Proposed Decision Memo for Acupuncture for Chronic Low Back Pain (CAG-00452N)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Decision Summary

A. The Centers for Medicare & Medicaid Services (CMS) proposes to cover acupuncture under section 1862(a)(1)(E) of the Social Security Act (the Act), with the support of the Agency for Healthcare Research and Quality under section 1142 of the Act. We propose that coverage would be available for Medicare patients with chronic low back pain in clinical trials supported by the National Institutes of Health (NIH) or in CMS approved studies meeting AHRQ criteria.

B. Covered Indications for CMS approved studies

Each study must be approved by CMS and as a fully-described, written part of its protocol, must address and adhere to the following:

- Enrollment of Medicare beneficiaries based on broad eligibility criteria to maximize diversity and minimize intentional or unintentional exclusions based on risk, multi-morbidity, age, health literacy, demographics, or expected adherence.
    - For the purpose of this decision, chronic low back pain (cLBP) is defined as:
        - Lasting 12 weeks or longer;
        - nonspecific, in that it has no identifiable systemic cause (i.e., not associated with metastatic, inflammatory, infectious, etc. disease);
        - not associated with surgery within 12 weeks of enrollment in the study; and
        - not associated with pregnancy.
- A minimum 12-week acupuncture intervention versus usual care or other intervention for chronic low back pain.
- Endpoints must be measured at 12 weeks, 6 months, and 12 months after enrollment, with comparison to usual care, or other planned comparator arm.
- The protocol design must incorporate rigorous controls, prospectively identified, preferably by randomization. If another method is used to generate the comparison group, it should provide comparable rigor.
- Be consistent with for the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) guidelines.

Physicians (as defined in 1861(r)(1)) may furnish acupuncture in accordance with applicable state requirements.

Physician assistants, nurse practitioners/clinical nurse specialists (as identified in 1861(aa)(5)), and auxiliary personnel may furnish acupuncture if they meet all applicable state requirements and have:

- A masters or doctoral level degree in acupuncture or Oriental Medicine from a school accredited by the Accreditation Commission on Acupuncture and Oriental Medicine (ACAOM);
- a current certification by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM); and
- maintained licensure in a U.S. state or territory to practice acupuncture.

Auxiliary personnel furnishing acupuncture must be under the direct supervision of a physician, physician assistant,

or nurse practitioner/clinical nurse specialist.

CMS approved studies must address one or more aspects of the research questions below:

- Does the use of acupuncture for the treatment of cLBP decrease pain and/or increase function?
- Does the use of acupuncture for the treatment of cLBP decrease the use of other continuing medical treatments and services (e.g. opioids)?

Research study designs may include, but are not limited to, randomized controlled trials, observational trials, and registries.

In addition, CMS will review studies to determine if they meet the 13 criteria listed below. If CMS determines that they meet these criteria, the study will be posted on CMS' CED website (https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html).

a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
b. The rationale for the study is well supported by available scientific and medical evidence.
c. The study results are not anticipated to unjustifiably duplicate existing knowledge.
d. The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
e. The study is sponsored by an organization or individual capable of completing it successfully.
f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.
g. All aspects of the study are conducted according to appropriate standards of scientific integrity.
h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).
k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
l. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the

recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, AHRQ supports clinical research studies in clinical trials supported by NIH and other trials that CMS determines meet the above-listed standards and address the above-listed research questions.

The principal investigator must submit the complete study protocol, identify the relevant CMS research questions that will be addressed and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS website.

Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850

C. Nationally Non-Covered Indications

Acupuncture for cLBP provided outside of clinical trials supported by the NIH or CMS approved studies, is non-covered.

See Appendix B for the proposed manual language.

CMS is seeking comments on our proposed decision. We are particularly interested in comments that address current studies of acupuncture (randomized controlled trials, observational trials, and registries) in the Medicare population. We will respond to public comments in a final decision memorandum, as required by §1862(l)(3) of the Social Security Act (the Act).

ProposedDecision Memo

TO: Administrative File: CAG-00452N

FROM: Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group

Joseph Chin, MD, MS
Deputy Director, Coverage and Analysis Group

Lori Ashby, MA
Director, Division of Policy and Evidence Review

Rosemarie Hakim, PhD
Acting Director, Evidence Development Division

Susan Miller, MD
Lead Medical Officer

David Dolan, MBA
Lead Analyst

Xiufen Sui, MD, MS
Biostatistician

SUBJECT: Proposed National Coverage Determination for Acupuncture for Chronic Low Back Pain

DATE: July 15, 2019

I. Proposed Decision

A. The Centers for Medicare & Medicaid Services (CMS) proposes to cover acupuncture under section 1862(a)(1)(E) of the Social Security Act (the Act), with the support of the Agency for Healthcare Research and Quality under section 1142 of the Act. We propose that coverage would be available for Medicare patients with chronic low back pain in clinical trials supported by the National Institutes of Health (NIH) or in CMS approved studies meeting AHRQ criteria.

B. Covered Indications for CMS approved studies

Each study must be approved by CMS and as a fully-described, written part of its protocol, must address and adhere to the following:

- Enrollment of Medicare beneficiaries based on broad eligibility criteria to maximize diversity and minimize intentional or unintentional exclusions based on risk, multi-morbidity, age, health literacy, demographics, or expected adherence.
    - For the purpose of this decision, chronic low back pain (cLBP) is defined as:
        - Lasting 12 weeks or longer;
        - nonspecific, in that it has no identifiable systemic cause (i.e., not associated with metastatic, inflammatory, infectious, etc. disease);
        - not associated with surgery within 12 weeks of enrollment in the study; and
        - not associated with pregnancy.
- A minimum 12-week acupuncture intervention versus usual care or other intervention for chronic low back pain.
- Endpoints must be measured at 12 weeks, 6 months, and 12 months after enrollment, with comparison to usual care, or other planned comparator arm.
- The protocol design must incorporate rigorous controls, prospectively identified, preferably by randomization. If another method is used to generate the comparison group, it should provide comparable rigor.
- Be consistent with for the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) guidelines.

Physicians (as defined in 1861(r)(1)) may furnish acupuncture in accordance with applicable state requirements.

Physician assistants, nurse practitioners/clinical nurse specialists (as identified in 1861(aa)(5)), and auxiliary personnel may furnish acupuncture if they meet all applicable state requirements and have:

- A masters or doctoral level degree in acupuncture or Oriental Medicine from a school accredited by the Accreditation Commission on Acupuncture and Oriental Medicine (ACAOM);
- a current certification by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM); and
- maintained licensure in a U.S. state or territory to practice acupuncture.

Auxiliary personnel furnishing acupuncture must be under the direct supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist.

CMS approved studies must address one or more aspects of the research questions below:

- Does the use of acupuncture for the treatment of cLBP decrease pain and/or increase function?
- Does the use of acupuncture for the treatment of cLBP decrease the use of other continuing medical treatments and services (e.g. opioids)?

Research study designs may include, but are not limited to, randomized controlled trials, observational trials, and registries.

In addition, CMS will review studies to determine if they meet the 13 criteria listed below. If CMS determines that they meet these criteria, the study will be posted on CMS' CED website (https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html).

a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
b. The rationale for the study is well supported by available scientific and medical evidence.
c. The study results are not anticipated to unjustifiably duplicate existing knowledge.
d. The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
e. The study is sponsored by an organization or individual capable of completing it successfully.
f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.
g. All aspects of the study are conducted according to appropriate standards of scientific integrity.
h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).
k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome

measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).

l. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, AHRQ supports clinical research studies in clinical trials supported by NIH and other trials that CMS determines meet the above-listed standards and address the above-listed research questions.

The principal investigator must submit the complete study protocol, identify the relevant CMS research questions that will be addressed and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS website.

Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850

C. Nationally Non-Covered Indications

Acupuncture for cLBP provided outside of clinical trials supported by the NIH or CMS approved studies, is non-covered.

See Appendix B for the proposed manual language.

CMS is seeking comments on our proposed decision. We are particularly interested in comments that address current studies of acupuncture (randomized controlled trials, observational trials, and registries) in the Medicare population. We will respond to public comments in a final decision memorandum, as required by §1862(l)(3) of the Social Security Act (the Act).

II. Background

Throughout this document we use numerous acronyms, some of which are not defined as they are presented in direct quotations. Please find below a list of these acronyms and corresponding full terminology:

ACEP - American College of Emergency Physicians
AHRQ - Agency for Healthcare Research and Quality

AAQ - Association of Acupuncturists Quebec
ANF - Acupuncture Now Foundation
ASA - American Society of Acupuncturists
CMS - Centers for Medicare & Medicaid Services
FDA - Food and Drug Administration
FOA - Funding Opportunity Announcement
NCA - National Coverage Analysis
NCAAOM - National Certification Commission for Acupuncture & Oriental Medicine
NCD - National Coverage Determination
NIH - National Institutes of Health
RCT – Randomized controlled trial
SAR - Society for Acupuncture Research
SMD – Standardized mean difference
SOE – Strength of evidence
STRICTA – Standards for Reporting Interventions in Clinical Trials of Acupuncture
US - United States
VAS – Visual analogue scale
WMD – Weighted mean difference

Chronic Pain

Chronic pain is one of the most common reasons that adults seek out medical care. Its true burden is difficult to assess, in part because the condition has been variably defined in the literature. For example, at times chronic pain is described as lasting at least three months; at other times it is defined as being present six months or more in the past year. Some require that the pain interfere with activities of daily living; others include any severity level of pain within the scope of "chronic" (Toblin, Mack, Perveen & Paulozzi, 2011).

Nevertheless, chronic pain is associated with loss of ability to perform activities of daily living, decreased mobility, opioid dependence, anxiety, depression and reduced quality of life. The Centers for Disease Control and Prevention analyzed data from the 2016 National Health Interview Survey, a cross-sectional, in-person, household health survey of the civilian noninstitutionalized United States population. Based on this information it was estimated that 50 million U.S. adults 18 years or older experience chronic pain (pain on most days or every day in the past six months) and 19.6 million experience high impact chronic pain (chronic pain that limited life or work activities on most days or every day of the past six months). Of individuals 65 years of age or older, approximately 1.4 million of those with both Medicare and Medicaid experience chronic pain and approximately 800,000 experienced high impact chronic pain. Of those individuals with Medicare only, approximately 2.1 million experience chronic pain and over 900,000 experience high impact chronic pain. A higher prevalence of pain was associated with advancing age (Dahlhamer et al., 2018).

Low back pain

Low back pain (LBP) is a common complaint that is experienced by most people sometime in their life (Hoy, Brooks, Blyth & Buchbinder, 2010). In the United States it has been reported that 25 million individuals experience this condition (Bevers, Hulla, Rice, Verdier, Salas & Gatchel, 2017). Further, LBP remained the leading cause of years lived with a disability, both in 1990 and 2016 (The U.S. Burden of Disease Collaborators, 2018).

The differential diagnosis of LBP is extensive. Cancer, infection and inflammatory disorders cause less than 1% of the cases. Structural disorders, such as fractures, stenosis and disc herniations together account for 10-15% of cases. But very commonly (approximately 85% of the time) the cause of LBP is "nonspecific," and it is this disorder

that is most generally associated with chronic or recurrent symptoms (Berman, Langevin, Witt & Dubner, 2010). However, while the structural etiology of the discomfort of chronic low back pain is often uncertain, psychosocial and behavioral factors appear to also influence the experience of low back pain (Berman et al., 2010).

Overall, LBP usually improves and/or resolves rapidly; frequently within four weeks. In those individuals with persistent symptoms, continued improvement is often seen up to 12 weeks. However, in a minority of patients, LBP lasts longer than 12 weeks and levels of pain and disability often remain relatively constant thereafter (Chou et al., 2016).

The literature describing persistent or chronic low back pain (cLBP) has focused on the working age population (Docking et al., 2011). As an example, cLBP in adults of working age (20-69 years old) was studied by the National Health and Nutrition Examination Survey (NHANES) in 2009-2010. Those who reported current pain in the area between the lower posterior margin of the ribcage and the horizontal gluteal fold were asked if they experienced pain, aching or stiffness lasting almost all day for at least three months and if the symptoms remained at the time they were interviewed. An affirmative answer to both questions defined those individuals with cLBP. Of the 700 hundred subjects with cLBP who were studied (out of the 5103 participants who were interviewed in the survey), only about 13% received Medicare benefits (Shmagel, Foley & Ibrahim, 2016).

While perception in the past has been that the prevalence of back pain decreases around the middle of the sixth decade, this conclusion may be a result of heterogeneity in methodology across studies. It has been suggested that though older persons may experience or report less frequent benign or mild back pain, they experience a higher prevalence of episodes of severe symptomatology (Dionne, Dunn, & Croft, 2006). In population based studies, the one year prevalence of LBP in community dwelling seniors ranged from 13 – 50% around the world (Wong, Karppinen & Samartzis, 2017). It is therefore quite possible that disabling back pain increases with aging in the United States. The public health implications of this information are immense.

Treatment

The management of chronic low back pain can take both pharmacologic and non-pharmacologic approaches. Among the drugs widely used for cLBP are prescription opioids. Severe refractory cLBP is the most common chronic non-cancer pain treated with long term opioid medications (Zgierska, Ircink, Burzinski & Mundt, 2017). Though opioid prescribing varies by treatment setting, one systematic review demonstrated that up to 66% of patients with cLBP are prescribed these medications (Martell et al., 2007). This therapy is associated with many harms, including addiction and overdose death (Zgierska et al, 2017). In 2016 alone, over 17,000 persons in the United States died from circumstances involving prescription opioids (Centers for Disease Control and Prevention, 2018).

Successful nonpharmacologic treatments may potentially decrease the need for, and the side effects of, assorted medications which are used to treat cLBP. Nonpharmacologic therapies have included various physical treatments, including acupuncture (Galicia-Castillo & Weiner, 2018).

Acupuncture

The origins of acupuncture are traditionally attributed to China, dating back approximately 3000 years in its earliest forms (Hao & Mittelman, 2014). The first documentation that described acupuncture as an organized system of diagnosis and treatment was written around 100 BCE (White & Ernst, 2004; Hao & Mittelman, 2014).

Western medical acupuncture refers to a modern adaptation "using current knowledge of anatomy, physiology and pathology, and the principles of evidence based medicine" (White, 2009). While there is a diversity of theoretical

models and techniques that are all described as acupuncture, all models and forms seek to treat symptoms and conditions through either: 1) the insertion of needles or "needling" at specifically chosen points on the body, or 2) other "non-needling" techniques focused on these points. Modern medical acupuncturists chose anatomically and physiologically important treatment points which may include both traditional acupuncture points and other non-traditional fixed points. "More attention is focused on the tissue level (eg, muscle rather than skin) and the type and amount of stimulation given" (White, 2009) as well. Western medical acupuncture has been an available treatment modality in the UK and other countries for many years. In the US, the Veterans Health Administration covers medical acupuncture for certain patients.

As we noted in our 2003 decision memos, there are several variations to traditional acupuncture including shallow needling, intradermal needling or intramuscular needling with or without a sensation of numbness, tingling, electrical sensation, fullness, distension, soreness, warmth or itching felt by a patient around an acupuncture point. Acupuncturists may additionally seek a sensation of tenseness or dragging to the needles obtained by twirling, plucking or thrusting of acupuncture needles. There are also numerous variations of manually or electrically stimulated "needling" techniques, as well as multiple "non-needling" acupuncture techniques.

The mechanism of action of analgesia secondary to acupuncture is unclear, possibly multimodal. However there are some physiologic effects that have been noted with its use. For example, it is thought that the immediate analgesic effects of acupuncture may be dependent on neural neural (nerve) innervation. Acupuncture has also been shown to induce the release of endogenous opioids in various parts of the brain. Local tissue effects including release of adenosine at the site of needle stimulation have also been observed as have increases in local blood flow. Other modes of action have been reported including local and myofascial trigger point needling effects, segmental pain effects, extrasegmental pain effects, and central regulatory effects (White, Cummings & Filshie, 2008).

III. History of Medicare Coverage

Currently, acupuncture is not covered by CMS. National Coverage Determination (NCD) for Acupuncture (30.3), issued in May 1980, states that Medicare reimbursement for acupuncture, as an anesthetic or as an analgesic or for other therapeutic purposes, may not be made. Accordingly, acupuncture was not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

In 2004, CMS considered the use of acupuncture for fibromyalgia and determined that there was no convincing evidence for the use of acupuncture for pain relief in patients with fibromyalgia (NCD 30.3.1; 2004). Similarly in that same year, CMS concluded that there was no convincing evidence for the use of acupuncture for pain relief in patients with osteoarthritis (NCD 30.3.2, 2004).

A. Current Request

CMS opened this national coverage determination (NCD) analysis to complete a thorough review of the evidence to consider coverage of acupuncture for chronic low back pain. CMS recognizes that the evidence base for acupuncture has grown in recent years, as noted in systematic evidence reviews evaluating non-pharmacological treatments for chronic pain.

B. Benefit Category

Medicare is a defined benefit program. For an item or service to be covered by the Medicare program, it must fall within one of the statutorily defined benefit categories outlined in the Social Security Act.

Acupuncture qualifies as:

- Incident to a physician's professional service (§ 1861(s)(2)(A))
- Inpatient Hospital Services (§ 1861(b))
- Outpatient Hospital Services Incident to a Physician's Service (§ 1861(s)(2)(B))
- Physicians' Services (§ 1861(s)(1))

Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

IV. Timeline of Recent Activities

Date	Action
January 15, 2019	CMS opens an NCA for Initial 30-day public comment period begins.
February 14, 2019	First public comment period ends. CMS receives 755 comments.
July 15, 2019	Proposed Decision Memorandum posted. 30-day public comment period begins.

V. Food and Drug Administration (FDA) Status

Acupuncture needles are classified by the FDA as a class II device, subject to special controls, as outlined in 21 CFR 880.5580, and exempt from premarket notification requirements, subject to certain limitations as outlined in 21 CFR 880.9. An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle and may have a handle attached to facilitate delivery of acupuncture. The device is subject to special controls with respect to labeling, biocompatibility and sterility and general controls, including but not limited to, labeling, good manufacturing practices, and registration and listing. The full product classification for acupuncture needles can be viewed at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=2692.

VI. General Methodological Principles

When making national coverage determinations, CMS generally evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for beneficiaries. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the Agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix A.

Public comments sometimes cite published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. Public comments that contain personal health

information will not be made available to the public. CMS responds in detail to the public comments on a proposed national coverage determination when issuing the final national coverage determination.

VII. Evidence

A. Introduction

This section provides a summary of the evidence we considered during our review. The evidence reviewed to date includes the published medical literature on acupuncture for chronic nonspecific low back pain. For this national coverage analysis (NCA), we reviewed the published medical literature in the form of systematic reviews and meta-analyses from 2014 to 2019, to determine if acupuncture for chronic nonspecific low back pain is reasonable and necessary.

B. Discussion of Evidence

1. Evidence Question(s)

Our review and analysis of the evidence concerning the clinical utility of acupuncture for chronic low back pain, and thus whether acupuncture for chronic low back pain is reasonable and necessary to treat certain Medicare patients, is guided by the following question:

Is the evidence sufficient to conclude that acupuncture improves health outcomes for Medicare beneficiaries with chronic low back pain?

2. External Technology Assessments

CMS did not request an external technology assessment (TA) on this issue.

3. Internal Technology Assessment

Literature Search Methods

For the purpose of this analysis, we reviewed systematic reviews/meta-analyses of randomized trials for the previous five years. We believe that the literature searches performed by these studies provide an adequate historical background to the subject matter discussed in this National Coverage Analysis. We identified studies in OVID and EMBASE using search terms such as acupuncture, chronic pain, chronic low back pain, systematic review and meta-analysis. The studies compared the use of acupuncture, sham acupuncture, and/or placebo acupuncture to either usual care/routine care/conventional care for low back pain (including medications), acupuncture + usual care, acupuncture + other treatments, sham acupuncture, no treatment, or wait list. Required outcomes included pain, function, drug use, and/or quality of life (including sleep quality). Of the references found, we read through the titles and abstracts to find those that met the criteria below. Further, we also reviewed references submitted to us by commenters and performed a hand search of bibliographies to identify other pertinent literature for our review.

Our evidence review comprised systematic reviews/meta-analyses studying adults with chronic pain of the low back, defined as pain lasting 12 weeks or longer. We further required the pain to be described as nonspecific, in that it had no identified cause and/or was stated to not be associated with metastatic, inflammatory, infectious, etc.

disease. Our review did not consider the outcomes of acupuncture on acute low back pain or pain associated with pregnancy or surgery.

Many systematic reviews/meta-analyses investigated the relationship of acupuncture therapy to painful conditions outside of the inclusion criteria noted above. These studies were retained in our analysis as long as there was a defined subgroup of investigations that met our criteria. We did not describe, nor discuss, the additional information found in these studies as it was considered to be outside the scope of this National Coverage Analysis.

Further, our search for guidelines relating to the treatment of acupuncture for cLBP was limited to those of the United States.

Systematic Reviews/Meta-Analyses

Chou R, Deyo R, Friedly J, et al. Noninvasive Treatments for Low Back Pain. Comparative Effectiveness Review No. 169. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2012-00014-I.) AHRQ Publication No. 16-EHC004-EF. Rockville, MD: Agency for Healthcare Research and Quality; February 2016. www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Chou R, Deyo R, Friedly J, et al. Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. Ann Intern Med. 2017;166(7):493-505. doi: 10.7326/M16-2459. Epub 2017 Feb 14.

Note: The methods for this review are found in Chou, et al., 2016. Results of the review, after an extended literature search was performed, are found primarily in Chou et al. 2017 and supplemented with information from Chou et al, 2016.

The goal of this systematic review was to examine the evidence concerning the comparative benefits and harms of nonpharmacologic, noninvasive treatments for low back pain. Literature searches were performed in the following databases: Ovid MEDLINE (January 2008 – November 2016), the Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews (through November, 2016). A prior systematic review with searches through October, 2008 (American Pain Society/American College of Physicians) was also examined for pertinent earlier studies.

Randomized trials of various therapies for low back pain were analyzed in the article's one systematic review focusing on the use of acupuncture for this condition. This systematic review was comprised of 32 trials (n = 5931; range 16-2831), and was supplemented with six additional randomized trials (n = 864; range 80 – 275). Treatments were compared with sham (functionally inert), no treatment, wait list or usual care (usually defined as provided at the discretion of the clinician). Comparisons of one therapy against another were also searched.

The pertinent population of interest was adults with chronic (≥ 12 weeks) low back pain. Excluded conditions were low back pain due to cancer, infection, inflammatory arthropathy, high-velocity trauma, or fracture; low back pain during pregnancy; and low back pain associated with the presence of severe or progressive neurologic deficits. Outcomes were short (≤ 6 months) or long (≥ one year) term pain, function, return to work or harms.

Magnitude of effects for pain and function classification			
	Slight/Small	**Moderate**	**Large/Substantial**
Pain	5-10 points on a 0-100	> 10-20 points on a 0-100 point	> 20 points on a 0-100 point

	VAS	VAS	VAS
Function	1-2 points on RMDQ	> 2-5 points on the RMDQ	> 5 points on the RMDQ
Pain or Function	0.2-0.5 SMD	> 0.5-0.8 SMD	> 0.8 SMD
RDMQ: Roland Morris Disability Questionnaire; SMD: Standardized mean difference; VAS: visual analogue scale			

The systematic review found that acupuncture was associated with lower pain intensity (4 trials: SMD:-0.72 [CI: -0.94 to - 0.49, I^2=51%]) and better function (3 trials: SMD: -0.94 [CI: - 1.41 to - 0. 47, I^2=78%]) immediately after the intervention compared with no acupuncture. Mean effects of pain ranged from 7-24 points on a 0-100 point scale; for function one trial reported an 8 point difference on a 0 – 100 point scale and two trials reported differences of 0.8 and 3.4 points on the Roland Morris Disability Questionnaire. In the long term, two trials showed small or no clear differences.

Comparing acupuncture with sham acupuncture revealed that pain intensity decreased more with the former than the latter immediately after the intervention (4 trials: WMD -16.76 [CI: -33.3 to -0.19, I^2=90%]) and up to 12 weeks (3 trials: WMD -9.55 [CI: -16.5 to -2.58, I^2 = 40%]) with no differences in function.

Five trials that were either not included in the systematic review or could not be pooled in the results revealed similar findings. The mean age of the study participants in these trials ranged from 31 to 51.7 years.

The systematic review also found that acupuncture resulted in greater pain relief (3 trials: WMD -10.56 on a 0-100 point scale) [CI: -20.34 to -0.78, I^2 = 0%]) and better function (3 trials: SMD -0.36 [CI: -0.67 to -0.04, I^2 = 7%]) when compared with medications (non-steroidal anti-inflammatory drugs, muscle relaxants or analgesics) immediately after the intervention.

The authors presented the following information to summarize their findings:

Intervention	**Magnitude of effect (Pain)**	**Evidence**	**Strength of Evidence**	**Magnitude of effect (Function)**	**Evidence**	**Strength of Evidence**
Acupuncture vs sham acupuncture	Moderate	1 SR (4 RCTs) + 5 RCTs	low	no effect	1 SR (4 RCTs) + 5 RCTs	low
Acupuncture vs no acupuncture	Moderate	1 SR (4 RCTs)	moderate	moderate	1 SR (4 RCTs)	moderate
Acupuncture vs medications	Small	1SR (3 RCTs)	low	small	1SR (3RCTs)	low
RCT: randomized controlled trial; SR: systematic review						

Overall, the authors concluded that the evidence supported the benefits of acupuncture for cLBP. Heterogenity of the evidence was noted by the authors, in that acupuncture trials varied in needling sites, length, number and duration

of sessions, and type of sham (e.g. nonpenetrating needles at acupuncture sites versus penetrating needles at nonacupuncture sites). An examination of the harms of acupuncture revealed no serious harms, though such occurrences were found to be poorly reported (SOE: low).

Skelly AC, Chou R, Dettori JR, et al. Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review. Comparative Effectiveness Review No. 209. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2015-00009-I.) AHRQ Publication No 18-EHC013-EF. Rockville, MD: Agency for Healthcare Research and Quality; June 2018.

The purpose of this review was to assess whether acupuncture for chronic low back pain could improve function and decrease pain for at least one month after treatment. The literature search was performed through November 2017, in Ovid MEDLINE, Cochrane Central Register of Controlled Trials, and Cochrane Database of Systematic Reviews. Reference lists and ClinicalTrials.gov also served as data sources. However primary studies of cLBP treatment published prior to and through 2016 were derived from the review noted above by Chou, et al., 2017.

The systematic review focused on the durability of treatment effects, defined as at least one month following the end of a course of treatment, as described in randomized controlled trials. Duration of follow-up post intervention was categorized as short term (1 to < 6 months), intermediate (≥ 6 to < 12 months), and long term (≥ 12 months). The included studies addressed efficacy or harms compared with usual care, placebo/sham intervention, or attention control. Studies of combination or adjunctive treatments were excluded. Primary outcomes were function and pain. The effects for measures were classified generally on a 0-100 scale for pain or function as slight/small (5-10 points), moderate (> 10-20 points), or large/substantial (> 20 points). The moderate range for functional outcomes roughly corresponded to reported minimum clinically important differences for the measure.

The studies included evaluated adults with chronic pain defined as lasting 12 weeks or longer or pain persisting past the time for normal tissue healing. Individuals younger than 18, pregnant or breastfeeding were excluded from study as were patients with chronic pain related to "active" cancer, infection, and inflammatory arthropathy. Those individuals experiencing radiculopathy, low back pain associated with severe or progressive neurological deficits, failed back surgery syndrome, neuropathic pain and pain at the end of life, were also excluded as was treatment delivered in a hospital, hospice or emergency department.

The authors evaluated eight trials of acupuncture for low back pain. All trials evaluated needle acupuncture to body acupoints; one trial also evaluated electroacupuncture. Sample sizes ranged from 40 to 1162 (total n = 2621). Comparators included sham acupuncture (four trials), usual care (three trials), a placebo intervention of sham cutaneous electrical nerve stimulation (two trials), and self-care education (one trial). The duration of acupuncture therapy ranged from 6 to 12 weeks provided in 6 to 15 sessions. Trials were conducted in the United States or Europe (seven trials) and one trial was conducted in Asia. One trial reported long term outcomes, four trials reported intermediate outcomes and the rest reported only short term outcomes. Trials were rated either to be of good quality (one), fair quality (five) or poor quality (two). Limitations that were noted included unblinded investigations, uncertain means of allocation concealment or randomization, and large attrition rates. Mean ages of all studied groups (intervention and control) ranged from 42 to 59 years.

The authors presented the following chart to summarize their findings regarding the treatment effects of acupuncture on chronic low back pain.

Intervention	Function (short term)	Function (intermediate term)	Function (long term)	Pain (short term)	Pain (intermediate term)	Pain (long term)
Acupuncture	slight	none	none	slight	none	slight

	+	+	+	++	+	+

Short term: 1 to < 6 months; Intermediate term: ≥ 6 to < 12 months; Long term: ≥ 12 months
Effect size: none, slight/small, moderate, or large improvement

Strength of evidence: + = low; ++ = moderate; +++ = high

The authors concluded that for chronic low back pain, compared with usual care, attention control, sham, or placebo, there was low evidence of slight improvement in function, at least in the short term, for acupuncture (SOE: low). Acupuncture also showed slight improvement in pain short term (SOE: low). No clear improvement in function was seen at intermediate term for acupuncture (SOE: low). Acupuncture was not associated with improved function long term, even though it demonstrated continued pain improvement (SOE: low).

The authors also reported that no trial evaluated effects of acupuncture on use of opioids. Harms were reported in a limited manner, but the existing evidence indicated no clear difference between acupuncture and comparators in terms of risk of study withdrawal due to adverse events. Furthermore, serious adverse events were rare with both acupuncture and the control interventions.

Tice JA, Kumar V, Otuonye I, et al. Cognitive and Mind-Body Therapies for Chronic Low Back and Neck Pain: Effectiveness and Value, Final Evidence Report, November 6, 2017. The Institute for Clinical and Economic Review (ICER), prepared for the California Technology Assessment Forum. Retrieved on May 13, 2019 form https://icer-review.org/wp-content/uploads/2017/03/CTAF_LBNP_Final_Evidence_Report_110617.pdf

The Institute for Clinical and Economic Review (ICER) performed a systematic review of acupuncture for the treatment of cLBP in adults 18 years and older to explore effective alternatives to both opioid therapy and invasive options for chronic pain.

Chronic low back pain was defined by the presence of symptoms for at least 12 weeks and was not due to cancer, infection, inflammatory arthropathy, high velocity trauma fracture or pregnancy. Further, the cLBP was not associated with progressive neurologic deficits. Primary outcomes sought were pain, function, depression, disability, quality of life and harms of treatment. The comparators for the acupuncture treatment were usual care or a sham/placebo intervention. Evidence on intervention effectiveness focused on studies of at least six months duration or studies of more limited duration with outcomes accessed at least four weeks after the cessation of active therapy (intermediate term). However trials with long term outcomes (one year or more) were preferred. All relevant settings were considered, with a focus on outpatient settings in the United States.

During the initiation of this review, the American College of Physicians (see Qaseem, 2017 below) released a guideline based on a systematic review of non-invasive interventions for low back pain performed by the Agency for Healthcare Research and Quality (see Chou, 2016, above). The authors of this investigation used the review as the basis of their own study, supplemented by newer randomized trials. However they found no new trials published since the AHRQ review (see Chou, 2017 above) in the databases searched (MEDLINE/PubMed, EMBASE and the Cochrane Central Register of Controlled Trials).

The authors found that the evidence for the effectiveness of acupuncture for the treatment of cLBP is complex. The majority of the evidence confirmed small to moderate improvements in function and pain compared with usual care immediately following the completion of therapy. However the authors stated that the differences in outcomes were smaller and often non-significant clinically as compared with sham acupuncture, suggesting much of acupuncture's benefit may be from a placebo effect. They also stated that the magnitude of the benefits decline with longer follow up and noted that many of the reviewed studies were small, had less than one year of follow up and there were inconsistencies in the results. However the harms of acupuncture treatment for cLBP were noted to be uncommon

and generally mild.

The net health benefit of acupuncture for the treatment of cLBP was assessed to be small, with a moderate certainty of a "comparable or better" evidence rating ("Comparable or better" benefit was defined as moderate certainty of a comparable, small or substantial net health benefit, with high certainty of at least a comparable net health benefit).

The authors concluded that acupuncture was comparable or better when added to usual care (physician recommendations, educational handouts with oral analgesics and physical therapy) for cLBP.

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. doi: 10.1016/j.jpain.2017.11.005. Epub 2017 Dec 2. PMID: 29198932.

The purpose of this article was to update a 2012 report of an individual patient data meta-analysis of trials of acupuncture for chronic pain. The literature search for the current analysis identified RCTs published between December 2008 and December 2015 that evaluated pertinent subjects with the following characteristics: non-specific [low] back pain lasting at least four weeks (see note below for further information); at least one studied group received acupuncture needling while the controls received either sham acupuncture or no acupuncture treatment; the primary endpoint was measured more than four weeks after the initial acupuncture treatment; and allocation concealment was adequate. Excluded from nonspecific back pain was that associated with specific pathologies (e.g. osteoporotic fracture) (Vickers, Cronin, Maschino, et al., 2010).

Note: This review contained information on various chronic musculoskeletal complaints. Of the trials concentrating on musculoskeletal pain, the authors note that "most" musculoskeletal conditions had an eligibility criterion of a minimum three to six months. However, they further note that the two trials for which the time period between first symptom and evaluation of outcome could be less than three months were those pertaining to chronic neck pain and rotator cuff tendonitis. As neither neck nor rotator cuff related pain was considered for this NCD, this investigation was included in our internal technology assessment as we interpreted the back pain data to meet our timeline for the definition of chronic pain.

Raw data from eligible studies was requested in order to replicate all analyses performed in the original publications so that data accuracy was ensured. The effect sizes for each study were entered into a meta-analysis where fixed and random effects estimates were calculated. Meta-analyses were separately performed to compare acupuncture versus sham acupuncture and acupuncture versus no acupuncture control within the population of patients at interest.

The authors reported that in the seven studies of back pain evaluated comparing acupuncture to sham acupuncture (n = 1614), acupuncture was demonstrated as statistically superior [fixed effects estimate 0.17 (95% CI: .07 - 0.26); random effects estimate .30 (95% CI: 0.08 - 0.52); heterogeneity p value <.001]. The Forest plot of these results showed that the confidence intervals in five of the seven studies crossed or were at zero. The authors further reported that in the nine studies (n = 4570) of back pain comparing acupuncture to a no acupuncture control, acupuncture was also demonstrated as statistically superior [fixed effects estimate: 0.46 (95% CI: 0.41 - 0.50); random effects estimate 0.52 (95% CI: 0.37 - 0.67); heterogeneity p value <.001]. The Forest plot of these results showed that the confidence intervals in three of the nine studies crossed or were at zero.

The authors' conclusions to their findings were generalized to all conditions studied and were stated to confirm that acupuncture has a clinically relevant effect compared with no acupuncture control. They also concluded that although the effects of acupuncture are not completely explicable in terms of placebo effects, factors other than the specific effects of needling at correct acupuncture point locations are important contributors to acupuncture treatment benefit. The authors also noted that sham acupuncture may be a physiologically active intervention.

Xiang Y, He J, Li R. Appropriateness of sham or placebo acupuncture for randomized controlled trials of acupuncture for nonspecific low back pain: a systematic review and meta-analysis. J Pain Res. 2018 (11):83-94. doi: 10.2147/JPR.S152743. eCollection 2018. PMID: 29343984.

The purpose of this systematic review and meta-analysis was to determine if sham acupuncture (SA), also known as placebo acupuncture (PA), performed away from the acupuncture points established by traditional Chinese medicine, or without stimulation and manipulation, or using a non-penetrating technique, improves LBP as compared to routine care.

The systematic review included RCTs published in either Chinese or English, with at least two control arms: a sham controlled acupuncture group and a routine care or waiting list group (individuals who did not receive acupuncture until the end of treatment) or those who received no treatment. Various databases were searched for appropriate articles (up through May 31, 2017) to include in this review, including the Cochrane Central Register of Controlled Trials, the Cochrane Library, PubMed, EMBASE, the China National Knowledge Infrastructure, the Wan Fang database and the Wei Pu database.

Among the inclusion criteria were: age greater than 18 years and lower back pain or myofascial pain in the lower back. Individuals with specific pathological etiologies to their LBP (e.g. infection, metastatic disease, neoplasm, osteoarthritis, rheumatoid arthritis, inflammatory processes, radicular syndrome, and fractures) were excluded from the investigation. Patients with sciatica as the major symptom or whose LBP was associated with a surgery, pregnancy or post-partum status, were also excluded. Chronic LBP was defined as that greater than 12 weeks.

Studies were included in which acupuncture points were stimulated by needle insertion (with/without electroacupuncture) accompanied by a definite sensation of "De Qi". De Qi sensation has been defined by the National Cancer Institute as tingling, numbness, heaviness, and other feelings that occur after an acupuncture needle has been properly placed in the body. The needle may be twirled, moved up and down at different speeds and depths, heated, or charged with a small electric current until the de qi sensation occurs (National Cancer Institute, NCI Dictionary). Also included were trials assessing the efficacy of acupuncture administered as an adjunct treatment to other therapies compared with SA/PA also administered as an adjunct treatment to other therapies. Studies that investigated acupressure, transcutaneous electrical nerve stimulation, infrared light for verum (true) acupuncture, bee venom acupuncture and ear acupuncture were excluded. Trials comparing two techniques of acupuncture were also excluded.

The type of SA/PA included in the investigated trials was noted to be a superficial insertion method at non-acupuncture points, a toothpick in a needle guide tube, penetration at nonspecific acupuncture points following usual procedure, and needles with blunt and retractable tips (but true acupuncture points were treated.

The data extracted from the studies included outcome measures reported immediately following and for up to one week after the end of the treatment sessions. Random effects models were used for all meta-analyses. The magnitude of the effect size was categorized as follows: small effect (0.2); moderate effect (0.5); large effect (0.8). RCTs were included if at least pain intensity (e.g. visual analogue scale [VAS]) or a back specific functional measure (e.g. Roland-Morris Disability Questionnaire) was utilized as an outcome.

Though most of the article compared combined results from acute and chronic low back pain patients, the authors performed two subgroup analyses pertinent to individuals with only chronic low back pain. These subgroup analyses were not originally planned within the protocol. Mean ages of the subjects ranged from mid-40s to 59 years.

In individuals with chronic low back pain who received SA/PA compared to those who received routine care (4 trials), the mean difference in VAS was -9.62 [95% CI: -13.89, -5.36] in favor of those receiving SA/PA (Tau^2 = 5.07; df =

3 (p=0.17); I^2= 41%). Test for overall effect produced a Z score = 4.42 (p= 0.00001). In individuals with chronic low back pain who received SA/PA compared to those who received routine care (1 trial), the mean difference in the Roland Morris Disability Questionnaire score was -3.5 [95% CI: -4.70, -2.30] in favor of those receiving SA/PA (Test for overall effect produced a Z score = 5.74 (p= 0.00001).

The authors concluded that the data were consistent with pain differences in favor of SA/PA versus routine care for individuals with cLBP. But they stated that there were no differences found in those with cLBP for the Roland Morris Disability Questionnaire score. The authors also stated that in clinical trials of acupuncture, the sham or placebo control should be indistinguishable from the active treatment, as well as also be physiologically inert. Additionally, variations in acupuncture technique must be considered, including needle placement, needle insertion, acupuncture points (or non-acupuncture points), and therapist experience, so as to distinguish real acupuncture from that designated the control. Additionally they noted that future research should focus on the standardization of outcome measures as well as the duration and frequency of symptoms.

Because SA/PA could function similarly to real acupuncture, the authors suggested that SA/PA may not be appropriate for acupuncture research. Moreover, they state guidelines should be developed to assess acupuncture sham/placebo controls. To promote homogenous information in the acupuncture literature, the Consolidated Standards of Reporting Trials (CONSORT) should be used. Further, the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) should be used to report interventions. Further studies to assess the superiority of SA/PA over routine care and wait listing should be performed.

Yeganeh M, Baradaran HR, Qorbani M, Moradi Y, Dastgiri S. The effectiveness of acupuncture, acupressure and chiropractic interventions on treatment of chronic nonspecific low back pain in Iran: A systematic review and meta-analysis. Complement Ther Clin Pract. 2017 May;27:11-18. doi: 10.1016/j.ctcp.2016.11.012. Epub 2016 Nov 30. PMID: 28438274.

The pertinent objective of this review was to assess the effectiveness of acupuncture for the treatment of chronic nonspecific low back pain in Iran, compared with sham or placebo intervention, other medical treatments or no treatment.

The authors reviewed all published and non-published reports of completed randomized controlled trials that were 1) reported in English or a Persian language, 2) evaluated non-pregnant adults > age 15 with chronic (>12 weeks) nonspecific LBP (alone or with leg pain) 3) evaluated acupuncture and 4) reported on at least one of the following outcomes: back-specific function, generic health status, pain, work disability, patient satisfaction and functional status expressed by validated instruments, such as the Roland Morris Disability Questionnaire, McGill Pain Questionnaire, SF-36 (the MOS 36-item short-form survey), or the Oswestry Disability Index.

LBP was defined as pain localized from the costal margin or twelfth rib to the inferior gluteal fold. "Nonspecific" LBP was defined as that with no specific cause detectable or associated, such as infection, neoplasm, cancer/metastasis, osteoporosis, rheumatoid arthritis, fracture, inflammatory process, radicularsyndrome, fibromyalgia, acute major trauma or cauda equine syndrome.

The authors searched the following databases for studies published from 1990–2012: CINAHL, MEDLINE, EMBASE, Institute for Scientific Information, Scopus, and IranMedex and Irandoc (Farsi language web-based data centers) web-based information and documentation centers. The bibliography of all articles were also searched for references of other studies. Authors of incomplete or unpublished articles were contacted up until December 2011 requesting details of their trials.

The authors evaluated three studies (mean age of subjects between 30 and 60 years) comparing various

combinations of acupuncture, pharmacologic treatment and no treatment. Two studies compared acupuncture to Piroxicam, 30 mg/day for 2 weeks. Acupuncture was provided in four sessions over two weeks. The difference in pain between baseline and two and four weeks, as measured by a visual analogue scale, was reported. Acupuncture was noted to be more effective than Piroxicam.

One other study compared acupuncture and acupuncture plus Baclofen (30 mg/day for five weeks) to Baclofen and a non-treatment. Acupuncture was performed for four sessions over two weeks. The primary outcome was pain (as measured by a visual analogue scale) and pain disability. The difference between baseline and one (pain intensity only), five and ten weeks was noted. The authors stated that acupuncture and acupuncture plus Baclofen were more effective than Baclofen.

An overall meta-analysis (n = 144) comparing acupuncture with pharmacologic treatment (using a random effects analysis) was performed. The standardized mean difference of these three studies as calculated by the authors at follow up week 2 (for the outcome of pain) was -0.99 [95% CI:-2.03, 0.04, I^2 = 88.0%; P < 0.001]; at follow up week 6 (for the outcome of pain) was -2.42 [95% CI:-4.35,- 0.49, I^2 = 94.7%; P < 0.001].

The authors concluded that based on low quality evidence, acupuncture may have a favorable effect on pain and functional limitations caused by nonspecific cLBP. However, the lack of studies with a low risk of bias precluded strong conclusions. Further research, along with discussions of the clinical relevance of findings, was noted to be required. Researchers were encouraged to follow the CONSORT statement for reporting trials.

Yuan Q, Guo T, Liu L, Sun F, Zhang Y. Traditional Chinese medicine for neck pain and low back pain: a systematic review and meta-analysis. PLoS One. 2015; 10(2):e0117146. doi: 10.1371/journal.pone.0117146. eCollection 2015. PMID: 25710765.

The relevant objective of this study was to determine if treatment with acupuncture provides better pain relief or improvement in disability as compared with other therapeutic approaches for people with cLBP.

The following databases were searched from their inception until May 25, 2014 for the systematic review: MEDLINE, EMBASE, the Cochrane Library and the Traditional Chinese Medical Literature Analysis and Retrieval System and China National Knowledge Infrastructure and the Wan Fang database. Randomized controlled trials (RCTs) meeting all of the following criteria were included in the relevant systematic review: (1) the work was published either in English or Chinese; (2) the subjects included were adults ≥ 17 years of age, with or without radiating pain; (3) at least one of the therapies assessed was acupuncture; (4) a comparison was made between acupuncture and other treatments (e.g. acupuncture versus other treatment, acupuncture versus no treatment, acupuncture plus other treatment versus other treatment); (5) at least one of the following outcomes was evaluated: pain intensity or disability; (6) the principle summary measures were commonly used, such as pain intensity (e.g., visual analogue scale,) and disability (e.g., Oswestry Disability Index (ODI); (7) the duration of follow-up was at least one day after all treatment sessions were concluded. Trials of back pain caused by trauma, infection, cauda equina syndrome, bone rarefaction, compression fracture of a vertebral body, tumor, or fibromyalgia were excluded.

Chronic pain was defined as that which was greater than or equal to three months. Post interventional follow up periods were defined as immediate term (≤ 1 week), short term (≤ 3 months), intermediate term (~ 3-12 months), and long term (≥ 1 year). Side effects, if present, were documented. If the data permitted such an assessment and there was statistically significant differences across the pooled data in pain relief or disability improvement, the rating of clinical importance was defined as:

> Small: a weighted mean difference (WMD) less than 10% of the scale (e.g., < 10 mm on a 100 mm VAS); a standardized mean difference (SMD) or "d" score < 0.5; a relative risk of < 1.25 or > 0.8 (depending on

whether the report referred to the risk of benefit or the risk of harm, respectively);

Medium: a WMD from 10–20% of the scale; an SMD or "d" score from 0.5 to 0.8; a relative risk between 1.25 and 2.0 or between 0.5 and 0.8 (depending on the factor described above);

Large: a WMD > 20% of the scale; an SMD or "d" score ≥ 0.8; a relative risk > 2.0 or < 0.5 (depending on the factor described above)

The authors highlight the below:

Acupuncture versus Sham acupuncture

Ten studies investigated cLBP (n = 1864). Nine studies (n = 1387) demonstrated that acupuncture was clinically superior to sham acupuncture for cLBP immediately post-treatment (SMD = -0.49, 95% CI-0.76 to-0.21) and up to 3 months post-treatment (SMD = -0.45, 95% CI -0.76 to -0.14) in terms of pain relief. However, these results were highly heterogeneous across studies (I^2 = 72.8% and 76.9%, respectively). The source of these heterogeneities was not apparent. No significant differences in terms of improvement in disability were observed between groups.

The authors specifically noted that the difference in clinical importance between acupuncture and sham acupuncture was small. They further note that a standardized sham acupuncture has not been established, making it difficult for researchers to choose acupoints for subjects in the sham group. Therefore it is possible that the effect of true acupuncture can be underestimated.

Acupuncture versus waitlist (no treatment)

Four trials (n = 2911) compared acupuncture with no treatment with respect to pain relief and disability improvement for cLBP. All four studies that evaluated the immediate relief of pain showed superiority in favor of acupuncture (SMD = -0.73, 95% CI -0.96 to -0.49). Three studies concerned with function revealed a significant advantage favoring acupuncture immediately post treatment (SMD = -0.95, 95% CI -1.42, -0.48).

Acupuncture versus TENS

Two studies (n = 70) compared acupuncture with TENS for cLBP and showed no significant differences between groups with respect to pain, not only in the immediate term (p = 0.81) but also at short term follow-up (p = 0.33). Functional status was not assessed.

Acupuncture versus medications

Six studies (n = 242) comparing acupuncture with medications for pain relief at immediate term had a pooled WMD of -0.52 (95% CI, -1.27 to 0.23, VAS 10 cm). Four studies (n = 186) compared disability at immediate term between acupuncture and medications. The estimated SMD was -0.23 (95% CI, -0.52 to 0.06). However, these differences were not statistically significant. The heterogeneities regarding pain and disability were small.

Acupuncture plus usual care (care, if any, chosen by patients themselves and/or their physicians, including massage, physical therapy, medications) versus usual care

Five studies (n = 320) demonstrated a significant difference in VAS scores in favor of acupuncture administered concomitantly over usual care for pain associated with cLBP immediately post-intervention (WMD = -11.47, 95% CI -

19.33 to -3.61, I^2 = 59.9%). Four studies (n = 195) were pooled investigating functional status and results in favor of the intervention group were found at follow-up (SMD = -0.55, 95% CI -1.00 to -0.10). However, function at immediate term showed no difference between groups (p = 0.231).

Acupuncture versus usual care

Six studies (n = 443) compared mean pain score between acupuncture and usual care. All six studies reported the pain at immediate term. The SMD in the random-effects model was -1.56 (95% CI, -2.45 to -0.67), which was in favor of acupuncture. However this was highly heterogeneous across studies (I^2 = 93.2%; p = 0.000). The source of this heterogeneity was not apparent.

Side effects of acupuncture

The authors also documented reported side effects from two acupuncture trials. These side effects included temporary worsening of LBP, pain, bruising at the site of needle insertion, shoulder pain, pain/numbness or other side effects in the leg and knee, redness and minor bleeding at the acupuncture site.

The authors concluded that several studies demonstrated that there was low strength evidence that acupuncture was more effective than sham acupuncture, waitlist care or usual care in reducing the pain and disability of cLBP immediately post treatment.

The authors also commented that findings of low strength of evidence meant that future research may change the results of the field. They also noted heterogeneities of the studies that could introduce weaknesses in the methodologic quality of the studied trials such as (1) differences in acupoints from study to study, as well as patient to patient (though they note such differences in design are inherent in trials where the selection of treatment sites is individualized to the patient); (2) the wide age span of the individuals studied (17-90 years); (3) the different countries of origins of the study participants; and (4) the variation in number, duration and intervals of treatment sessions. The authors suggested that in general, studies with higher quality methodology, longer term follow up and more standardized treatment are needed to produce a more homogenous set of evidence in this field.

Zeng Y and Chung JW. Acupuncture for chronic nonspecific low back pain: An overview of systematic reviews. European Journal of Integrative Medicine. 2015; 7(2): 94-107. doi.org/10.1016/j.eujim.2014.11.001.

The article's objective was to summarize and evaluate the available systematic reviews on the clinical effectiveness of acupuncture for chronic nonspecific LBP and to identify the safety of this treatment technique.

Systematic reviews of acupuncture and chronic nonspecific LBP, published between January, 2003 and May, 2014, were sourced from Medline, the Cochrane Library, Allied and Complementary Medicine Database, Scopus, and the Chinese Academic Journal full text database. Articles published in English and Chinese were included. Inclusion criteria for systematic reviews included a study population with chronic (duration of symptoms > 12 weeks) nonspecific LBP (pain of no known underlying pathology or disease; pain not related to pregnancy). Exclusion criteria comprised systematic reviews of populations with acute (< six weeks) or subacute (3-12 weeks) LBP or LBP caused by specific pathological disorders such as infection, inflammatory disorders, systemic or metastatic diseases.

Acupuncture was defined as a process involving needles to be inserted into the skin (without an injection) at classical meridian points, extra points or Ah-shi points (painful points), accompanied by a definite feeling of "De Qi." De Qi was defined as "a sensation of numbness or distention sometimes generated by stimulating acupuncture needles by hand or with an electrical current." Sham acupuncture was defined as any intervention designed to make patients

believe that they were receiving acupuncture by either puncturing a location near the acupoint with tingling only (but not De Qi), or by delivering a simulated acupuncture technique using a toothpick or other needle-like object in the needle guide tube. Acupuncture that did not involve needle insertion such as laser acupuncture, or electro-acupuncture without needles, was excluded.

Outcome measures included pain intensity, patient global assessment of pain and specific functional measures related to chronic nonspecific LBP. Other outcome measures included the presence and frequency of adverse events.

Evaluating systematic reviews and meta-analyses which only included RCTs, the authors stated that there was consistent evidence that acupuncture was more effective than no treatment/waiting list controls with effect sizes that range from 0.49 to 0.69. They also stated that there is relatively consistent evidence that acupuncture is more effective than sham acupuncture with overall effect sizes ranging from 0.26 to 0.54.

Further statements of the authors indicated that acupuncture added to conventional therapy was better than conventional therapy alone (e.g. physiotherapy, standard medical care, exercise) but that the evidence is conflicting as to whether or not acupuncture is more effective than other active treatments (e.g. massage, spinal manipulative therapy). Moreover the authors stated that there was inconclusive evidence about the most effective acupuncture technique.

The authors also noted that adverse effects of acupuncture were only minor, including soreness/pain at the site of the needling, minor bleeding, dizziness or headache. Therefore they concluded it was a relatively safe procedure.

In summary the authors concluded there is consistent evidence that acupuncture is more effective than no treatment, waiting list control, sham acupuncture and when acting as an adjunct treatment modality for the management of cLBP. Further they stated that that there is conflicting evidence whether acupuncture is more effective than other treatment modalities. The authors concluded that the evidence reviewed indicates that acupuncture should be considered as one of the active treatment options for chronic low back pain.

The article noted that it has been reported that the 'core components' of an 'adequate' acupuncture protocol consist of acupoint selections, number of points needled, depth of insertion, responses elicited, needle stimulation- method and strength, needle retention time, needle types and the experience of the acupuncturist. They believe that future trials are needed to establish the standardization of these characteristics as well as to compare the effectiveness of different acupuncture techniques.

4. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

A MEDCAC meeting was not convened on this issue.

5. Evidence-Based Guidelines

The pertinent evidence-based guidelines are summarized below.

American Chronic Pain Association Resource Guide to Chronic Pain management, An Integrated Guide to Medical, Interventional, Behavioral Pharmacologic and Rehabilitation Therapies. Feinberg S (ed.) American Chronic Pain Association Inc., Rocklin, California. 2019. Retrieved May 13, 2019 from: https://www.theacpa.org/wp-content/uploads/2019/02/ACPA_Resource_Guide_2019.pdf

The American Chronic Pain Association Resource Guide combines practical pain experience and scientific information to provide an educational and informative format for consumers and professionals. Input is gathered from many sources including both individuals and industry. The Guide is written, reviewed and updated yearly.

The Guide states that there is a strong body of research supporting the efficacy of acupuncture for low back pain (as well as other conditions).

Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive Treatments for Acute, Subacute and Chronic Low Back Pain: A Clinical Guideline from the American College of Physicians. Ann Intern Med. 2017; 166(7):514-530. doi: 10.7326/M16-2367. Epub 2017 Feb 14.

The pertinent portions of this guideline from the American College of Physicians provide treatment guidance based on the efficacy, comparative effectiveness and safety of noninvasive nonpharmacologic treatments for chronic low back pain (> 12weeks) in primary care.

The American College of Physicians stated that low quality evidence demonstrated that acupuncture was associated with moderate improvement in pain relief immediately after treatment and up to 12 weeks later compared with sham acupuncture. However there was no improvement in function. Further, compared with no acupuncture, moderate quality evidence demonstrated that acupuncture was associated with moderately lower pain intensity and improved function at end of treatment. A small improvement in pain relief and function was noted in low quality evidence when acupuncture was compared to medications (non-steroidal anti-inflammatory drugs, muscle relaxants or analgesics).

Moreover, low quality evidence demonstrated no reported harms or serious adverse events associated with acupuncture.

In summary, the American College of Physicians stated that acupuncture had a moderate effect on pain and function compared with no acupuncture (moderate quality evidence) and a moderate effect on pain with no clear effect on function compared with sham acupuncture (low quality evidence). The College provided a strong recommendation that nonpharmacologic treatments, including acupuncture, should be selected for first line treatment of chronic low back pain (low quality evidence), because of the paucity of harms associated with them, compared to pharmacologic therapies. The College also stated that it is important that physical therapies be administered by providers with appropriate training.

VA/DoD Clinical Practice Guideline for Diagnosis and Treatment of Low Back Pain. Department of Veterans Affairs, Department of Defense. Version 2.0 – 2017. Retrieved on May 13, 2019 from:
https://www.healthquality.va.gov/guidelines/Pain/lbp/VADoDLBPCPG092917.pdf

This Clinical Practice Guideline (CPG) focuses mainly on the management of patients with axial/nonradiating LBP, rather than specific underlying causes. It was developed by a panel of multidisciplinary experts from the VA and DoD. Based on a systemic review of clinical and epidemiologic evidence, these individuals assessed the direction (for/against) and relative strength (strong or weak) of various recommendations regarding the diagnosis and treatment of LBP. The direction indicates that the desirable effects of the recommendation outweigh the undesirable effects of the recommendation (for) or that the opposite is true (against). The strength indicates the level of confidence in the balance of desirable and undesirable effects of the recommendation among the intended patient population. A strong recommendation indicates that there is confidence in this balance (e.g., that the desirable effects outweigh the undesirable effects). A weak recommendation indicates that the balance is still likely, but confidence in the balance is lower than for a strong recommendation.

The clinical studies and systematic reviews used for this CPG were published between December 1, 2006 and October 21, 2016. The searched databases included those of AHRQ, the Canadian Agency for Drugs and Technologies in Health, CINHAL, the Cochrane Library, EMBASE.com, Healthcare Standards, National Guideline Clearinghouse, National Institute for Health and Care Excellence, PsycINFO, and PubMed. For a study to be included, 80% of the patient population (or designated subgroup) were required to have LBP and be 18 years of age or older. Excluded diagnoses were spondylolisthesis, post-operative LBP and pregnancy related back pain. A focus group was also convened to discuss patient perspectives regarding the treatment of LBP. All such participants had experienced LBP for at least one year.

Chronic pain was denoted as that occurring more than 12 weeks.

The CPG concluded that the offer of acupuncture for patients with cLBP was a 'weak/for' recommendation, meaning that acupuncture was suggested (but not recommended) to be offered to those individuals with cLBP. According to the authors' discussion, acupuncture appears to help patients in the long term (three to six months). There was moderate quality evidence to support the use of acupuncture for modest long-term improvements in disability and the perceived impact of pain associated with chronic LBP. Data were inconclusive regarding general quality of life and adverse events. It was noted that there was variation in comparator groups; standard acupuncture was compared to sham acupuncture with blunt needles, intensive inpatient rehabilitation, or back pain acupuncture. There was also large variation in patient preferences and acceptance of acupuncture. It was stated that clinicians should consider personal preferences and focus on shared decision making when offering acupuncture to patients.

6. Professional Society Recommendations / Consensus Statements / Other Expert Opinion

Because an internet search located only a few statements exclusively addressed acupuncture for chronic nonspecific low back pain, we have also included in this section professional recommendations/consensus statements regarding the general use of acupuncture for analgesia.

Complementary and Integrative Health (CIH) Resource Guide. Version 2. Office of Patient Centered Care and Cultural Transformation (OPCC&CT). Last Update: October 2017. Retrieved April 18, 2019 at: https://n1s1t23sxna2acyes3x4cz0h-wpengine.netdna-ssl.com/wp-content/uploads/2017/12/CIH-Resource-Guide_Final-Sept-2017-3.pdf.

The Integrative Health Coordinating Center (IHCC) in collaboration with the IHCC Advisory Workgroup (IHCCAW) has identified CIH approaches for inclusion in VA's medical benefits package. These approaches have been vetted by IHCCAW and found to have published evidence of promising or potential benefit. VA must provide a mechanism to offer these approaches either within the VA facility or in the community if they are recommended by the Veteran's health care team. As of September 28, 2017, this list of CIH approaches approved by the USH includes:

a. **acupuncture**
b. meditation
c. yoga
d. tai chi
e. guided imagery
f. hypnosis
g. biofeedback
h. massage

Further, the VHA has approved the request to establish the profession of Acupuncture to be covered under 38 U.S.C. §7401(3) and for the development of qualification standards under this authority; meaning that the VA will be able to

hire acupuncturists as Hybrid Title 38 employees to provide acupuncture service to Veterans. [Emphasis added]

National Academies of Sciences, Engineering, and Medicine. 2017. Pain management and the opioid epidemic: Balancing societal and individual benefits and risks of prescription opioid use. Washington, DC: The National Academies Press. doi: https://doi.org/10.17226/24781. Retrieved April 17, 2019 at https://www.nap.edu/read/24781/chapter/5#84.

This document states that systematic reviews evaluating the effect of acupuncture in treating pain from a variety of conditions, have revealed mixed results. Some reviews have found minimal or no effect, while others have found acupuncture to be superior to sham acupuncture and placebo, and still others have concluded that data are insufficient to support a recommendation. Recent reviews and meta-analyses examining the effect of acupuncture on musculoskeletal pain (neck and back pain, osteoarthritis, chronic headache, shoulder pain, fibromyalgia) have found that overall, acupuncture is superior to sham and no acupuncture, but with relatively modest differences between true and sham acupuncture. Although it has been suggested that acupuncture is an effective treatment for pain, additional factors, such as potent placebo and context effects, may play a role in its observed effect as well.

R3 Report | Requirement, Rationale, Reference: A publication of The Joint Commission (Issue 11, August 29, 2017). Retrieved April 18, 2019 at: https://www.jointcommission.org/assets/1/18/R3_Report_Issue_11_Pain_Assessment_8_25_17_FINAL.pdf.

Requirement: The hospital provides nonpharmacologic pain treatment modalities.

Rationale: While evidence for some nonpharmacologic modalities is mixed and/or limited, they may serve as a complementary approach for pain management and potentially reduce the need for opioid medications in some circumstances. The hospital should promote nonpharmacologic modalities by ensuring that patient preferences are discussed and, at a minimum, providing some nonpharmacologic treatment options relevant to their patient population. When a patient's preference for a safe nonpharmacologic therapy cannot be provided, hospitals should educate the patient on where the treatment may be accessed post-discharge. Nonpharmacologic strategies include, but are not limited to: physical modalities (for example, **acupuncture therapy**, chiropractic therapy, osteopathic manipulative treatment, massage therapy, and physical therapy), relaxation therapy, and cognitive behavioral therapy. [Emphasis added]

The Joint Commission: Pain Management - Leadership Responsibilities for Providing Nonpharmacologic Modalities for Managing Pain - LD.04.03.13 EP 2; Retrieved April 17, 2019 at https://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFaqId=1881&ProgramId=46.

Organizations are required to provide non-pharmacologic pain treatment modalities relevant to its patient population and assessed needs of the patient. These modalities serve as a complementary approach for pain management and may potentially reduce the need for opioid medication in some circumstances.

Additionally, it is important to have non-pharmacologic pain treatment modalities available for patients that refuse opioids or for whom physicians believe may benefit from complementary therapies. Non-pharmacologic strategies include, but are not limited to transcutaneous electrical nerve stimulation, physical modalities (i.e.: **acupuncture therapy**, chiropractic therapy, osteopathic manipulative treatment, massage therapy, and physical therapy) relaxation therapy, music therapy, cognitive behavioral therapy, etc. The level of evidence for these therapies is highly variable, and it is evolving. Therefore, our standards do not mandate that any specific complementary options are provided, but allow organizations to determine what modality(s) to offer. [Emphasis added]

Organizations should ensure that patient preferences for pain management are considered, and, when a patient's preference for a safe non-pharmacologic therapy cannot be provided, provide education to patients on where the treatment may be accessed post-discharge. There is not an expectation that the hospital will fulfill any and all requested non-pharmacologic therapies during the inpatient stay."

7. Public Comment

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination.

CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum. All comments that were submitted without personal health information may be viewed in their entirety by using the following link https://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=295.

Initial Comment Period: 1/15/2019 – 2/14/2019

During the initial 30-day public comment period CMS received 755 comments. Of these 755 comments, 329 were omitted from publication on the CMS website due to excessive personal health information content. The vast majority of the comments received supported CMS coverage of acupuncture for chronic low back pain. Most of the commenters supporting coverage made reference to the opioid epidemic, and that acupuncture is a safe and effective non-pharmacologic treatment option for patients suffering from chronic pain. Most of the commenters also mentioned that acupuncture is a cost-effective treatment option for chronic low back pain. There were a few commenters that did not support CMS coverage of acupuncture, stating that it is a "pseudoscience" that lacks a standard of care and credentialing training body. Most of these commenters also made reference to the lack of science supporting the effectiveness of acupuncture, indicating that positive results can be attributed to a placebo effect.

The majority of comments were provided by licensed acupuncturists and other healthcare professionals, as well as commenters that did not specify their titles and/or organizations. There were eight comments that represented seven professional associations, including the Acupuncture Now Foundation (ANF), American College of Emergency Physicians (ACEP), Association of Acupuncturists Quebec (AAQ), The Academic Consortium for Integrative Medicine & Health (the Consortium), Society for Acupuncture Research (SAR), National Certification Commission for Acupuncture & Oriental Medicine (NCAAOM), American Society of Acupuncturists (ASA). Additional group comments were submitted by Advocate Aurora Health, the Cleveland Clinic, and America's Health Insurance Plans.

VIII. CMS Analysis

Introduction: National coverage determinations are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act (§1869(f)(1)(B)) by Medicare (§1862(l) of the Act). Among other things, in order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A) of the Act).

In addition to §1862(a)(1)(A) of the Act, a second statutory provision may permit Medicare payment for items and

services in some circumstances. That statute, section 1862(a)(1)(E) of the Act, provides, in pertinent part, that:

> (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—
> . . .
> (1)(E) in the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section.

Section 1142 of the Act describes the authority of the Agency for Healthcare Research and Quality (AHRQ) to conduct and support research on outcomes, effectiveness, and appropriateness of services and procedures to identify the most effective and appropriate means to prevent, diagnose, treat, and manage diseases, disorders, and other health conditions. That section includes a requirement that the Secretary assure that AHRQ research priorities under Section 1142 appropriately reflect the needs and priorities of the Medicare program.

Evidence Review Summary:

For this reconsideration, CMS focused on the following question:

Question: Is the evidence sufficient to conclude that acupuncture improves health outcomes for Medicare beneficiaries with chronic low back pain?

While we believe the evidence is promising, we do not believe the evidence is sufficient at this time for representative older patients with chronic nonspecific low back pain. We believe additional research would be needed in order to make a favorable coverage determination under § 1862(a)(1)(A) but, with AHRQ's support, will propose to cover acupuncture for chronic low back pain in appropriate clinical studies in order to provide access for certain Medicare beneficiaries while developing additional evidence on this treatment.

Quality and strength of evidence

The majority of reviewed studies incorporated placebo or sham acupuncture methodology into their trial design as a comparator to true acupuncture. The purpose of these placebo/sham comparators is to blind the study subjects; in other words to provide a comparable treatment to a true acupuncture intervention that is both indistinguishable from true acupuncture and inactive in its physiologic mechanisms. In doing so, the study design helps to eliminate the bias of conscious or unconscious preference that affects human response to healing therapies and therefore helps to maintain an objective atmosphere as possible when comparing two or more treatments.

In acupuncture studies, various methods are used to produce a sham or placebo control. For example, trials have used superficial/shallow needling of true acupuncture points, needling of true acupuncture points that were not indicated for the condition being treated and thus considered ineffective, the insertion of needles at sites outside true acupuncture points, and devices that mimic acupuncture but do not break the skin (Dincer & Linde, 2003). Such methods may not be fair control groups to true acupuncture. Because they may induce a clinical modification of pain perception as they all involve the touch of the skin, such sham/placebo methodology has been thought of as a diluted dose of acupuncture, but still physiologically active (Taylor-Swanson, Stone, Gale, et al., 2018).

In our review, six published systematic evidence reviews (Chou, 2017; Skelly, 2018; Tice, 2017; Vickers, 2018; Yeganeh, 2017; Yuan, 2015) on several trials (e.g., the review by Chou included 8 trials on low back pain) reported overall small to moderate benefits of acupuncture with few serious harms. The systematic reviews evaluated appropriate pain and functional outcomes. However, the quality of evidence was low to moderate and a number of limitations of the evidence base were reported. It has been noted by several authors that some studies have shown

little or no difference between true acupuncture and sham/placebo acupuncture, suggesting that differing methods of acupuncture applied either both produce similar results and/or that neither one has any significant effect upon a patient's pain (Walji and Boon, 2006). As noted above, this appears to indicate the need for well-designed studies with appropriate control groups.

We note that some studies compared acupuncture therapy to conventional therapies. Many of these studies demonstrated an improvement with acupuncture that exceeded the outcome provided by the more traditional treatment. However, we are unaware if these conventional treatments had previously been applied in individuals with chronic nonspecific low back pain and failed to reduce their symptoms or level of disability.

Importantly we did not find published studies that enrolled sufficient representative Medicare patients who have chronic low back pain. We note that studied populations (where such information was available) do not necessarily represent Medicare's largest beneficiary group; that being individuals over the age of 65. The largest United States study to date of acupuncture for cLBP was performed in patients up to the age of 65, with a median age of 47 years (HEAL Initiative, 2019). Additionally, trials differ considerably regarding whether or not a decrease in pain allows functional improvements to be observed.

Overall, our analysis indicates that the reviewed studies showed that acupuncture is promising in the treatment of chronic low back pain. Because published studies to date have not enrolled any or adequate numbers of Medicare patients, generalizability is a question. Additional evidence is needed to determine whether acupuncture improves health outcomes for Medicare patients with chronic nonspecific low back pain. Several professional societies and experts (such as the American Pain Association and American College of Physicians) also supported acupuncture as a nonpharmacologic treatment option to consider.

Coverage of Research under § 1862(a)(1)(E)

As was described in the Background section of this NCA, pharmacologic treatments, and opioids in particular, are often prescribed for treatment of cLBP. Opioid therapy is associated with addiction and death; it has reached epidemic proportions in the United States. In response to the country's opioid crisis, the Department of Health and Human Services is focused on reducing the extreme consequences of opioid use, in part by supporting more nonpharmacologic treatment options for chronic pain.

In the systematic reviews noted above, it was demonstrated that acupuncture can improve pain for varying periods of time in persons with chronic nonspecific LBP, however, this published research has not included representative Medicare patients. In light of the opioid crisis, CMS believes that the published evidence on acupuncture provides sufficient evidence to provide coverage within the context of well-designed clinical studies.

We note that there are differences in applied acupuncture techniques that may affect the outcome of investigations where acupuncture has been compared to various other treatments/no treatment. For example, sites of needle insertion, duration and frequency of sessions, and whether or not needles are manipulated during the session, may account for heterogeneity in systematic reviews/meta-analyses. Similarly the diversity of training, experience and skills of the acupuncturist, plus differences in the patient – practitioner interaction, may unevenly influence the outcomes of studies thought otherwise to be similar (Molsberger, Mau, Gotthardt, Schneider & Drabik, 2004; Walji & Boon, 2006). To ensure a standardized approach to investigative studies, these characteristics must be carefully described in the investigative protocol and reported in the scientific literature.

Therefore, CMS, with the support of AHRQ, proposes to collaborate with the NIH to further develop the evidence on this intervention, under § 1862(a)(1)(E). AHRQ believes that NIH is positioned to rapidly begin the work necessary to advance medical knowledge concerning acupuncture and more specifically, its impact upon chronic nonspecific low

back pain in older adults, through oversight of the design and execution of unbiased research methodology.

The NIH is poised to begin funding research to evaluate the impact of acupuncture treatment in adults 65 years and older with chronic low back pain through its Helping to End Addiction Long-term (HEAL) Initiative. The purpose of the HEAL Initiative is to find scientific solutions to the national opioid public health crisis. The NIH HEAL Initiative will bolster research across NIH to both improve treatment for opioid misuse and addiction and enhance pain management (HEAL Initiative, 2019).

As part of the HEAL Initiative, the NIH has now administered a Funding Opportunity Announcement (FOA) to encourage research applications to conduct an efficient, large scale, pragmatic trial to evaluate the impact of, and strategies to best implement, acupuncture treatment of adults 65 years and older with chronic LBP. Trials will be conducted across two or more health care systems, in a manner to determine the effects of acupuncture under the usual conditions in which it will be applied. Awardee(s) will work with the resources of the NIH in both the planning and implementation of their trials in order to overcome the barriers presented by working across various health care systems, including the capture of outcomes through the use of electronic health records, ensuring diversity of the study population, and developing an analytic strategy to produce meaningful results (HEAL Initiative, 2019).

The NIH is providing substantial research planning support to the recipients of its HEAL Initiative grants. CMS can provide payment for items and services used in this research for acupuncture for chronic low back pain for Medicare beneficiaries enrolled in clinical trials sponsored by the NIH. By focusing on older adults and addressing the limitations of previous published research, evidence derived from this initiative would assist CMS in determining future Medicare coverage for acupuncture treatment for cLBP.

In addition, CMS is also proposing to cover acupuncture for cLBP in CMS approved studies that meet criteria established and supported by AHRQ. Consistent with previous research, we propose cLBP be defined as lasting for 12 weeks or longer; nonspecific, in that it has no identifiable systemic cause (i.e., not associated with metastatic, inflammatory, infectious, etc. disease); not associated with surgery within 12 weeks of enrollment in the study; and not associated with pregnancy.

CMS further proposes to require that all CMS approved studies be consistent with the STRICTA (Standards for Reporting Interventions in Clinical Trials of Acupuncture) guidelines. The STRICTA reporting guidelines, first published in 2001 and revised further throughout the years, were designed to improve the completeness and transparency of reporting of interventions in controlled trials of acupuncture to improve the interpretation and replicability of these investigations. Though the resources of the NIH and CMS differ, we believe that the STRICTA criteria are consistent with those of the HEAL Initiative (MacPherson, Altman, Hammerschlag, et al., 2015).

The STRICTA checklist of information when reporting interventions in a clinical trial of acupuncture includes descriptions of all of the below:

1. Acupuncture rationale including a description of the style of acupuncture, reasoning for the treatment provided and extent to which the treatment varied;
2. Details of the needling, including number of needle insertions per session; names or locations of points, depth of insertion, response sought (de qi or muscle twitch), type of needle stimulation (e.g. manual or electrical), needle retention time, and needle type;
3. Treatment regimen including number, frequency, and duration of sessions;
4. Other components of treatment of the intervention group including other therapies being provided as well as the setting and context of the treatment, including instructions provided to investigative practitioners and information/explanations provided to patients;
5. Description of practitioner background including the qualifications of the participating acupuncturists, years in

practice and other relevant experiences;
6. Control or comparator interventions including precise description of the method selected and its rationale (MacPherson et al., 2015).

To ensure the quality of services received by Medicare beneficiaries, as is also required by the Veterans Health Administration, licensed acupuncturists who provide acupuncture services for Medicare beneficiaries must have a masters or doctoral level degree in acupuncture or Oriental Medicine from a school accredited by the Accreditation Commission on Acupuncture and Oriental Medicine (ACAOM), have current certification by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM), and maintain licensure in a U.S. state or territory (Olson, 2018). Physicians who wish to furnish acupuncture to Medicare beneficiaries may do so in accordance with applicable state requirements (Lin & Tung, 2017).

In order to produce meaningful patient results, protocols should use outcomes that foster reproducibility and comparability of different investigations. A number of research entities and agencies including AHRQ have been involved in efforts to harmonize outcomes including pain measures in acupuncture research (https://pdfs.semanticscholar.org/de4f/a9311d706b740309051d67595e144f25eff9.pdf). Additional examples of core instruments for patient reported outcomes representing pain and function measures, including the NIH PROMIS®, for individuals with chronic nonspecific LBP are also described at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5828378/). The use of validated core outcome sets in research studies will facilitate future evidence synthesis and ability to inform practice and policy.

CMS believes that the proposed criteria for CMS approved studies, including the description of the STRICTA criteria, is consistent with the HEAL Initiative.

Health Disparities

In addition to its reported physiologic effects, acupuncture has been stated to demonstrate psychologic effects; and in particular those associated with patient perceptions, beliefs and expectations (Yuan, Wang, Liu et al. 2016). As culture is defined as the beliefs and attitudes that are learned and shared by members of a group, cultural beliefs help to shape that which constitutes illness and its accepted means of treatment (Juckett, 2005; Mao, Wax, Barg, Margo & Walrath, 2007). In fact, it has been found that patterns of complementary and alternative medicine (CAM) use among ethnic and socioeconomic subgroups of the United States reflect cultural differences in approaches to health and illnesses (Mao et al., 2007).

The evidence reviewed above did little to delineate those subsets of individuals within the Medicare population who may/may not be responsive to acupuncture for relief of their cLBP based on cultural beliefs. Additionally other predictors of acupuncture use related to patient characteristics (e.g. age, gender, race, education, etc.) are similarly important to study (Austin, Ramamonjiarivelo, Qu, & Ellis-Griffith, 2015). We encourage future investigators to investigate these factors which may be relevant to improving the evidence base.

Summary

CMS recognizes the current opioid epidemic in the United States, and the need for nonpharmacologic alternatives to such treatment, for conditions such as cLBP.

Based on the evidence, we believe that acupuncture for chronic nonspecific low back pain is promising but not convincing. Coverage in the context of ongoing clinical research helps assure that the treatment is provided to appropriate patients in controlled settings while developing evidence that the treatment improves health outcomes.

To ensure benefits to Medicare beneficiaries CMS proposes to cover acupuncture for cLBP through CED for beneficiaries enrolled in trials sponsored by the NIH, and in CMS approved studies.

IX. Conclusion

A. The Centers for Medicare & Medicaid Services (CMS) proposes to cover acupuncture under section 1862(a)(1)(E) of the Social Security Act (the Act), with the support of the Agency for Healthcare Research and Quality under section 1142 of the Act. We propose that coverage would be available for Medicare patients with chronic low back pain in clinical trials supported by the National Institutes of Health (NIH) or in CMS approved studies meeting AHRQ criteria.

B. Covered Indications for CMS approved studies

Each study must be approved by CMS and as a fully-described, written part of its protocol, must address and adhere to the following:

- Enrollment of Medicare beneficiaries based on broad eligibility criteria to maximize diversity and minimize intentional or unintentional exclusions based on risk, multi-morbidity, age, health literacy, demographics, or expected adherence.
    - For the purpose of this decision, chronic low back pain (cLBP) is defined as:
        - Lasting 12 weeks or longer;
        - nonspecific, in that it has no identifiable systemic cause (i.e., not associated with metastatic, inflammatory, infectious, etc. disease);
        - not associated with surgery within 12 weeks of enrollment in the study; and
        - not associated with pregnancy.
- A minimum 12-week acupuncture intervention versus usual care or other intervention for chronic low back pain.
- Endpoints must be measured at 12 weeks, 6 months, and 12 months after enrollment, with comparison to usual care, or other planned comparator arm.
- The protocol design must incorporate rigorous controls, prospectively identified, preferably by randomization. If another method is used to generate the comparison group, it should provide comparable rigor.
- Be consistent with for the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) guidelines.

Physicians (as defined in 1861(r)(1)) may furnish acupuncture in accordance with applicable state requirements.

Physician assistants, nurse practitioners/clinical nurse specialists (as identified in 1861(aa)(5)), and auxiliary personnel may furnish acupuncture if they meet all applicable state requirements and have:

- A masters or doctoral level degree in acupuncture or Oriental Medicine from a school accredited by the Accreditation Commission on Acupuncture and Oriental Medicine (ACAOM);
- a current certification by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM); and
- maintained licensure in a U.S. state or territory to practice acupuncture.

Auxiliary personnel furnishing acupuncture must be under the direct supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist.

CMS approved studies must address one or more aspects of the research questions below:

- Does the use of acupuncture for the treatment of cLBP decrease pain and/or increase function?
- Does the use of acupuncture for the treatment of cLBP decrease the use of other continuing medical treatments and services (e.g. opioids)?

Research study designs may include, but are not limited to, randomized controlled trials, observational trials, and registries.

In addition, CMS will review studies to determine if they meet the 13 criteria listed below. If CMS determines that they meet these criteria, the study will be posted on CMS' CED website (https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html).

a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
b. The rationale for the study is well supported by available scientific and medical evidence.
c. The study results are not anticipated to unjustifiably duplicate existing knowledge.
d. The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
e. The study is sponsored by an organization or individual capable of completing it successfully.
f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.
g. All aspects of the study are conducted according to appropriate standards of scientific integrity.
h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).
k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
l. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, AHRQ supports clinical research studies in clinical trials supported by NIH and other trials that CMS determines meet the above-listed standards and address the above-listed research questions.

The principal investigator must submit the complete study protocol, identify the relevant CMS research questions that will be addressed and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS website.

Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850

C. Nationally Non-Covered Indications

Acupuncture for cLBP provided outside of clinical trials supported by the NIH or CMS approved studies, is non-covered.

See Appendix B for the proposed manual language.

CMS is seeking comments on our proposed decision. We are particularly interested in comments that address current studies of acupuncture (randomized controlled trials, observational trials, and registries) in the Medicare population. We will respond to public comments in a final decision memorandum, as required by §1862(l)(3) of the Social Security Act (the Act).

APPENDIX A
General Methodological Principles of Study Design
(Section VI of the Decision Memorandum)

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing

clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to that group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is to the extent that differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well-designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of that have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

Randomized controlled trials
Non-randomized controlled trials
Prospective cohort studies
Retrospective case control studies
Cross-sectional studies
Surveillance studies (e. g. , using registries or surveys)

Consecutive case series
Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in that confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and consider the evidence.

Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to that the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. One of the goals of our determination process is to assess health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal

or short-lived. Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

APPENDIX B
Medicare National Coverage Determinations Manual

Draft

We are seeking public comments on the proposed language that we would include in the Medicare National Coverage Determinations Manual. This proposed language does not reflect public comments that will be received on the proposed decision memorandum, and which may be revised in response to those comments.

Table of Contents
(Rev.)

[XXX.X]

The Centers for Medicare & Medicaid Services (CMS) is proposing changes to its acupuncture National Coverage Determination (NCD) policy that will expand Medicare coverage. The scope of this review is limited to acupuncture for chronic low back pain (cLBP) and will be manualized under NCD 30.3.3, Acupuncture for cLBP. However, any corresponding policy changes that appear in the final decision memorandum will also be manualized in changes to NCD 30.3, Acupuncture. In addition, clarifying changes would be necessary in NCD 30.3.1 and NCD 30.3.2.

A. General

Acupuncture is the selection and manipulation of specific acupuncture points by penetrating the skin with fine needles.

B. Nationally Covered Indications

Effective for services performed on or after [Month/XX] [Day/XX], [20XX] CMS proposes to cover acupuncture for Medicare patients with chronic low back pain in clinical trials supported by the National Institutes of Health (NIH) or

in CMS approved studies.

Covered Indications for CMS approved studies

Each study must be approved by CMS and as a fully-described, written part of its protocol, must address and adhere to the following:

- Enrollment of Medicare beneficiaries based on broad eligibility criteria to maximize diversity and minimize intentional or unintentional exclusions based on risk, multi-morbidity, age, health literacy, demographics, or expected adherence.
    - For the purpose of this decision, chronic low back pain (cLBP) is defined as:
        - Lasting 12 weeks or longer;
        - nonspecific, in that it has no identifiable systemic cause (i.e., not associated with metastatic, inflammatory, infectious, etc. disease);
        - not associated with surgery within 12 weeks of enrollment in the study; and
        - not associated with pregnancy.
- A minimum 12-week acupuncture intervention versus usual care or other intervention for chronic low back pain.
- Endpoints must be measured at 12 weeks, 6 months, and 12 months after enrollment, with comparison to usual care, or other planned comparator arm.
- The protocol design must incorporate rigorous controls, prospectively identified, preferably by randomization. If another method is used to generate the comparison group, it should provide comparable rigor.
- Be consistent with for the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) guidelines.

Physicians may furnish acupuncture in accordance with applicable state requirements.

Physician assistants, nurse practitioners/clinical nurse specialists, and auxiliary personnel may furnish acupuncture if they meet all applicable state requirements and have:

- A masters or doctoral level degree in acupuncture or Oriental Medicine from a school accredited by the Accreditation Commission on Acupuncture and Oriental Medicine (ACAOM);
- a current certification by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM); and
- maintained licensure in a U.S. state or territory to practice acupuncture.

Auxiliary personnel furnishing acupuncture must be under the direct supervision of a physician (as defined in 1861(r)(1)), physician assistant, or nurse practitioner/clinical nurse specialist (as identified in 1861(aa)(5)).

CMS approved studies must address one or more aspects of the research questions below:

- Does the use of acupuncture for the treatment of cLBP decrease pain and/or increase function?
- Does the use of acupuncture for the treatment of cLBP decrease the use of other continuing medical treatments and services (e.g. opioids)?

Research study designs may include, but are not limited to, randomized controlled trials, observational trials, and registries.

In addition, CMS will review studies to determine if they meet the 13 criteria listed below. If CMS determines that they meet these criteria, the study will be posted on CMS' CED website (https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html).

a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
b. The rationale for the study is well supported by available scientific and medical evidence.
c. The study results are not anticipated to unjustifiably duplicate existing knowledge.
d. The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
e. The study is sponsored by an organization or individual capable of completing it successfully.
f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.
g. All aspects of the study are conducted according to appropriate standards of scientific integrity.
h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).
k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
l. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, AHRQ supports clinical research studies in clinical trials supported by NIH and other trials that CMS determines meet the above-listed standards and address the above-listed research questions.

The principal investigator must submit the complete study protocol, identify the relevant CMS research questions that will be addressed and cite the location of the detailed analysis plan for those questions in the protocol, plus

provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS website.

Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850

C. Nationally Non-Covered Indications

Acupuncture for cLBP provided outside of clinical trials supported by the NIH or CMS approved studies, is non-covered.

D. Other

N/A

Bibliography

Austin S, Ramamonjiarivelo Z, Qu H, Ellis-Griffith G. Acupuncture Use in the United States: Who, Where, Why, and at What Price? *Health Mark Q.* 2015; 32(2): 113-128, DOI: 10.1080/07359683.2015.1033929. PMID: 26075541.

Berman BM, Langevin HM, Witt CM, Dubner R. Acupuncture for chronic low back pain. *N Engl J Med.* 2010; 363(5):454-61. doi: 10.1056/NEJMct0806114. PMID: 20818865.

Bevers K, Hulla R, Rice O, Verdier G, Salas E, Gatchel RJ. The Chronic Low Back Pain Epidemic in Older Adults in America. *J Pain Relief.* 2017*;* 6 (2):285. doi: 10.4172/2167-0846.1000285.

Centers for Disease Control and Prevention. *2018 Annual Surveillance Report of Drug-Related Risks and Outcomes — United States.* Surveillance Special Report. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. Published August 31, 2018. Retrieved April 10, 2019 at https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf

Chiarotto A, Boers M, Deyo RA, et al. Core outcome measurement instruments for clinical trials in nonspecific low back pain. Pain. 2018 Mar;159(3):481-495. doi: 10.1097/j.pain.0000000000001117. PMID: 29194127.

Chou R, Deyo R, Friedly J, et al. Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. *Ann Intern Med.* 2017; 166(7):493-505. doi: 10.7326/M16-2459. Epub 2017 Feb 14. PMID: 28192793.

Chou R, Deyo R, Friedly J, et al. Noninvasive Treatments for Low Back Pain.

Comparative Effectiveness Review No. 169. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2012-00014-I.) AHRQ Publication No. 16-EHC004-EF. Rockville, MD: Agency for Healthcare Research and Quality; February 2016.

Complementary and Integrative Health (CIH) Resource Guide. Version 2. Office of Patient Centered Care and Cultural Transformation (OPCC&CT). Last Update: October 2017. Retrieved April 18, 2019 at: https://n1s1t23sxna2acyes3x4cz0h-wpengine.netdna-ssl.com/wp-content/uploads/2017/12/CIH-Resource-Guide_Final-Sept-2017-3.pdf .

Dahlhamer, J, Lucas J, Zelaya C, et al. Prevalence of Chronic Pain and High-Impact Pain Among Adults – United States, 2016. *Morbidity and Mortality Weekly Report.* 2018; 67 (36): 1001 - 1006.

Dincer F and Linde K. Sham interventions in randomized clinical trials of acupuncturea review. *Complement Ther Med.* 2003; 11(4):235-42. PMID: 15022656.

Dionne CE, Dunn KM, Croft PR. Does back pain prevalence really decrease with increasing age? A systematic review. *Age Ageing.* 2006; 35(3):229-34. Epub 2006 Mar 17. PMID: 16547119.

Docking RE, Fleming J, Brayne C, Zhao J, Macfarlane GJ, Jones GT on behalf of the Cambridge City over-75s Cohort Study collaboration. Epidemiology of back pain in older adults: prevalence and risk factors for back pain onset. *Rheumatology (Oxford).* 2011; 50(9):1645-53. doi: 10.1093/rheumatology/ker175. Epub 2011 May 23. PMID: 21606130.

Feinberg S. American Chronic Pain Association Resource Guide to Chronic Pain Management, An Integrated Guide to Medical, Interventional, Behavioral, Pharmacologic and Rehabilitation Therapies. American Chronic Pain Association, Rocklin, California. 2019. Retrieved May 13, 2019 from: https://www.theacpa.org/wp-content/uploads/2019/02/ACPA_Resource_Guide_2019.pdf

Furlan AD, van Tulder MW, Cherkin D, et al.. Acupuncture and dry-needling for low back pain. Cochrane Database of Systematic Reviews 2005, Issue 1. Art. No.: CD001351. DOI: 10.1002/14651858.CD001351.pub2. Retrieved July 1, 2019 at: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001351.pub2/epdf/full

Galicia-Castillo MC and Weiner DK. Treatment of Persistent Pain in Older Adults. *Up ToDate.* Eds: Schmader KE, Fishman S, Crowley M. Retrieved January 8, 2019 at https://www.uptodate.com/contents/treatment-of-persistent-pain-in-older-adults .

Hao JJ and Mettelman M. Acupuncture: Past, Present, and Future. *Glob Adv Health Med.* 2014; 3(4): 6–8. doi: 10.7453/gahmj.2014.042. PMID: 25105069.

HEAL Initiative: Pragmatic Randomized Controlled Trial of Acupuncture for Management of Chronic Low Back Pain in Older Adults (UG3/UH3 Clinical Trial Required).Department of health and Human Services. Retrieved April 19, 2019 at: https://grants.nih.gov/grants/guide/rfa-files/RFA-AT-19-005.html

Hempel S, Taylor SL, Solloway M, et al. Evidence Map of Acupuncture. VA-ESP Project #05-226; 2013. Retrieved February 4, 2019 at: https://www.ncbi.nlm.nih.gov/books/NBK185072/pdf/Bookshelf_NBK185072.pdf .

Hoy D, Brooks P, Blyth F, Buchbinder R. The Epidemiology of low back pain. *Best Pract Res Clin Rheumatol.* 2010; 24(6):769-81. doi: 10.1016/j.berh.2010.10.002. PMID: 21665125.

Juckett, G. Cross-Cultural Medicine. *Am Fam Physician.* 2005; 72(11):2267-2274. PMID: 163428512851

Leggit, JC. Musculoskeletal Therapies: Acupuncture, Dry Needling, Cupping. *FP essentials.* 2018; 470:27-31.

Lin K and Tung C. The Regulation of the Practice of Acupuncture by Physicians in the United States. *Med Acupunc.* 2017; 29(3): 121- 126. DOI: 10.1089/acu.2017. 1235. PMID: 28736588

MacPherson H, Altman DG, Hammerschlag R, et al. Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): Extending the CONSORT statement. *PLoS Med.* 2010; 7(6):e1000261.PMID: 21349059.

MacPherson H, Altman DG, Hammerschlag R, et al. Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): Extending the CONSORT statement. *Acupuncture and Related Therapies.* 2015; 3: 35-46. doi.org/10.1016/arthe.2016.03.001.

Mao JJ, Wax J; Barg FK, Margo M, Walrath D. A Gain in Cultural Competence Through an International Acupuncture Elective. *Fam Med.* 2007; 39(1):16-8. PMID: 17186440.

Medical News and Perspectives. Acceptance of Some Acupuncture Applications. *JAMA.* 1997; 278 (21): 1725.

Molsberger AF, Mau J, Gotthardt H, Schneider T, Drabik A. Designing an Acupuncture Study to Meet Evidence-based Medical Criteria: Methodological Considerations for Logistic Design and Development of Treatment Interventions Arising from the German Randomized Controlled Acupuncture Trial on Chronic Shoulder Pain (GRASP). *Eur J Med Res.* 2004; 9(8):405-11. PMID: 15337631.

National Academies of Sciences, Engineering, and Medicine 2017. Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use. Washington, DC: The National Academies Press. https://doi.org/10.17226/24781. Retrieved April 17, 2019 at: https://www.nap.edu/read/24781/chapter/5#84

National Academies of Sciences, Engineering and Medicine 2019. The Role of Nonpharmacological Approaches to Pain Management: Proceedings of a Workshop. Washington, DC: The National Academies Press. https://doi.org/10.17226/25406 .

National Coverage Determination (NCD) for Acupuncture (30.3). Retrieved May 3, 2019 at: https://www.cms.gov/medicare-coverage-database/(S(cnbxfa45qfwykj45ydhic5qj))/details/ncd-details.aspx?NCDId=11&ncdver=1&NCAId=2&ver=5&NcaName=Acupuncture+for+Nausea+after+Chemotherapy+and+P
operative+Pain&bc=AAAAABAAEAgA&

National Coverage Determination (NCD) for Acupuncture for Fibromyalgia (30.3.1). Retrieved May 3, 2019 at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=283&ncdver=1&DocID=30.3.1&SearchType=Advanced&bc=IAAAABAAAAAA&

National Coverage Determination (NCD) for Acupuncture for Osteoarthritis (30.3.2). Retrieved May 3, 2019 at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=284&ncdver=1&DocID=30.3.2&SearchType=Advanced&bc=IAAAABAAAAAA&

Olson JL. Licensed Acupuncturists Join the Veterans Health Administration. *Med Acupunc.* 2018; 30(5): 248 – 251. doi; 10.1089/acu.2018.1298. PMID: 30377460.

Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive Treatments for Acute, Subacute and Chronic Low Back Pain: A Clinical Guideline from the American College of Physicians. *Ann Intern Med.* 2017; 166(7):514-530. doi: 10.7326/M16-2367. Epub 2017 Feb 14.

R3 Report | Requirement, Rationale, Reference: A publication of The Joint Commission (Issue 11, August 29, 2017). Retrieved April 18, 2019 at: https://www.jointcommission.org/assets/1/18/R3_Report_Issue_11_Pain_Assessment_8_25_17_FINAL.pdf

Shmagel A, Foley R, Ibrahim H. Epidemiology of chronic low back pain in US Adults: National Health and Nutrition Examination Survey 2009-2010 . *Arthritis Care Res (Hoboken).* 2016; 68(11):1688-1694. doi: 10.1002/acr.22890. PMID: 26991822.

Skelly AC, Chou R, Dettori JR, et al. Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review. Comparative Effectiveness Review No. 209. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2015-00009-I.) AHRQ Publication No 18-EHC013-EF. Rockville, MD: Agency for Healthcare Research and Quality; June 2018.

Taylor – Swanson L, Stone JAM, Gale MK, et al. Systematic Review of Acupuncture for Low Back Pain: Efficacy and Clinically – Meaningful Change. *MJAOM.* 2018 (summer); 18 – 39.

The Joint Commission: Pain Management - Leadership Responsibilities for Providing Nonpharmacologic Modalities for Managing Pain - LD.04.03.13 EP 2. ; Retrieved April 17, 2019 at https://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFaqId=1881&ProgramId=46

The US Burden of Disease Collaborators. The State of US Health, 1990-2016: Burden of Diseases, Injuries, and Risk Factors Among US States. *JAMA.* 2018; 319(14):1444-1472. doi: 10.1001/jama.2018.0158. PMID: 29634829.

Tice JA, Kumar V, Otuonye I, et al. Cognitive and Mind-Body Therapies for Chronic Low Back and Neck Pain: Effectiveness and Value, Final Evidence Report, November 6, 2017. Institute for Clinical and Economic Review (ICER), prepared for the California Technology Assessment Forum. Retrieved on May 13, 2019 form https://icer-review.org/wp-content/uploads/2017/03/CTAF_LBNP_Final_Evidence_Report_110617.pdf

Toblin RL, Mack KA, Perveen G, Paulozzi LJ. A population-based survey of chronic pain and its treatment with prescription drugs. *Pain.* 2011; 152(6):1249-55. doi: 10.1016/j.pain.2010.12.036. Epub 2011 Mar 11. PMID: 21397401.

VA/DoD Clinical Practice Guideline for Diagnosis and Treatment of Low Back Pain. Department of Veterans Affairs, Department of Defense. Version 2.0 – 2017. Retrieved on May 13, 2019 from: https://www.healthquality.va.gov/guidelines/Pain/lbp/VADoDLBPCPG092917.pdf

Vickers AJ, Cronin AM, Maschino AC, et al. Individual patient data meta-analysis of acupuncture for chronic pain: protocol of the Acupuncture Trialists' Collaboration. *Trials.* 2010; 11:90. doi: 10.1186/1745-6215-11-90. PMID: 20920180.

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. doi: 10.1016/j.jpain.2017.11.005. Epub 2017 Dec 2. PMID: 29198932.

Walji R and Boon H. Redefining the randomized controlled trial in the context of acupuncture research. *Complement Ther Clin Pract.* 2006; 12(2):91-6. Epub 2006 Mar 30. PMID: 16648085.

Wang Y, Zhao J, Hao D. Is sham acupuncture a real placebo: Skepitcal for sham acupuncture. *WJAM.* 2017; 27(2); 1-5.

White A, Cummings TM, Filshie J. An introduction to Western medical acupuncture. Edinburgh: Churchill Livingstone/Elsevier, 2008.

White A and Editorial Board of *Acupuncture in Medicine*. Western medical acupuncture: a definition. *Acupunct Med.* 2009; 27(1):33-35. doi: 10.1136/aim.2008.000372. PMID: 19369193.

White A and Ernst E. A brief history of acupuncture. *Rheumatology (Oxford).* 2004; 43(5):662-3. PMID: 15103027.

Wong AYL, Karppinen J, Samartzis D.Low back pain in older adults: risk factors, management options and future directions. *Scoliosis Spinal Disord.* 2017; 12:14. doi: 10.1186/s13013-017-0121-3. eCollection 2017. PMID: 28435906.

Xiang Y, He J, Li R. Appropriateness of sham or placebo acupuncture for randomized controlled trials of acupuncture for nonspecific low back pain: a systematic review and meta-analysis. *J Pain Res.* 2018 (11):83-94. doi: 10.2147/JPR.S152743. eCollection 2018. PMID: 29343984.

Yeganeh M, Baradaran HR, Qorbani M, Moradi Y, Dastgiri S. The effectiveness of acupuncture, acupressure and chiropractic interventions on treatment of chronic nonspecific low back pain in Iran: A systematic review and meta-analysis. *Complement Ther Clin Pract*. 2017 May; 27:11-18. doi: 10.1016/j.ctcp.2016.11.012. Epub 2016 Nov 30. PMID: 28438274.

Yuan Q, Guo T, Liu L, Sun F, Zhang Y. Traditional Chinese medicine for neck pain and low back pain: a systematic review and meta-analysis. *PLoS One.* 2015; 10(2):e0117146. doi: 10.1371/journal.pone.0117146. eCollection 2015. PMID: 25710765.

Yuan Q, Wang P, Liu L, et al. Acupuncture for musculoskeletal pain: A meta-analysis and meta-regression of sham-controlled randomized clinical trials. *Sci Rep.* 2016; 6:30675. doi: 10.1038/srep30675. PMID: 27471137.

Zeng Y and Chung JW. Acupuncture for chronic nonspecific low back pain: An overview of systematic reviews. *European Journal of Integrative Medicine.* 2015; 7(2): 94-107. doi.org/10.1016/j.eujim.2014.11.001.

Zgierska AE, Ircink J, Burzinski CA, Mundt MP. Cost of Opioid-Treated Chronic Low Back Pain: Findings from a Pilot Randomized Controlled Trial of MindfulnessMeditation-Based Intervention. *J Opioid Manag.* 2017; 13(3):169-181. doi: 10.5055/jom.2017.0384. PMID: 28829518.