

Academic Consortium for Integrative Medicine & Health Commentary to CMS; RE: National Coverage Analysis (NCA) Tracking Sheet for Acupuncture for Chronic Low Back Pain (CAG-00452N)

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The Academic Consortium for Integrative Medicine & Health (the Consortium) is the organizational home for the major academic health centers and health systems in North America that have programs in integrative medicine and health. Integrative medicine and health reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic and lifestyle approaches, healthcare professionals and disciplines to achieve optimal health and healing. The Consortium was founded in 1999 by eight academic health centers including Duke University, Harvard University, Stanford University, University of California, San Francisco, University of Arizona, University of Maryland, University of Massachusetts, and the University of Minnesota. Now with over 75 institutional members, the Consortium continues to grow and represents thousands of scientists, educators, clinicians and other health professionals who share an interest in the field of integrative medicine and health. The Consortium's mission is to advance evidence-based integrative medicine and health in research, curricula and sustainable models of clinical care.

The Consortium supports the decision of CMS Medicare to evaluate the evidence for acupuncture for chronic low back pain (cLBP) and consider Medicare coverage for Americans 65 years or older. Our organization provides leadership and has extensive experience in incorporating evidence-based options such as acupuncture into comprehensive pain care. In response to the CMS call to comment, we respectfully submit this statement supported by the current literature.

Definitions

Acupuncture therapy and chronic low back pain:

Acupuncture therapy is a state-regulated system of care in which practitioners stimulate specific areas or points on the body by application of heat, pressure, electrical stimulation, or insertion and manipulation of thin (pre-sterilized, single-use, filiform) needles for the purpose of achieving a therapeutic or prophylactic effect.¹ Kinds of stimulation, dosage and locations, are based on a physiological interrelationship of body organs and tissue with associated points or combination of points, informed by historical medical texts and modern research. Acupuncture therapy may be used to alleviate pain as a stand-alone therapy or as part of comprehensive pain care as well as to treat other physical, mental, and emotional conditions.

Low back pain: Low back pain is considered chronic if it persists for 3 months or longer. Chronic low back pain (cLBP) is among the most common chronic pain conditions in the United States and one of the leading global causes of disability in most countries.² Low back pain is the most common health problem among older adults reporting pain and disability.^{3–10}

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Acupuncture therapy is effective for cLBP:

Acupuncture therapy has been shown to be effective for cLBP in adults.^{11–14} In a large individual patient data meta-analysis (39 trials and 20 837 patients), acupuncture was found to be superior to placebo/sham controls and usual care in the treatment of chronic pain (low back, neck, shoulder, osteoarthritis of the knee, and headache/migraine). The average effect size was 0.5 compared to a nonacupuncture control group and 0.2 compared to sham (penetrating needles or high intensity controls).¹⁵ Acupuncture demonstrates an equal or superior effect in cLBP compared to placebo or nonsteroidal anti-inflammatory drugs (NSAIDs) with a reduced adverse effect profile.^{15–17} In the cited meta-analysis, the change in pain scores with acupuncture can be summarized as follows: if the baseline pain score in a typical randomized controlled trial was 60 on a scale of 0 to 100, with a standard deviation of 25, follow-up scores might be 43 in a no-acupuncture control group, 35 in a sham acupuncture group, and 30 among true acupuncture patients. If response was defined as a pain reduction of 50% or more from baseline, response rates would be approximately 30% in no acupuncture control group, 42.5% in sham acupuncture controls (using penetrating needles now considered not to be inert),¹⁸ and 50% in true acupuncture intervention. Moreover, in this large meta-analysis, 85% of benefit from acupuncture relative to control persisted at 1 year following care, indicating the persistence of treatment effect.¹⁵

Acupuncture is recommended by the American College of Physicians (ACP)¹⁹ the National Institutes of Health (NIH)²⁰ and the U.S. Agency for Healthcare Research and Quality (AHRQ)²¹ for cLBP, and is among the primary treatment options recommended for cLBP and neck pain without serious pathology by the Global Spine Care Initiative.²² While older patients were not excluded in trials that support these recommendations, acupuncture for cLBP specifically in the elderly has been investigated, though less so.^{23–26} There is an association between multimorbidity patterns and chronic pain in elderly primary care patients, particularly with cLBP.²⁷ Lower socioeconomic groups are more likely to suffer from low back pain than higher.²⁸ While degenerative disc and facet pathology is ubiquitous in older adults, and severe disc pathology associated with a 2-fold greater odds of having cLBP, radiographic severity of disc and facet disease is not necessarily associated with pain severity among elderly with cLBP. Radiographic severity of disc and facet disease is not necessarily associated with pain severity among elderly with cLBP.²⁹ For lumbar disc herniation, acupuncture demonstrates benefit in a systematic review of comparative trials,¹³ as well as for lumbar spinal stenosis, a condition that can increase with age.^{30,31} Finally, the Joint Commission revised their pain management standard, effective January 1, 2018,

requiring their accredited hospitals and facilities provide nonpharmacologic therapy options for pain, with acupuncture as one option.³²

Limitations and risks of opioids highlight the need for evidence-based options in pain care: Providers in the United States prescribe 50 times more opioids than the rest of the world combined.³³ And the United States continues to suffer a persistent national epidemic of opioid use that is responsible for an average of 130 deaths per day.³⁴ Unique to the current U.S. opioid epidemic is its basis in medical prescribing³⁵ founded primarily on expert consensus and without strong evidence, for example, for opioid effectiveness in chronic noncancer pain.^{36–38} Initiation of opioid medication for pain-related function, pain intensity, and adverse effects is not supported for moderate to severe chronic back pain.³⁹ For people with cLBP who tolerate the medicine, opioid analgesics provide modest short-term pain relief, but the effect is not likely to be clinically important within guideline recommended doses. Evidence on long-term efficacy is lacking.³⁸ Overuse of opioid prescribing in many cases is a surrogate for inadequate pain management resources.⁴⁰ Because the probability of long-term opioid use increases after as little as 5 days of prescribed opioids as the initial treatment of pain,⁴¹ access to effective options for comprehensive pain care has become central to stemming the opioid epidemic while responding to the needs of patients who continue to suffer.

NSAIDs limitations and risk in pain care: In general, older adults are underrepresented in the literature on systemic pharmacologic therapies for cLBP, including in research on commonly prescribed and over-the-counter medications such as NSAIDs.⁴² Compared with placebo, NSAIDs are associated with small but significant improvements in pain and disability in patients with cLBP, but associated benefits are small and not clinically meaningful.^{17,18} In a review for the ACP, for cLBP, NSAIDs have a small to moderate effect in short-term improvement of pain and no-to-small effect on function with increased risk of adverse events versus placebo.²⁰ NSAIDs are recommended by the ACP for cLBP patients who have inadequate response to nonpharmacologic therapy.²⁰

However, many patients have difficulty tolerating NSAID medicines due to gastrointestinal (GI) side effects such as nausea and abdominal pain.⁴³ The U.S. Food and Drug Administration has issued new warnings on NSAIDs,⁴⁴ adding stroke and heart attack to the list of already well-known risks, which include delayed healing,^{45,46} renal failure,⁴⁷ particularly in elderly patients, and GI complications including acute and chronic GI bleeding.^{48–50} There are 16 500 deaths annually from NSAID associated GI complications among rheumatoid arthritis and osteoarthritis patients alone.^{43,51}

In addition to mortality and morbidity, NSAIDs interfere with healing which cannot be ignored when considering their ubiquitous use for cLBP including in the elderly^{45,46} as well as the potential for rebound pain on discontinuation.⁵² Chronic NSAID use increases the risk of a second hip fracture in patients after hip fracture surgery.⁵³ The limitations of pharmacologic therapies increase the importance of access to safe and effective nonpharmacologic therapies for cLBP.

Biological mechanisms of acupuncture: Acupuncture research over 40 years provides a robust and complex physiological basis for its therapeutic effects. Early research showed acupuncture stimulates endogenous opioid release in the brain and into the cerebral spinal fluid, contributing to a systemic analgesic effect able to be blocked by naloxone.^{54,55} This endorphin response can be activated with sham acupuncture as well, contributing to the confusion in early randomized acupuncture trials that used penetrating needles as controls, assuming them to be inert. More recently, neuroimaging has established central neurobiological mechanisms of acupuncture in the treatment of pain, and as distinct from placebo interventions.⁵⁶ verum acupuncture elicits more and distinct modulation effects on neurological components than sham acupuncture.⁵⁷ In humans, brain imaging using positron emission tomography (PET) found that acupuncture treatment increases short- and long-term opioid receptor-binding potential in multiple pain and sensory processing regions of the brain in patients with fibromyalgia.⁵⁶ Long-term increases in opioid receptors following acupuncture were associated with greater reduction in pain.⁵⁶ Translational research using functional magnetic resonance imaging (fMRI) in carpal tunnel patients found verum acupuncture modulates the somatosensory cortex area of the brain, providing a correction for maladaptive change present in carpal tunnel syndrome patients.^{58,59} Acupuncture also deactivates limbic brain areas, important for emotion and internal homeostasis, processes that are relevant in chronic pain.⁶⁰⁻⁶² In addition to systemic effects of endorphins and brain modulation, acupuncture needling can modulate local tissue producing an anti-inflammatory effect.^{63,64} Research in both animals and humans has shown acupuncture needling can modulate proteins and fibroblast cells in connective tissue that, in turn, produce mechanotransductive signals able to restore tissue integrity,⁶⁵⁻⁶⁷ an emerging field relevant to acupuncture's role in treating pain and improving function in cLBP.^{65,68}

Acupuncture therapy has an established record of safety: Acupuncture by well-trained practitioners has a low risk of adverse events. The NIH Consensus Statement on Acupuncture published in 1998 found that "the incidence of adverse effects is substantially lower than that of many drugs or other accepted procedures for the same conditions".⁶⁹ Systematic reviews and surveys have clarified that acupuncture is safe when

performed by appropriately trained practitioners³⁻¹⁰ with infrequent minor side effects such as feeling relaxed, elated, tired, or having sensation or itching at point of insertion.⁷ Rare serious complications such as infection or pneumothorax are directly related to insufficient training.^{8,9,70,71}

Acupuncture therapy is cost-effective: There may be a common perception that nonpharmacologic therapies are an "add on" expense. An analysis of the scope of economic benefits corrects this view. There is evidence of cost-effectiveness and cost savings through avoided high tech conventional care, lower future health-care utilization, and reduction of productivity losses.⁷² In a matched retrospective cohort study of low back pain in Korea (>130 000 patients), acupuncture treatment significantly lowered the lumbar surgery rate.⁷³ Economic evaluations conducted alongside randomized controlled trials investigating treatments for LBP endorsed by the guideline of the ACP and the American Pain Society support the cost-effectiveness of acupuncture therapy for cLBP.⁷⁴ According to the World Health Organization (WHO), acupuncture in addition to standard care for relief of cLBP is highly cost-effective.⁷⁵ Economic benefits have been established in both the short and long term,⁷⁶⁻⁷⁸ particularly when considering 85% of benefit from a course of acupuncture treatment for chronic pain, including cLBP, persists at 1 year.¹⁵ Despite the evidence in the literature to support use of acupuncture for low back pain, it is not covered by most insurance plans in the United States.^{79,80} A study by the State of Washington found that even with a substantial number of people using insurance benefits for nonpharmacologic therapies, including acupuncture, the effect on insurance expenditures was modest.⁸¹ In a follow-up study of Washington state-insured patients with back pain, fibromyalgia and menopause symptoms, users of nonpharmacologic therapy providers had lower insurance expenditures than those who did not use them.⁸²

Training: Required acupuncture training should be consistent with current State laws that have established a standard of practice in the United States as well as a record of safety associated with decreased risk of adverse events.^{71,83} Forty-six states plus the District of Columbia (98% of the states that regulate acupuncturists) recognize the National Commission for Certification of Acupuncture and Oriental Medicine (NCCAOM) examinations as a prerequisite for licensure, including an exam in safety and infection control.⁸⁴ The national education standard for a clinical Master's degree requires a minimum course of 1905 hours of training in an approved 3-year program including 660 hours supervised clinical training. As of 2018, there are over 37 000 acupuncturists in the United States.⁸⁵ In 38 states, physicians may practice acupuncture without

acupuncture specific training; 12 states require a course of acupuncture specific training (up to 300 h) for physicians to be “certified”, although much of it is completed online.⁸⁶ The Consortium recommends acupuncture practice that complies with state laws and scopes of practice.

Pragmatic trial: While acupuncture has demonstrated effectiveness for cLBP, additional well-designed pragmatic trials⁷⁸ are needed to clarify the effectiveness of acupuncture for cLBP in the elderly particularly in terms of dosage and cost-effective access models as well as the impact on opioid utilization. Pragmatic clinical trials (PCTs) are performed in real-world clinical settings with highly generalizable populations to generate actionable clinical evidence at a fraction of the typical cost/time needed to conduct a traditional clinical trial.^{87,88} PCTs are part of the NIH’s vision for bridging the gap between research and care,^{88,89} and are also supported through initiatives at the Centers for Medicare & Medicaid (CMS), the Agency for Healthcare Research and Quality (AHRQ), the Patient Centered Outcomes Research Institute (PCORI), Practice-Based Research Networks (PBRNs), and community-based participatory research initiatives across the Federal government.⁹⁰ Designed to inform clinical decisions, to improve practice and policy, PCTs engage multilevel partners in patients, practitioners, and health system communities. Classical efficacy trials as “traditional randomized controlled trials” (tRCTs) test interventions against a placebo using rigid study protocols and minimal variation in a highly defined and carefully selected population. In 17 years, only 14% of tRCT research findings led to widespread changes in care.^{87,91} The NIH Collaboratory on pragmatic trials also recommends early and ongoing stakeholder engagement.⁸⁸ PCTs are recommended in real-world settings comparing an adequate dosage of acupuncture therapy (12–15 treatments in as many weeks) to usual care, with the option of maintenance sessions after a course of treatment and with long-term follow-up to evaluate any benefits in function, self-efficacy and pain intensity. In addition to stakeholder participation, a PCT should include qualitative interviews of health system stakeholders, providers as well as patients, in terms of their experience and issues regarding facilitation and communication.

Other Research Considerations

Dosage, multimorbidity, socioeconomic status and minimally important clinical changes: Research shows that most people who use acupuncture do not receive a full treatment course due to cost barriers and lack of guidelines on dose (number and frequency of treatments).^{92,93}

Because older adults are understudied in terms of medication and acupuncture for cLBP, minimally clinical differences in function and pain must be evaluated for the elderly. The potential role of multimorbidity and socioeconomic status as effect modifiers also needs to be assessed. Study populations must include minority and lower socioeconomic populations and also explore models that facilitate cost-effective access to care, such as acupuncture therapy in a group setting.^{94,95}

Summary Statement

Healthcare practitioners and patients are in critical need of evidence-based nonpharmacologic approaches to management of cLBP that can be reimbursed by Medicare and other health insurance. Based on the current evidence of effectiveness, safety, cost-effectiveness, and the systematic reviews and clinical guidelines of professional and government organizations such as the American College of Physicians, NIH, and AHRQ, the Academic Consortium for Integrative Medicine & Health strongly supports CMS including coverage for a course of acupuncture therapy for cLBP in people over 65 years of age.

Declaration of Conflicting Interests

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