



February 13, 2019

David Dolan
Susan Miller, MD
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Miller and Mr. Dolan:

On behalf of the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM)® and the American Society of Acupuncturists (ASA), we would like to thank you for the opportunity to provide comments on the Centers' National Coverage Analysis for acupuncture in the treatment of chronic low back pain (CAG-00452N). Together, our organizations represent more than 20,000 professional acupuncturists across the United States. As the largest payers in the American healthcare system, the Medicare and Medicaid programs are uniquely situated to have a significant impact on how Americans can access treatments for pain. Especially in light of the opioid crisis, we commend CMS for considering access to acupuncture as a non-pharmacologic treatment for pain, specifically chronic low back pain (CLBP). We offer this document as a summary of the status of the evidence on this topic, and hope to help contextualize that information. We believe acupuncture is a truly effective component in efforts to stem the tide of the pain management epidemic. As such, we have presented a summary of the evidence demonstrating that acupuncture coverage for CLBP is reasonable and necessary under the Medicare program.

Who We Are

The NCCAOM was established to assure the safety and well-being of the public and to advance the professional practice of acupuncture by establishing and promoting national, evidence-supported standards of competence and credentialing. Since our inception, the NCCAOM has issued more than 21,000 certificates in acupuncture, Oriental medicine, Chinese herbology, and Asian Bodywork Therapy. Currently, the NCCAOM certifies 1,200-1,500 acupuncturists per year and represents almost 18,000 nationally certified practitioners. In recent years, the NCCAOM has worked directly with federal agencies to establish recognition of our certification programs and our Diplomates in the federal arena. This has included the creation of a distinct classification code with the Bureau of Labor Statistics (BLS) for the profession "Acupuncturist," and the development of a qualification standard within the Veterans Health Administration (VHA) for acupuncture practitioners. We would offer the VHA qualification standard as a model for determining appropriate clinicians and training requirements in the provision of acupuncture through CMS.

The ASA represents the largest voluntary professional membership body of practitioners under the BLS professional designation "Acupuncturists." ASA's mission is to promote the highest standards of professional practice for acupuncture and East Asian medicine in the United States to benefit the public health. The ASA strives to strengthen the profession at the state level while promoting collaboration



nationally and internationally, in addition to providing resources to its members, the public, and legislators. The ASA has 46 participating professional acupuncture state associations as part of its federation.

Introduction

Back pain is one of the most common reasons for Americans to visit their doctor. In a recent survey,¹ chronic neck and/or back pain was found to affect 54 percent of American adults in 2017. Another survey found that 32.5 percent of those 65 years and older suffer from back pain,² 29 percent of Americans believe their low back pain was due to stress, 26 percent believed it was due to being sedentary/weak muscles, and 26 percent blamed physical work.²

Acupuncture, along with other complementary and integrative treatments, is commonly used as a supplement or replacement for opioid prescriptions when treating a multitude of pain complaints, including chronic low back pain. Integrative pain management pilot programs have demonstrated impressive reductions in opioid use, emergency room visits, and annual costs of healthcare.³ Providing American seniors with a safe, cost-effective approach to managing CLBP will reduce the burden on our healthcare system while supporting the triple aim of lower cost, better outcome, and improved patient satisfaction. Acupuncture has been practiced in the U.S. for more than a century and has been properly state licensed and certified since the early 1980s, with roughly 32 million acupuncture treatments provided each year according to the latest NCCIH survey.⁴

Acupuncture for Chronic Lower Back Pain

There is a significant body of evidence supporting the use of acupuncture for treating chronic lower back pain. We respectfully submit 17 studies of acupuncture for CLBP in Appendix A, and have summarized some of the key findings below.

- A systematic review of acupuncture for low back pain (Appendix B) demonstrated that in 11 trials comparing acupuncture to usual or conventional care, acupuncture outperformed usual care in all 11 reports.
- In 2017, Vickers et al., updated their 2012 meta-analysis of acupuncture research up through trials published in 2015. Data from 39 trials and 20,827 patients were analyzed. Acupuncture was shown to be superior to both sham and no acupuncture controls for each pain condition (all $P < .001$) with differences between groups close to 0.5 standard deviations compared with no

¹ <https://www.statista.com/statistics/680812/self-reported-causes-of-back-pain-adults-us/>

² <https://www.statista.com/topics/4333/back-pain-in-the-us/>

³ Gobeille, AI and Cory Gustafson. "Medicaid Acupuncture Pilot Project Outcomes Report." September 29, 2017. Department of Vermont Health Access.

⁴ Clarke TC, Black LI, Stussman BJ, Barnes PM, Nahin RL. Trends in the use of complementary health approaches among adults: United States, 2002–2012. National health statistics reports; no 79. Hyattsville, MD: National Center for Health Statistics. 2015



acupuncture control, and close to 0.2 standard deviations compared with sham acupuncture. The meta-analysis also found clear evidence that the effects of acupuncture persist over time, with only a small decrease (approximately 15%) in treatment effect at 1 year.⁵

- In Germany, a large-scale observational study was set up by ten health insurance funds. The study examined 454,920 patients with one or more diagnoses of chronic pain, including low back pain (45% of patients), headache (36%), and osteoarthritis (12%), who were treated with acupuncture. Effectiveness of acupuncture was rated by physicians in 22% of the patients as marked, in 54% as moderate, in 16% as minimal, and in 4% as poor (unchanged). Results indicate that acupuncture provided by qualified therapists is safe, and patients benefited from the treatment.⁶
- Another German study involving 340 outpatient acupuncture practices and 1,162 patients with a mean of eight years of back pain, received ten treatments over a five-week period. The patients' back pain reduced for more than six months post treatment, and the acupuncture effectiveness was almost twice that of conventional therapy.⁷

Additional Benefits of Acupuncture

The evidence for acupuncture's role in treating pain, preventing the overuse and unnecessary use of opioids, and treating opioid addiction has been summarized in the white paper, "*Acupuncture's Role in Solving the Opioid Epidemic: Evidence, Cost-Effectiveness, and Care Availability for Acupuncture as a Primary, Non-Pharmacologic Method for Pain Relief and Management*" (Appendix C). Acupuncture has been cited as one of the strongly recommended treatments for back pain in guidelines published by the American College of Physicians⁸ and a number of national and state agencies. In an article by Birch, et al. "a total of 1,311 publications were found that recommended using acupuncture published between 1991 and 2017. The number per year reached 50 in 2005 and 100 in 2009. In addition, 2,189 positive recommendations were found for the use of acupuncture. Of these, 1486 were related to 107 pain indications and 703 were related to 97 non-pain indications."⁹

Acupuncture has also been demonstrated to provide a wide range of benefits beyond the treatment of chronic pain. According to the 1998 NIH Acupuncture Consensus Statement,¹⁰ acupuncture is effective at

⁵ Acupuncture for Chronic Pain: Update of an Individual Patient Data Meta-Analysis

Vickers, Andrew J. et al. *The Journal of Pain*, May 2018, Volume 19, Issue 5, 455 – 474

⁶ Weidenhammer W, Streng A, Linde K, Hoppe A, Melchart D. Acupuncture for Chronic Pain within the Research Program of 10 German Health Insurance Funds--Basic Results from an Observational Study. *Complementary Therapies in Medicine*. 2007;15(4):238-46.

⁷ Haake M, Muller HH, Schade-Brittinger C, Basler HD, Schafer H, Maier C, Endres HG, Trampisch HJ, Molsberger A. German acupuncture trials (GERAC) for chronic low back pain: randomized, multicenter, blinded, parallel-group trial with 3 groups. *Arch Intern Med*. 2007;167(17):1892–1898.

⁸ Qaseem A, Wilt TJ, McLean RM, Forcica MA. Clinical Guidelines Committee of the American College of Physicians. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline from the American College of Physicians

⁹ Birch, S., Soo Lee, M., et al. Overview of Treatment Guidelines and Clinical Practical Guidelines That Recommend the Use of Acupuncture: A Bibliometric Analysis, *The Journal of Complementary and Alternative Medicine*, Volume 24, Number 8, 2018, pp. 752–769.

¹⁰ NIH Consensus Conference Acupuncture. *JAMA*. 1998;280(17):1518–1524. doi: 10.1001/jama.280.17.1518.



treating more than 40 health conditions, including colds and flu, hepatitis, asthma, colitis, diarrhea and constipation, stroke, stress including PTSD, anxiety and depression, insomnia and infertility. Additionally, acupuncture has been shown to be effective in reducing opioid prescription and utilization.^{11,12}

In addition to the studies supporting acupuncture for CLBP, we have included seven studies on the cost-effectiveness of acupuncture, four of which specifically focus on CLBP (Appendix D). We believe that with support and appropriate reimbursement policies, acupuncture can provide significant cost savings to the Medicare program by reducing opioid prescriptions, and by reducing spending on opioid-related complications.

An excellent summary of the current evidence for acupuncture in general was recently published in “*The Acupuncture Evidence Project*.” This is included in Appendix E, and the full results of the project in Appendix F.

Figure 1 (in the document *NCCAOM-ASA Figures*) presents a graphic depiction of acupuncture’s evidence base from the Department of Veterans Affairs’ Evidence Map of Acupuncture for Pain.

In one of the largest 2-year prospective surveys to date of 89,000 acupuncture patients, American Specialty Health Incorporated (ASH), in conjunction with the Agency for Healthcare Research and Quality (AHRQ), were looking to achieve the following objectives:

- Assess and track patient satisfaction based on the type of specialist seen
- Measure overall and specific areas of patient satisfaction with their practitioner
- Examine patient satisfaction with the access and availability of specialty care
- Measure patient satisfaction with their specialty benefits design
- Determine the effectiveness of treatment from the specialty practitioner

ASH contracts with approximately 6,000 licensed acupuncturists across the country, and, since 2012, the ASH acupuncturist network has cared for more than 157,000 patients. The 2014-2015 survey results showed 99% of their patients rating the quality of care as good to excellent, 90.5% of those surveyed were willing to recommend their health plan to others, and 93% of the respondents said their acupuncturist was successful in treating their primary condition. For further detail, please see Appendix G.

Safety

When performed by properly trained and certified providers, acupuncture is widely recognized to be an impressively safe, frequently effective, non-pharmacological option for the treatment of chronic and acute pain syndromes. A thorough systematic review by Chan, et al. published in 2017 concludes that while some adverse events are reported, “all the reviews have suggested that adverse events are rare and

¹¹ Wang B, Tang J, White PF, Naruse R, Sloninsky A, Kariger R, et al. Effect of the Intensity of Transcutaneous Acupoint Electrical Stimulation on the Postoperative Analgesic Requirement. *Anesthesia and Analgesia*, 1997; 85(2): 406-13.

¹² Crawford P, Penzien DB, Coeytaux R. Reduction in Pain Medication Prescriptions and Self-Reported Outcomes Associated with Acupuncture in a Military Patient Population. *Med Acupunct*. 2017;29(4):229-231.

often minor.”¹³ These findings are consistent with prior studies.^{14,15,16} Some severe adverse events such as brain stem piercing, spinal lesions, infectious disease transmission, organ puncture, needle breaking and migrating, and death have been documented in other countries, but may be associated with provider competence and training, and could be avoided with sufficient regulations determining appropriate clinicians. We have included nine studies addressing safety and adverse events with acupuncture treatment in Appendix H.

Study Design

It is critical when reviewing any of the literature surrounding acupuncture and pain management to understand the state of the science in acupuncture research. Because large-scale studies are expensive and difficult to fund, most of the acupuncture trials are performed on relatively smaller populations. Further, various attempts to create an inert, “placebo” control with “sham acupuncture” are found throughout the literature base. What has been learned over the past two decades of research is that it is problematic to utilize sham acupuncture as a control. Sham acupuncture is not only biologically active; it activates all the non-specific mechanisms of acupuncture’s effects. Many of these physiologic responses have been identified and include at least endorphin release in many subjects, as well as activation of innate and conditioned relaxation responses, modulation of limbic processing (mood improvement and stabilization), and the creation of a therapeutic experience.¹⁷ These effects alone are sufficient to improve a subject’s scale ratings of disability and pain perception. What is seen, however, is that as study size increases, the effects of true acupuncture begin to meaningfully exceed those of sham. It has been estimated that a study would require more than 4,000 subjects to begin to meaningfully distinguish between the short-term improvements in *verum* versus sham groups.¹⁸

What is also frequently lost in research analysis is the clarity that despite the difficulty distinguishing *verum* from sham groups, both *verum* and sham acupuncture significantly outperform conventional care or wait listing, indicating clear clinical benefit over usual care.¹⁹

Further, acupuncture theory firmly adheres to the assertion that care must be administered appropriately and in an individualized fashion to be optimally effective. The majority of prior study

¹³ Chan, M., Wu, XY, et al. Safety of Acupuncture: Overview of Systematic Reviews

Sci Rep. 2017; 7: 3369. Published online 2017 Jun 13. doi: [10.1038/s41598-017-03272-0](https://doi.org/10.1038/s41598-017-03272-0)

¹⁴ Witt CM, Pach D, Brinkhaus B, et al. Safety of acupuncture: results of a prospective observational study with 229,230 patients and introduction of a medical information and consent form. *Forsch Komplementmed* 2009; 16:91–97.

¹⁵ MacPherson H, Thomas K, Walters S, et al. The York acupuncture safety study: prospective survey of 34,000 treatments by traditional acupuncturists. *BMJ* 2001; 323:486–487.

¹⁶ Lao, Lixing; Hamilton, Gayle R; Fu, Jianping; Berman, Brian M. “Is Acupuncture Safe? A Systematic Review of Case Reports.” *Alternative Therapies in Health and Medicine*; Aliso Viejo Vol. 9, Iss. 1, (Jan/Feb 2003): 72-83.

¹⁷ Kenji Kawakita and Kaoru Okada, Acupuncture therapy: mechanism of action, efficacy, and safety: a potential intervention for psychogenic disorders? *Biopsychosoc Med* 2014; 8: 4.

Published online 2014 Jan 20. doi: [10.1186/1751-0759-8-4](https://doi.org/10.1186/1751-0759-8-4)

¹⁸ MacPherson H1, Vickers A2, Bland M1, Torgerson D1, Corbett M3, Spackman E4, Saramago P4, Woods B4, Weatherly H4, Sculpher M4, Manca A4, Richmond S1, Hopton A1, Eldred J1, Watt I5. “Acupuncture for chronic pain and depression in primary care: a programme of research.” Southampton (UK): NIHR Journals Library; 2017 Jan. Programme Grants for Applied Research.

¹⁹ Kawakita and Okada.



designs have attempted to create a uniform treatment protocol for acupuncture's application to the study group. Despite this fact, acupuncture still obtains results superior to conventional care while operating under suboptimal application conditions. We anticipate that acupuncture performed most correctly would yield even greater divergence between *verum* and sham groups, as well as over usual care. It should also be noted that when studying acupuncture's effectiveness for a condition such as "low back pain," there is an obvious problem with design in that "low back pain" is not truly a diagnosis, but rather a symptom description. There are many etiologies of both acute and chronic low back pain, and so studies must be designed to account for the differences in underlying pathology.

Critique of the acupuncture literature based on a lack of divergence between *verum* and sham groups displays an outdated view of research methods and an oversimplified understanding of the complexity of acupuncture and its numerous mechanisms of clinical effect. More attention should be focused on the divergence between any acupuncture and usual care (Appendix E). It is also critical to observe that proper training is likely to yield improved clinical outcomes and is more likely to optimize the use of healthcare funds. Future studies should provide more focus on meaningful outcome measures of an integrative care approach, such as overall perceived pain, reduced side effects of pharmacological interventions, and overall cost-effectiveness.

Appropriate Clinicians and Training Requirements

Licensed acupuncturists are currently the only health profession authorized to provide acupuncture with federally regulated and accredited independent oversight agencies. The Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM) is a specialized accreditation agency recognized by the U.S. Department of Education that monitors academic curricula of professional non-degree and graduate degree programs (including doctoral programs) in acupuncture and Oriental medicine. A master's degree in acupuncture requires a minimum of three years and 1,905 hours of training, covering acupuncture theory, clinical practice, biomedicine, ethics, counseling, patient communication, and practice management. A minimum of a master's degree level program is required to become a licensed acupuncturist and be eligible to sit for the NCCAOM national board exams. In addition, all graduates must also document in-person training and passage of a Clean Needle Technique course.

The NCCAOM establishes and promotes national evidence-based standards of competence and credentialing. The four psychometrically-validated NCCAOM national board exams establish minimal competency for an entry level practitioner. NCCAOM's three certification programs are accredited by the National Commission for Certifying Agencies (NCCA). NCCAOM Diplomates (National Board-Certified Acupuncturists™) are required to be recertified every four years in order to maintain their knowledge and clinical performance at the highest levels of competency for acupuncture practice. The recertification process includes 60 hours of Professional Development Activity, which must also include at least 30 hours of re-training in acupuncture core competencies, at least 4 hours of safety and ethics training, including education on bloodborne pathogens, clean needle technique, and more, as well as a continually updated CPR certification. All NCCAOM nationally board-certified Diplomates must agree and adhere to the NCCAOM Code of Ethics. Violations of the Code of Ethics may include denial of certification, probation, or permanent revocation of certification.



While “Acupuncturists” are recognized by the Bureau of Labor Statistics as an independent profession and are occupationally titled in the Veterans Health Administration System, they are currently not included in the Medicare program as providers. Given their extensive training and assessment of competency, board-certified, licensed acupuncturists would be the most reliably identifiable group to provide acupuncture services.

The Veterans Health Administration, which has worked to expand access to acupuncture for all of its covered veterans, currently requires NCCAOM board certification for an acupuncturist to be appointed as a VHA practitioner. The VHA represents the largest health system in the United States with more than 1,200 locations. 88% of their facilities currently offer acupuncture services using NCCAOM Board-Certified Diplomates to fill their acupuncturist positions. There are also a large number of VHA general practitioners who are narrowly scoped to provide battlefield acupuncture and acupuncture detox protocols, but for general acupuncture services, NCCAOM certification is required. The VHA also requires an acupuncturist to be NCCAOM Board-Certified in order to serve in their extensive outpatient referral system. The agency requires maintenance of NCCAOM certification as well as engagement in continuing education as required by the NCCAOM. This classification allows the thousands of veterans who suffer from chronic and acute pain to be treated by the most reliably credentialed and qualified acupuncturists.

Workforce

There are approximately 38,000 trained acupuncturists in the U.S.²⁰ (Figure 2), and the growth of the profession has been impressive over the past approximately two decades (Figures 3 and 4). Figure 5 depicts the distribution of NCCAOM Diplomates across the U.S. There are an additional 7,000 students in this system of approximately 56 ACAOM-accredited institutions currently due to graduate in the next four years. There is more than enough capacity for acupuncturists to absorb additional patients that would likely seek out this service, should CMS begin to cover acupuncture for chronic low back pain with reasonable reimbursements.

Conclusion

When delivered by qualified healthcare professionals, acupuncture is a safe, cost-effective, increasingly evidence-based treatment option for chronic low back pain, as well as numerous other conditions, including many that potentiate both pain and addiction. There is a well-developed system already in place to educate, train, certify, and regulate acupuncturists, and the educational system can accommodate the training of many more interested applicants than currently enter the system. The inclusion of acupuncture as a Medicare benefit for the treatment of CLBP is both a timely and rational consideration. We feel it should stand as a reasonable and necessary component of the Medicare program, and there is a growing, reliable workforce able to provide the service.

²⁰ Fan AY, Stumpf SH, Faggert Alemi S, Matecki A. Distribution of licensed acupuncturists and educational institutions in the United States at the start of 2018. *Complement Ther Med*. 2018 Dec;41:295-301. doi: 10.1016/j.ctim.2018.10.015



Acupuncture will prove to be a valuable addition to CMS' efforts to treat pain and help to minimize or even eliminate the use of opioids in many circumstances. It also offers promising secondary benefits that may further boost the health of seniors, as well as potentially increasing satisfaction with the Medicare program. Appropriate reimbursement by the federal government for these services to support qualified acupuncturists is critical to the success of any program expanding coverage of acupuncture.

Our organizations are grateful to the Centers for prioritizing this inquiry that could meaningfully alter the current medical management of chronic low back pain, and for examining integrative treatment options to address pain among program beneficiaries. We look forward to working with CMS to further the development of coverage policies that allow beneficiaries access to proven, non-pharmacological treatments for their pain. We stand ready to provide any additional information as requested and look forward to continuing to combat the opioid crisis through advocacy for safer and more effective treatments. If our organizations can offer any further information, please contact the NCCAOM Government Relations department by phone at 202-367-2494 or by email at advocacy@thenccaom.org, and the American Society of Acupuncturists by email at asapolicy@asacu.org.

Sincerely,

A handwritten signature in black ink that reads "Afua Bromley". The signature is written in a cursive, flowing style.

Afua Bromley, MSOM, Dipl. Ac. (NCCAOM)[®], L.Ac.
Chair, NCCAOM Board of Commissioners

A handwritten signature in black ink that reads "David W. Miller". The signature is written in a cursive, flowing style.

David W. Miller, M.D., L.Ac.
Chair, American Society of Acupuncturists