane Review on acupuncture for rheumatoid arthritis. 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. This evidence is clearly insufficient to permit conclusions about the effects of acupuncture on rheumatoid arthritis. The literature search found no studies appearing since the last update to the Cochrane Review on this topic.

Other Chronic 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, (16, 17) both of which stated that the evidence did not support conclusions about the efficacy of acupuncture, relative to placebo, for chronic pain. Recent systematic reviews make the same observation on the use of acupuncture for general chronic pain, (18) knee osteoarthritis, (19) fibromyalgia, (20) and myofascial pain. (21)

Induction of Labor: The Cochrane Review on acupuncture for the induction of labor was conducted by Smith and Crowther. (22) The review found no randomized trials meeting study quality standards comparing acupuncture with placebo, no treatment, or alternative treatments. The literature search found no studies appearing since the last update to the Cochrane Review on this topic.

Chronic Asthma: Linde et al (23) reviewed use of acupuncture for chronic asthma. 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. (24, 25)

Smoking Cessation: Acupuncture for smoking cessation was reviewed by White et al in 2002. (26) The authors found 22 randomized trials. Of these, none found active acupuncture to be superior to placebo acupuncture at any time interval. The literature search found no studies appearing since the last update to the Cochrane Review on this topic.

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. (27, 28) 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 NHICDP report, but it did not include a placebo acupuncture group (29), nor did a study of cocaine dependence. (30) A recent study comparing active and sham acupuncture for both inpatient and outpatient treatment of cocaine abuse failed to find significant effects favoring active acupuncture. (31)

Stroke Rehabilitation: The NHICDP report cited only 1 study comparing active and sham acupuncture for stroke rehabilitation. (32) Response to active treatment was rated as good in 4 of 10 patients, compared with 0 of 6 placebo group patients. A recent study (33) compared acupuncture with low-intensity control electrostimulation and found no significant effects favoring acupuncture in functional outcome or quality of life. These studies are clearly insufficient to demonstrate the effectiveness of acupuncture for stroke rehabilitation.

2005 Update: A review of the literature for the period of 2004 through April 2005 identified several additional randomized placebo-controlled trials of the role of acupuncture in treating osteoarthritis and other conditions. However, these studies report conflicting results, and the interpretation of the trials reporting positive results are limited due to methodologic flaws in the trial. Therefore, the policy statement is unchanged. The following discussion reviews these trials in detail.

Berman and colleagues reported on a study of 570 patients with osteoarthritis. Patients were randomized to receive a 26-week course of gradually tapering true acupuncture or the same schedule of sham acupuncture. (34) 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 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. A total of 9 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.

Other randomized studies by Vickers and coworkers and Kvorning et al, focusing on chronic headache and pregnancy-associated back pain, respectively, did not include a sham acupuncture control group, limiting any interpretation of results. (36,37) Randomized studies by White and colleagues and Streitberger and colleagues of patients with chronic neck pain and postoperative nausea and vomiting, respectively, reported that acupuncture provided no additional benefit compared to placebo acupuncture. (38, 39) Finally, Stener-Victorin and colleagues conducted a study of 45 patients with hip osteoarthritis awaiting hip replacement surgery who were randomized to receive either hydrotherapy, electro acupuncture, or education. While positive results of

both electro acupuncture and hydrotherapy were reported compared to no changes in the education group, the small numbers in each group (n=15) require confirmation in larger studies. (40)

Medicare Coverage Policy Position: The Centers for Medicare and Medicaid Services (CMS) currently do 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. (41, 42) 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.

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⁴ Based on the Blue Cross Blue Cross Blue Shield Association policy 8.03.12, Hippotherapy, reviewed 2/2011.

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