ANF Submission to the Centers for Medicare & Medicaid Services Proposed Decision Memo for Acupuncture for Chronic Low Back Pain (CAG-00452N)

August 14, 2019

We appreciate the opportunity to respond to the Proposed Decision Memo regarding acupuncture for chronic low back pain (cLBP).

We first would like to ask for the CMS to correct how it classified the Acupuncture Now Foundation (ANF) in the Proposed Decision Memo. You indicated the ANF was one of several "professional associations" who offered comments. The ANF is not a professional association. We are a public benefit educational non-profit (501c3). Our work focuses on benefiting the public, not the acupuncture profession.

As an organization with the goal of serving the interest of the public, we are concerned by the decision proposed in this memo, as it appears to be at odds with that goal. The opioid crisis is the worst public health epidemic of modern time, wreaking havoc on millions of people and entire communities. It is also a unique epidemic in that it resulted from a tragic failing by key decision-makers to accurately evaluate the benefit-to-harm ratio of a pain management therapy.

The CMS decision-makers now have an opportunity to support the use of a therapy that its own research found to have a much better benefit-to-harm ratio. After months of compiling and evaluating the most recent evidence on acupuncture for cLBP, the CMS' research uncovered a surprisingly high number of systematic reviews/meta-analyses. All eight of these studies were published within the last five years and met CMS' inclusion criteria. Systematic reviews and meta-analyses are high-level research evidence. All eight studies found acupuncture to be effective for cLBP, with some of them verifying acupuncture's excellent safety record, and one endorsing its cost effectiveness. Yet, despite such sound evidence, the CMS is proposing that this is not evidence enough because none of the reviews specifically targeted Medicare-aged subjects.

Some of the studies reviewed by the CMS reported subjects with an average age of up to 59 years. The CMS did not offer, nor were we able to uncover, any scientific evidence or rationale suggesting that acupuncture found to be effective on adults in their 50s would not be effective for those aged 65 and over. Those of us who practice acupuncture on Medicare-aged patients observe little to no change in the level of effectiveness between adult age groups.

Adding to the urgency to expand third-party coverage for acupuncture is the fact that several U.S. evidence-based medical guidelines now recommend acupuncture for chronic pain conditions, including cLBP, but physicians complain that they cannot follow those guidelines due to their patients' lack of insurance coverage for non-drug therapies like acupuncture. In 2017, 37-State Attorney Generals signed a letter to a health insurance lobbying group imploring to expand coverage for non-drug therapies, including acupuncture, to help combat the opioid crisis. Considering Medicare has never covered acupuncture, they could have just as well have addressed that letter to the CMS.

In a July 24th 2019 Washington Post editorial, CMS Administrator Seema Verma wrote about how slow Medicare coverage policies are to adopt new innovations, saying: "The result is innovation stagnation and limited access to new treatments. The president's budget includes several proposals that attempt to address this."

We trust the CMS is sincere in its goal to do all it can to combat the opioid epidemic and understand that doing something as innovative as approving acupuncture for the first time may meet with the innovation stagnation Administrator Verma complained of. While it would be preferable in a perfect world for the CMS to have research that targeted Medicare-aged patients, the world of pain management in the age of the opioid crisis is far from perfect. Considering that cLBP is the top reason why Medicare patients are prescribed opioids, that physicians are being put in a position where they may not be able to follow guidelines recommending acupuncture, and that the CMS has researched eight systematic reviews/meta-analyses all with positive findings, we hope this would prompt the CMS to find a way to confront this stagnation and avoid making Medicare cLBP patients wait years for the results of new studies with no guarantee of coverage even then.

We also hope CMS will be clearer in acknowledging that the studies it already reviewed constitute a strong body of evidence showing that acupuncture is effective for cLBP and that the statement CMS made in the proposed decision memo referring to the evidence as "promising but not convincing" is referring only to Medicare-aged patients. We ask this because acupuncture is constantly questioned by a small group of critics often quoted in the media who claim that its positive clinical results are due to the placebo effect, even though the latest evidence shows otherwise. If the CMS made it clear that the evidence it complied and reviewed was convincing for the adult age groups under 65 years of age, it would help those of us who advocate for the expanded use of acupuncture and its third-party coverage based on the latest evidence.

Opioids kill, acupuncture does not. While this proposed delay goes on, Medicare will continue to cover the cost of opioids and other risky drugs, but not acupuncture. For these reasons, we believe CMS'

decision to at least delay approving coverage for acupuncture for cLBP is a sign of misplaced priorities and we ask CMS to reconsider this proposal.

Our Suggestions and Questions.

We urge CMS to find a way to accept the evidence it already has as sufficient to classify acupuncture for cLBP as medically necessary, even if it is a provisional approval until other studies can be carried out. The state of Missouri is currently taking this approach to curb the opioid crisis, i.e. providing coverage for acupuncture and other non-drug therapies to the state's Medicaid population diagnosed with chronic pain while additional studies are ongoing.
https://dss.mo.gov/mhd/providers/education/files/2019-Complementary-Alternative-Therapy-Training.pdf

If the CMS determines that there is no other path toward approval except collecting data specific to Medicare-aged patients, it could try conducting an individual patient data meta-analysis using raw patient-specific data from the eight trials recently reviewed. This would help CMS understand how many patients of Medicare age were in those trials and what the outcomes among them were. This would be less time-consuming and more cost-effective to complete, as those studies may already provide the additional answers that the CMS seeks regarding Medicare-aged patients.

If the CMS considers it necessary to make cLBP Medicare patients wait on acupuncture coverage until the additional studies are conducted and reviewed, we would like to highlight below some important limitations to the CMS' trial guidelines that should be carefully considered and addressed to allow for better quality research.

Limited Trials vs. Striving for Maximum Therapeutic Benefit

In the comments the Acupuncture Now Foundation submitted to the CMS on this matter in February, we pointed out that due to a lack of clinical practice guidelines for acupuncture practice, many acupuncture studies are conducted in a way that does not allow acupuncture to reach its maximum therapeutic benefit (MTB). There are no trial reporting guidelines (including those in STRICTA) that require researchers to state if their study was attempting to achieve acupuncture's MTB or if it was

designed to only investigate a limited application of acupuncture. While limited-application studies have their place within research, they would not be appropriate for answering the questions the CMS is trying to answer around the effectiveness of acupuncture on Medicare-aged patients suffering from cLBP.

There are two main factors that differentiate studies investigating a limited application of acupuncture from those attempting to achieve MBT. The first is that limited-application studies do not allow for an optimal dosage of acupuncture (frequency and total number of treatments). The second is the involvement of "acupuncturists" with limited training. The proposed "covered indications for CMS approved studies" do not adequately address these two challenges, risking the acceptance of trials that are by design unable to effectively measure the full benefits of acupuncture.

While acupuncture done with sub-optimal treatment dosage or by acupuncturists with sub-optimal training could still yield positive benefits, they will not likely be as effective, thus leading to false negatives. As such, the CMS should not use evidence from limited-application trials as the basis to determine whether acupuncture is medically necessary for cLBP.

Acupuncture is Dose Dependent

Just as a drug trial would need to establish the optimal dosage of the drug being studied to investigate its MTB, studies investigating acupuncture's potential MTB need to establish the adequate dosage of acupuncture. This is achieved through a combination of adequate frequency of treatments over a long enough period of time. CMS is proposing studies utilizing "A minimum 12-week acupuncture intervention". Although 12 weeks is an acceptable minimum timeframe to study acupuncture for cLBP, we are concerned that there are no requirements for a minimum number of treatments throughout the 12 weeks.

In the CMS' decision memo on Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD) (CAG-00449N), the CMS seemed to appreciate the importance of therapeutic dosage in specifying Medicare would cover up to 36 sessions over 12 weeks. 36 treatments over 12 weeks would also be a reasonable protocol for acupuncture treatment frequency for cLBP patients. Although such frequency may appear higher than the average treatment frequency in the U.S., it is cost factors and especially the lack of insurance coverage that limits many patients from getting the optimal number of treatments. In China, where there is socialized medicine, the standard is to start with daily or every

other day treatments, and dozens of treatments are often required to achieve MTB when treating chronic conditions like cLBP. At a minimum, we recommend requiring at least two treatments per week for at least 6-8 weeks that could then tapper down to once a week over the next 4-6 weeks.

In our February submission to CMS, we included a section titled "Acupuncture is Dose Dependent", where we described evidence showing that the effectiveness of acupuncture for chronic conditions increases with more frequent treatments carried out over longer periods of time. We cited references of several acupuncture trials to support this perspective. A good example of a study that utilized an adequate dosage of treatments allowing acupuncture to reach MTB is " Effectiveness of Acupuncture as Adjunctive Therapy in Osteoarthritis of the Knee A Randomized, Controlled Trial" by Brian M. Berman, MD; Lixing Lao, PhD; Patricia Langenberg, PhD; Wen Lin Lee, PhD; Adele M.K. Gilpin, PhD; and Marc C. Hochberg, MD (Ann Intern Med. 2004;141:901-910).

Training and Qualifications of Acupuncturists Involved in Trails

Guidelines regarding who can perform acupuncture in CMS approved studies are unclear. They do not mention the types of providers who would typically have the highest required level of training and competency testing, i.e. Licensed Acupuncturists. It is also unclear whether CMS will allow this type of providers to take part in the studies if they are not licensed as physician assistants or nurse practitioners/clinical nurse specialists (as identified in 1861(aa)(5)). CMS makes it clear that it will allow physicians to furnish acupuncture in these studies "in accordance with applicable state requirements." However, most states do not require physicians to have any training or pass any competency exams in acupuncture. Although STRICTA has a requirement to report the years of experience the participating acupuncturists have, it does not require reporting the acupuncturists' training.

Given these limitations in the requirements for approved studies, CMS could end up accepting studies that involve physicians with no acupuncture training and result in the application of a limited number of treatments, which are factors not conducive for acupuncture to reach its MTB.

As these studies will be employed to determine whether acupuncture is recognized by CMS as medically necessary, we urge the CMS to address these two major challenges in the study design protocol so as to avoid pre-introducing biases into the research. We specifically ask for CMS to clarify both the minimum number of treatments required to be done over the 12-week timeline and to establish guidelines for ensuring that the acupuncturists providing the treatments and developing the clinical protocols in these studies are well trained. The ANF would be happy to work with CMS to improve these protocols.

More on Acupuncturists' Training and Legal Status

We understand that the laws regarding what types of providers can legally practice acupuncture vary from state to state. We also can appreciate that your standards for who can administer acupuncture in these studies may get even more complicated due to Medicare billing requirements. However, there is a real concern among acupuncture providers that the manner in which CMS describes what types of providers will be allowed to perform acupuncture in these studies may disqualify Licensed Acupuncturists as a type of provider who could bill for those services, even in the event of CMS eventually approving the procedure of acupuncture for Medicare coverage.

CMS states that "Auxiliary personnel furnishing acupuncture must be under the direct supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist." It seems the "auxiliary personnel" could be a "Licensed Acupuncturist", although this is not explicit. The vast majority of acupuncture treatments carried out in the U.S. are performed by Licensed Acupuncturists in private practice or in small clinic settings where there is no direct supervision by physicians, physician assistants, or nurse practitioners/clinical nurse specialists. If CMS' current guidelines on who can perform acupuncture in these trials are also being used to test how acupuncture providers could eventually bill Medicare for that procedure, we ask that CMS gives careful consideration to this point. By requiring direct supervision by someone with no required training in acupuncture, CMS is greatly limiting the pool of the most experienced acupuncturists who could potentially participate in these studies and eventually treat and bill under Medicare.

Questions we ask CMS to address:

It is our understanding that CMS will respond to public input and so we ask that you please respond to the following:

Will you state for the record that seeing positive outcomes in research trials of Medicare-aged cLBP patients is the final requirement that acupuncture must meet to be covered by Medicare for cLBP?

How much time do you estimate it will take to conduct and review these studies and, if found medically necessary, approve acupuncture for Medicare coverage for cLBP?

Is it CMS National Coverage Determination policy that you must have studies on Medicare-aged patients before you will consider approving a therapy?

Did the CMS require studies specifically based on Medicare-aged patients for all of the therapies that are currently covered by Medicare for cLBP, such as various physical therapy techniques and medications like opioids? If so, could you please advise where we could find such studies?

If it is CMS policy to require studies on Medicare-aged patients before you can consider approving a therapy, did you consider changing that requirement in light of the dangers of the opioid crisis and can you share why you did not see fit to change that policy?

Current evidence supports the finding of acupuncture as being effective and thus medically necessary for conditions other than cLBP. Does CMS have plans for NCAs for acupuncture for other conditions?

If the CMS is looking at the possibility of considering acupuncture for other medical conditions, will it require the evidence to be specific to Medicare-aged patients in those other conditions as well?

If the CMS is looking at the possibility of considering acupuncture for other medical conditions, and if it will require the evidence to be specific to Medicare-aged patients in those other conditions, are there plans to carry-out studies on Medicare aged patients with other conditions as well?

Can you tell us how the CMS selects advisors to help you undertake an NCA on acupuncture and how those with specialized knowledge could offer their expertise to the CMS ?

We thank you for the opportunity to provide comments on this important policy decision process and we again offer our expertise to support you with this or any further NCAs on acupuncture.

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