



August 14, 2019

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Syrek Jensen and Colleagues:

The National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services' (CMS) Proposed Decision Memo for Acupuncture for Chronic Low Back Pain (cLBP) (CAG-00452N). The NCCAOM applauds CMS' proposed decision to allow acupuncture services from **an NCCAOM National Board-Certified Acupuncturist™** for Medicare beneficiaries participating in sanctioned research to determine acupuncture's effect on cLBP. Facilitating research among Medicare beneficiaries will help strengthen the evidence base demonstrating acupuncture as an effective, safe, and affordable pain-management option.

The NCCAOM's comments focus on three major points:

1. The importance of CMS maintaining its requirement that practitioners providing acupuncture hold a current NCCAOM certification.
2. Supervision requirements.
3. Evidence demonstrating the efficacy, safety, and cost-effectiveness of acupuncture for cLBP.

NCCAOM Certification

As the nation's only certifying body for acupuncturists, the NCCAOM seeks to ensure the public's safety and well-being while advancing the professional practice of acupuncture by establishing and promoting national, evidence-supported standards of competence and credentialing. The National Commission for Certifying Agencies accredits the NCCAOM's three certification programs, making NCCAOM the gold standard for acupuncture certification.

Since its inception in 1982, the NCCAOM has issued more than 25,000 certificates in acupuncture, Oriental medicine, and Chinese herbology. Currently, **the NCCAOM certifies 1,200-1,500 acupuncturists annually and represents more than 18,000 nationally certified practitioners.**

NCCAOM Diplomates (National Board-Certified Acupuncturists) must recertify every four years to maintain their certifications. Recertification includes 60 hours of Professional Development Activity/continuing education—30 of these hours must include retraining in acupuncture core competencies. Recertifying Diplomates must also complete at least four hours of safety and ethics training, including education on blood-borne pathogens, clean-needle technique, and CPR recertification. NCCAOM National Board-Certified Acupuncturists must agree and adhere to the *NCCAOM Code of Ethics*. Diplomates who violate the *NCCAOM Code of Ethics* may face certification denial, probation, suspension, or revoked certification.

The certification standards Diplomates meet by passing one of the NCCAOM examinations in Foundations of Oriental Medicine, Acupuncture with Point Location, and Biomedicine represent the minimum requirements necessary for acupuncturists to deliver acupuncture safely and competently without physician supervision. The Biomedicine exam, in particular, ensures that the NCCAOM Diplomates have the knowledge to know when to refer a patient to a physician or other healthcare practitioner.

In addition, it allows acupuncturists to communicate effectively with western medical practitioners. To pass the NCCAOM Biomedicine Examination, candidates must demonstrate knowledge, skills, and abilities in referral and safety, uphold professional ethics, and perform practice management in compliance with all federal and state laws. Please see [NCCAOM Biomedicine Exam Expanded Content Outline](#).

In recent years, the NCCAOM has worked directly with federal agencies to establish certification programs to verify competency and ensure access to the NCCAOM Diplomates in the federal arena. This includes creating a distinct classification code with the Bureau of Labor Statistics for Acupuncturists, and developing a qualification standard within the Veterans Health Administration (VHA) for acupuncture practitioners, which states that VHA-hired acupuncturists “...**must be board certified through the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM). The board certification must be current, and the acupuncturist must abide by the certifying body's requirements for continuing education.**”

NCCAOM Board-Certification requirements **do not reduce or inhibit access to acupuncture practitioners**—the requirement actually ensures that those furnishing these services have met nationally recognized standards for training, competency, and adherence to safety protocol.

NCCAOM certification is especially critical for acupuncturists because **education and training requirements significantly differ among state acupuncturist licensure laws and not all state acupuncturist licensure laws require Board certification.** Forty-seven states (and the District of Columbia) have practice acts in place to define and regulate the practice of acupuncture. Of

these, 25 require NCCAOM Board Certification for acupuncture licensure. Twenty-one more use NCCAOM examinations as a portion of the licensure requirements. As a result, all states except California require candidates to either pass the NCCAOM examinations or obtain NCCAOM certification.

In fact, NCCAOM Diplomates practice across the country including the three unregulated states: Alabama, Oklahoma and South Dakota. As written, the decision memo would exclude those acupuncturists in these states, and the NCCAOM suggests that CMS waive the state licensure requirement for the states where licensure is not available.

California, which has its own licensing exam, has over 3,800 NCCAOM-Certified Acupuncturists, as many California acupuncturists choose to become NCCAOM certified. California-licensed acupuncturists can also apply for NCCAOM certification under a time-limited route after demonstrating good standing under California licensure and other requirements (for details visit: <https://www.nccaom.org/certification/california-route/>). California created this route after performing an exam audit and equivalency study that determined the NCCAOM to be equivalent to the California Acupuncture Licensing Exam. This resulted in the California Acupuncture Board recommending legislation requiring the NCCAOM exams in California.

The NCCAOM stands by the NCCAOM Board-Certification process and its examinations as they demonstrate achievement, safety, quality, and competence in the practice of acupuncture. The NCCAOM's state-level work continues to help improve state licensure requirements to protect patients across the country, and the NCCAOM works closely with state governments to provide information and support for any developments with acupuncture practice acts.

It is important that CMS recognize National Board Certification as a method for ensuring competency standards, adequate training, and patient safety. As noted above, three states currently do not license acupuncturists, which presents major quality and patient-safety issues—and makes Board certification essential. As such, the requirement that those providing acupuncture services be NCCAOM-certified is critical to ensuring competence and Medicare beneficiaries' safety.

Supervision Requirements

The NCCAOM notes that the proposed decision memo includes a provision that acupuncturists deliver services as auxiliary personal under "direct supervision." The challenge is that the majority of board-certified acupuncturists do not practice under any sort of physician supervision. They are in private practice. Most physicians do not have any acupuncture training and do not have the qualifications to supervise from a patient-safety perspective. Physicians who have training are usually NCCAOM Board Certified. The NCCAOM suggests that if CMS has to have a supervision requirement, CMS define it as "general supervision."

In fact, acupuncturists qualified under the proposal should have the capacity to be principal investigators (PI) on studies to ensure the studies are well constructed. In the past, research efforts have wasted significant resources on poorly constructed studies by PIs with limited understanding of acupuncture as a medicine and not just the placement of needles.

Evidence focused on Acupuncture for Chronic Low Back Pain

The body of evidence showing acupuncture's efficacy for cLBP continues to grow. The following studies specifically pertain to acupuncture for CLBP:

1. Brinkhaus B, Witt CM, Jena S, et al. Acupuncture in patients with chronic low back pain: a randomized controlled trial. *Arch Intern Med.* 2006 Feb 27; 166(4):450-7. Doi: 10.1001/archinte.166.4.450. PMID: 16505266.
2. Brinkhaus B, Witt CM, Jena S, et al. Interventions and physician characteristics in a randomized multicenter trial of acupuncture in patients with low-back pain. *J Altern Complement Med.* 2006 Sep;12(7):649-57. doi: 10.1089/acm.2006.12/649. PMID: 16970535.
3. Chou R, Deyo R, Friedly J, Skelly A, Hashimoto R, Weimer M, et al. AHRQ Comparative Effectiveness Reviews. Noninvasive Treatments for Low Back Pain. Rockville (MD): Agency for Healthcare Research and Quality (US); 2016.
4. Furlan AD, Yazdi F, Tsertsvadze A, et al. A systematic review and meta-analysis of efficacy, cost-effectiveness, and safety of selected complementary and alternative medicine for neck and low-back pain. *Evid Based Complement Alternat Med.* 2012;2012:953139.
5. Gao H, Wei C. Extra point acupuncture treatment of 36 cases of acute lumbar sprain [in Chinese]. *Journal of Gansu College of Traditional Chinese Medicine.* 2006;2006:49-50.
6. Haake M, Muller HH, Schade-Brittinger C, et al. German Acupuncture Trials (GERAC) for chronic low back pain: randomized, multicenter, blinded, parallel-group trial with 3 groups. *Arch Intern Med.* 2007 Sep 24;167(17):1892-8. doi: 10.1001/archinte.167.17.1892. PMID: 17893311.
7. Hasegawa TM, Baptista AS, de Souza MC, Yoshizumi AM, Natour J. Acupuncture for acute non-specific low back pain: a randomised, controlled, double-blind, placebo trial. *Acupunct Med.* 2014;32:109-15. [PMID: 24316509] doi:10.1136/acupmed-2013-010333.
8. Jin M, Chen J. Acupuncture treatment for 40 cases of acute lumbar sprain [in Chinese]. *Journal of Gansu College of Traditional Chinese Medicine.* 2008;2006:49-50.
9. Lam M, Galvin R, Curry P. Effectiveness of acupuncture for nonspecific chronic low back pain: a systematic review and meta-analysis. *Spine (Phila Pa 1976).* 2013 Nov 15;38(24):2124-38.

10. Lan J. Analysis of application of acupuncture analgesia in acute lumbar sprain [in Chinese]. *Journal of Community Medicine*. 2009;68-9.
11. Lee JH, Choi TY, Lee MS, Lee H, Shin BC, Lee H. Acupuncture for acute low back pain: a systematic review. *Clin J Pain*. 2013;29:172-85. [PMID: 23269281] doi:10.1097/AJP.0b013e31824909f9.
12. Liu L, Skinner M, McDonough S, Mabire L, Baxter GD. Acupuncture for low back pain: an overview of systematic reviews. *Evid Based Complement Alternat Med*. 2015;2015:328196.
13. Montes LA, Valenzuela MJ. Effectiveness of low back pain treatment with acupuncture [in Spanish]. *Biomedica*. 2017 Jun 2;38(0);54-60. Doi:10.7705/biomedical.v38i0.3546. PMID: 29809328.
14. Standaert CJ, Friedly J, Erwin MW, et al. Comparative effectiveness of exercise, acupuncture, and spinal manipulation for low back pain. *Spine (Phila Pa 1976)*. Oct 1 2011;36(21 Suppl):S120-130.
15. Thomas KJ, MacPherson H, Thorpe L, et al. Randomised controlled trial of a short course of traditional acupuncture compared with usual care for persistent non-specific low back pain. *BMJ*. 2006 Sep 23;333(7569):623. doi: 10.1136/bmj.38878.907361.7C. PMID: 16980316.
16. Vas J, Aranda JM, Modesto M, Benitez-Parejo N, Herrera A, Martinez-Barquin DM, et al. Acupuncture in patients with acute low back pain: a multicentre randomised controlled clinical trial. *Pain*. 2012;153:1883-9. [PMID: 22770838] doi:10.1016/j.pain.2012.05.033
17. Wellington J. Noninvasive and alternative management of chronic low back pain (efficacy and outcomes). *Neuromodulation*. 2014 Oct;17 Suppl 2:24-30.

Evidence for Acupuncture and Pain Management

Additional studies show that acupuncture is an effective pain-management option for chronic pain:

- In 2017, Vickers et al., updated their 2012 meta-analysis of acupuncture research to include trials published through 2015. The research analyzed data from 39 trials and 20,827 patients to show that acupuncture was more effective than both the 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 acupuncture control, and close to 0.2 standard deviations compared with sham acupuncture. The meta-analysis also

found that acupuncture generates long-term pain management, with only a small reduction (approximately 15 percent) in treatment effect at one year.¹

- In Germany, a large-scale observational study examined 454,920 patients diagnosed with one or more sources of chronic pain, including cLBP (45 percent of patients), headache (36 percent), and osteoarthritis (12 percent), who received acupuncture. Physicians rated acupuncture's effectiveness in 22 percent of the patients as marked, 54 percent as moderate, 16 percent as minimal, and 4 percent as poor (unchanged).²
- Another German study involving 340 outpatient acupuncture practices and 1,162 patients with a mean of eight years of cLBP, received 10 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.³

Additional Benefits of Acupuncture

The American College of Physicians cites acupuncture as one of the strongly recommended treatments for back pain in guidelines published⁴ and a number of national and state agencies. A Birch, et al. article states:

...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.⁵

"*The Acupuncture Evidence Project*" recently published a summary of the current evidence for acupuncture and used the GRADE evidence framework to conclude the following:

- Chronic Pain: The effect of a treatment course of acupuncture for individuals with chronic pain appears to persist over 12 months and that such a treatment course is cost-effective.

¹ Vickers AJ, Vertosick EA, Lewith G, et al. Acupuncture for chronic pain: update of an individual patient data meta-analysis. *J Pain*. 2018; 19(5):455–474

² 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.

³ 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.

⁴ Qaseem A, Wilt TJ, McLean RM, Forciea 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

⁵ 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.

- cLBP: Moderate-to-high quality evidence for acupuncture’s effectiveness, cost-effectiveness, and safety exists for individuals with cLBP.⁶

The Department of Veterans Affairs’ *Evidence Map of Acupuncture for Pain* (final page Figure 1), examined all available systematic reviews and randomized-controlled trials and concluded that acupuncture had a “positive effect” on chronic pain, based on recent systematic reviews and randomized-controlled trials.⁷

Evidence for Safety

When performed by properly trained and certified practitioners, acupuncture is widely recognized to be a safe, frequently effective, non-pharmacological option for treating chronic and acute pain syndromes. A 2017 Chan, et al. systematic review concluded that while some adverse events are reported, “all the reviews have suggested that adverse events are rare and often minor.”⁸ Other studies support these findings.^{9,10,11}

Other countries have documented cases of severe adverse events such as pierced brain-stems, spinal lesions, transmitted infectious disease, punctured organs, broken needle migration, and death. These events may be associated with inadequate practitioner competence and training, which sufficient standardized regulations (e.g. NCCAOM certification) can help prevent. The following studies address safety and adverse events with acupuncture treatment:

1. Given, S., “Clean Needle Technique Manual for Acupuncturists: Guidelines and Standards for the Clean and Safe Practice of Acupuncture, 6th Edition,” National Acupuncture Foundation: Nov 2009.
2. Guerreiro de Silva, JB., Saidah, R., Megid, CB., Ramos, NA., “Adverse events following acupuncture: a prospective survey of 13,884 consultations in a university outpatient acupuncture training clinic in Brazil,” *European Journal of Integrative Medicine*. Vol. 6, Aug 2014.

⁶ John McDonald, J., Janz, S. The Acupuncture Evidence Project: A Comparative Literature Review. Jan. 2017.

⁷ Hempel S, Taylor SL, Solloway MR, et al. Evidence Map of Acupuncture [Internet]. Washington (DC): Department of Veterans Affairs (US); 2014 Jan.

⁸ 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)

⁹ 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.

¹⁰ 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.

¹¹ 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.

3. Jaung-Geng Lin, Yi-Hung Chen, Xin-Yan Gao, Lixing Hao, Hyejung Lee, and Gerhard Litscher, "Clinical Efficacy, Mechanisms, and Safety of Acupuncture and Moxibustion," *Evidence-Based Complementary and Alternative Medicine*, vol. 2014, Article ID 356258, 2 pages, 2014.
4. Kim, Me-Riong et al. "Safety of Acupuncture and Pharmacupuncture in 80,523 Musculoskeletal Disorder Patients: A Retrospective Review of Internal Safety Inspection and Electronic Medical Records." Ed. Romy Lauche. *Medicine* 95.18 (2016): e3635. *PMC*. Web. 17 Nov. 2017.
5. Kim, YJ., Kim, SK., Cho, SY., Park, SU., Jung, WS., Moon, SK., Ko, CN., Cho, KH., Kim, SB., Shin WC., Park, JM., "Safety of acupuncture treatments for patients taking warfarin or antiplatelet medications: Retrospective chart review study," *European Journal of Integrative Medicine*, Vol. 6, Aug 2014.
6. 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.
7. MacPherson H, Thomas K., Walters S, et al. The York acupuncture safety study: prospective survey of 34,000 treatments by traditional acupuncturists. *BMJ* 2001; 323:486-87.
8. 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.
9. Wu, J., Hu, Y., Zhu, Y., Yin, P., Litscher, G., & Xu, S., "Systematic Review of Adverse Effects: a Further Step Towards Modernization of Acupuncture in China." *Evidence-based Complementary and Alternative Medicine*. July 2014.

Conclusion

Evidence demonstrating acupuncture's effectiveness on chronic conditions such as low-back pain continue to grow and the NCCAOM appreciates CMS considering this treatment method as a viable service for Medicare beneficiaries. While the evidence base continues to grow, the NCCAOM recognizes that most of the cited studies do not specifically address individuals from the Medicare demographic. The forthcoming AHRQ-sanctioned studies will help close this gap and CMS' coverage will facilitate this research. Existing evidence that shows long-term benefits of an acupuncture treatment course suggests that such a treatment plan could provide steady relief to Medicare beneficiaries from a pain- and opioid-reliance standpoint—as well as long-term cost savings.

In seeking effective methods for treating cLBP, ensuring patient-safety is critical. As such, the NCCAOM commends CMS for requiring current NCCAOM-Board Certification for any individual providing acupuncture in sanctioned research. This criterion ensures that Medicare beneficiaries receive appropriate, safe, and effective care from individuals who have the proper training and experience in acupuncture.

Thank you again for this initiative and the public-comment opportunity. The NCCAOM stands by as resource in providing expertise, evidence, and quality standards to CMS-based acupuncture services.

Sincerely,



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

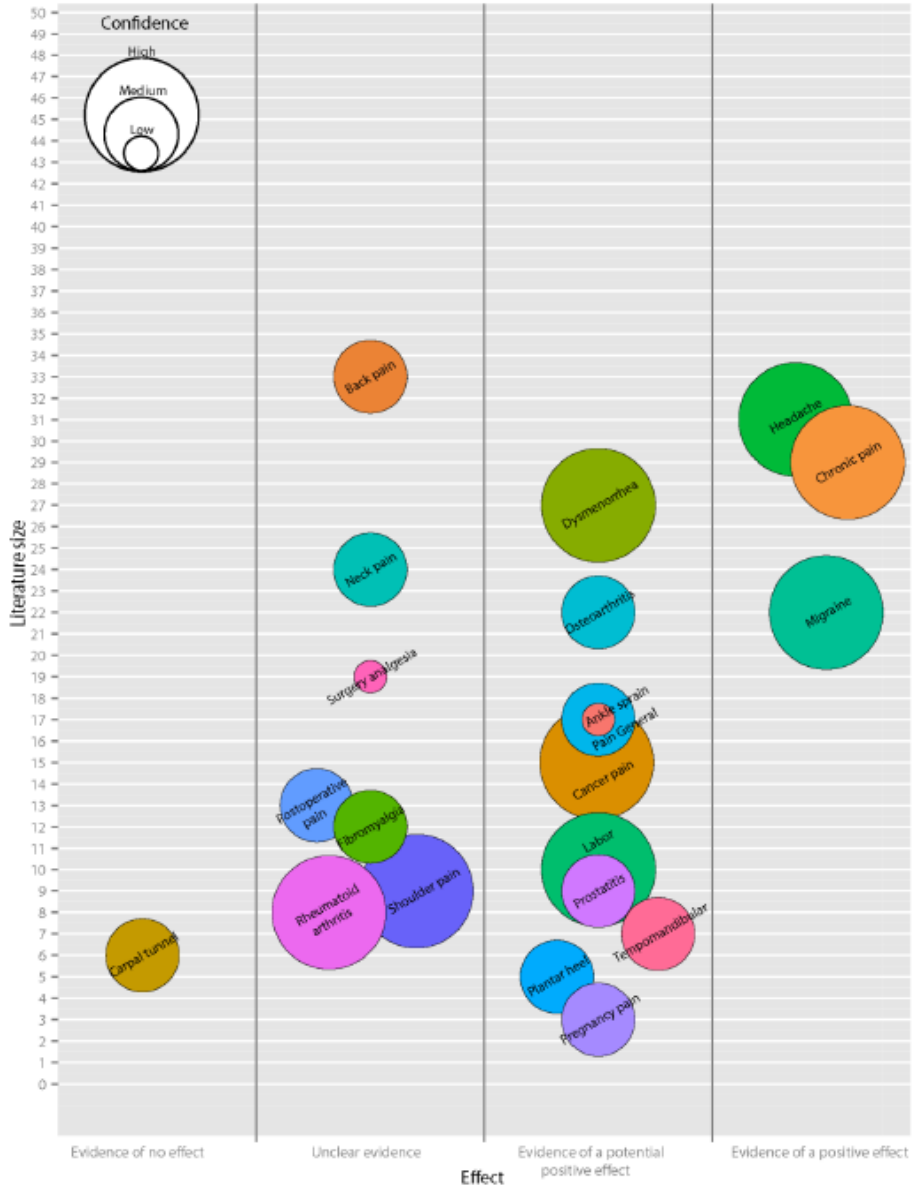


Mina M. Larson, M.S., MBA, CAE
Chief Executive Officer
NCCAOM

Figure 1

EVIDENCE MAP OF ACUPUNCTURE FOR PAIN

The results for the clinical indication Pain are presented in the bubble plot and a text summary below. The bubble plot summarizes the results of 59 systematic reviews for 21 distinct indications relevant to the outcome pain [search date: March 2013].



Legend: The bubble plot shows an estimate of the evidence base for pain-related indications judging from systematic reviews and recent large RCTs. The plot depicts the estimated size of the literature (y-axis, number of RCTs included in largest review), the estimated effect (x-axis), and the confidence in the estimate (bubble size).