

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

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Decision Summary

A. The Centers for Medicare & Medicaid Services (CMS) will cover acupuncture for chronic low back pain under section 1862(a)(1)(A) of the Social Security Act. Up to 12 visits in 90 days are covered for Medicare beneficiaries under the following circumstances:

- 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; and
 - not associated with pregnancy.
- An additional eight sessions will be covered for those patients demonstrating an improvement. No more than 20 acupuncture treatments may be administered annually.
- Treatment must be discontinued if the patient is not improving or is regressing.

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); and
- current, full, active, and unrestricted license to practice acupuncture in a State, Territory, or Commonwealth (i.e. Puerto Rico) of the United States, or District of Columbia.

Auxiliary personnel furnishing acupuncture must be under the appropriate level of supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist required by our regulations at 42 CFR §§ 410.26 and 410.27.

B. Nationally Non-Covered Indications

All types of acupuncture including dry needling for any condition other than cLBP are non-covered by Medicare.

See Appendix B for the NCD manual language.

Decision Memo

TO: Administrative File: CAG-00452N

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

DATE: January 21, 2020

I. Decision

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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:

AAFP - American Academy of Family Physicians
AANS - American Association of Neurological Surgeons
AANA - American Association of Nurse Anesthetists
AAOA - American Alliance of Acupuncture
AAPM&R - American Academy of Physical Medicine & Rehabilitation
AAQ - Association of Acupuncturists Quebec
ACA - American Chiropractic Association
ACEP - American College of Emergency Physicians
AfBPM - Alliance for Balanced Pain Management
AHIP - America's Health Insurance Plans
AHRQ - Agency for Healthcare Research and Quality
ANF - Acupuncture Now Foundation
APTA - American Physical Therapy Association
ASA - American Society of Acupuncturists
ASDC - Acupuncture Society of Washington, DC
ASNY - Acupuncture Society of New York
CalATMA - California Acupuncture and Traditional Medicine Association
CAOMA - Council of Acupuncture and Oriental Medicine Associations
CFI - Center for Inquiry
CMS - Centers for Medicare & Medicaid Services
CNS - Congress of Neurological Surgeons
CTSA - Connecticut Society of Acupuncturists
FDA - Food and Drug Administration
FOA - Funding Opportunity Announcement
MAA - Minnesota Acupuncture Association
MDMA - Medical Device Manufacturers Association
NASHO - National Association of Specialty Health Organization
NCA - National Coverage Analysis
NCASI - National Center for Acupuncture Safety and Integrity
NCCAOM - 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 (Bever, 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 (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.
August 14, 2019	30-day public comment period ends. CMS receives 644 comments.

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 (\geq 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 VAS	> 10-20 points on a 0-100 point VAS	> 20 points on a 0-100 point 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
RMDQ: 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. Heterogeneity 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 from 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 assessed 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 ($\text{Tau}^2 = 5.07$; $df = 3$ ($p=0.17$); $I^2 = 41\%$). 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, radicular syndrome, 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.

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 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 needed, 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://n1s1t23sxn2acyes3x4cz0h-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 (NCCAOM), American Society of Acupuncturists (ASA). Additional group comments were submitted by Advocate Aurora Health, the Cleveland Clinic, and America's Health Insurance Plans.

Second Comment Period: 7/15/2019 – 8/14/2019

During the 30-day public comment period following the release of the proposed NCD and decision memorandum, CMS received 644 comments. Of these 644 comments, 47 were omitted from publication on the CMS website due to excessive personal health information content, and 119 were form letters which contained nearly identical suggested changes to the proposed CMS study criteria. The vast majority of the comments received supported CMS coverage of acupuncture for chronic low back pain, and also supported additional research on acupuncture for chronic low back pain in the Medicare population. Most of the comments supporting coverage of additional research for acupuncture suggested changes to the proposed study criteria, including referring to auxiliary personnel specifically as licensed acupuncturists, modifying the direct supervision requirement, and allowing certification other than NCCAOM. There were a few commenters that did not support CMS coverage of acupuncture, stating, for example, that this therapy is unsupported by research, can cause substantial harm to patients, does not outperform placebo effects and/or is inappropriate to receive public funding in order to further its scientific investigation.

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 39 comments that represented 32 various groups, including professional associations and public benefit organizations. These groups included the American Physical Therapy Association (APTA), Council of Acupuncture and Oriental Medicine Associations (CAOMA), American Alliance of Acupuncture (AAOA), North Carolina Society for Acupuncture and Asian Medicine, American Association of Nurse Anesthetists (AANA), National Center for Acupuncture Safety and Integrity (NCASI), California Acupuncture and Traditional Medicine Association (CalATMA), Acupuncture Society of MA, American Specialty Health, Minnesota Acupuncture Association (MAA), Acupuncture Society of New York (ASNY), Acupuncture Society of Washington, DC (ASDC), Hawaii Acupuncture Association, Connecticut Society of Acupuncturists (CTSA), Acupuncture Association of Colorado, American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), American Chiropractic Association (ACA), America's Health Insurance Plans (AHIP), University Hospitals Connor Integrative Health Network, U.S. Pain Foundation, National Association of Specialty Health Organization (NASHO), Alliance for Balanced Pain Management (AfBPM), American Academy of Family Physicians (AAFP), American Academy of Physical Medicine & Rehabilitation (AAPM&R), Tivity Health, Northeast Ohio Opioid Consortium, Center for Inquiry (CFI), Medical Device Manufacturers Association (MDMA), Allina Health, ASA, NCCAOM, and ANF.

Coverage of Acupuncture for Chronic Low Back Pain

Comment: Some commenters suggested that no further research is needed for CMS to cover acupuncture.

Response: We appreciate the comments. The decision regarding coverage takes into account an assessment of benefits and harms and the opioid public health crisis. While a small number of adults 65 years of age or older have been enrolled in published acupuncture studies, patients with chronic low back pain in these studies showed improvements in function and pain. The evidence reviewed for this decision supports clinical strategies that include nonpharmacologic therapies for chronic low back pain. CMS notes too that while there is variation in covered indications and frequency of services, a number of large private payers provide some coverage of acupuncture for certain indications. We provide a more detailed description for the change from proposed to final decisions in the Analysis section of this decision memo.

Future Research

Comment: Some commenters suggested study criteria, such as having studies be limited to muscle origin low back pain in seniors, or a randomized controlled trial where one arm receives no acupuncture, one arm receives Five Element acupuncture, and another arm receives TCM acupuncture.

Response: Though CMS is not requiring a CED study for coverage of acupuncture for chronic low back pain, we encourage further investigations on this topic in the Medicare population.

Comment: Some commenters suggested CMS cover acupuncture for other conditions in addition to other treatments for chronic low back pain.

Response: The scope of the review for this national coverage determination (NCD) is limited to acupuncture for chronic low back pain where the majority of relevant evidence is present. All other uses of acupuncture remain noncovered.

Comment: Some commenters suggested that CMS cover other forms of nonpharmacologic therapy which are often used in conjunction with acupuncture, such as Tuina massage.

Response: As previously stated, the scope of the review for this national coverage determination (NCD) is limited to acupuncture. Coverage for therapies other than acupuncture are outside the scope of this NCD.

Comment: Some comments were related to coding and payment for acupuncture and other nonpharmacological therapies that have been proven to be effective for the prevention or treatment of pain.

Response: Reimbursement and coding is beyond the scope of this decision memo. Coding and payment information is usual presented in other Medicare documents.

Personnel Furnishing Acupuncture and Direct Supervision

Comment: Several commenters requested that CMS remove the term "auxiliary personnel" from the final decision, and instead refer to these providers specifically as "licensed acupuncturists." Most of these commenters also suggested editing the "direct supervision" requirement to only allow physicians to provide supervision, stating that physician assistants, nurse practitioners/clinical nurse specialists would not be qualified to supervise licensed acupuncturists.

Response: Currently, acupuncturists are not recognized by CMS as Medicare providers, and are not eligible to bill for acupuncture services. It is possible, however, for acupuncturists to provide acupuncture as auxiliary personnel

“incident to” a physician’s service in certain settings. The incident to regulations requires supervision by a physician or other practitioner. For further details regarding “incident to” services, we recommend that interested parties consult 42 CFR §§ 410.26 and 410.27. We are not able to amend these regulations through the national coverage determination process, however, we will change the specific reference to “direct supervision” and will substitute “the appropriate level of supervision required by our regulations at 42 CFR §§ 410.26 and 410.27.”

Comment: Several commenters suggested that acupuncture should only be performed by licensed acupuncturists and not be physicians, physician assistants, or nurse practitioners/clinical nurse specialists who would not have the specialized training a licensed acupuncturist would have.

Response: The coverage criteria defined in section I of this decision memo states that physician assistants, nurse practitioners/clinical nurse specialists, and auxiliary personnel must have a masters or doctoral level degree in acupuncture or Oriental Medicine from a school accredited by the ACAOM, and language has been added to specify a current, full, active, and unrestricted license to practice acupuncture in a State, Territory, or Commonwealth (i.e. Puerto Rico) of the United States, or District of Columbia. These requirements are consistent either with the requirements of the qualification standards of private payers (which vary as discussed further below) for licensed acupuncturists who treat patients (and also the standards for VA medical centers or the requirements used to identify providers who perform acupuncture paid by the VA in the community). As noted above, licensed acupuncturists cannot directly bill Medicare for services.

Comment: Some commenters specified that dry needling performed by practitioners who are not acupuncturists be excluded from the CMS covered studies.

Response: As described in the background of this decision memo, 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. Dry needling was assessed together in the AHRQ systematic evidence reviews, the Cochrane Collaboration systematic evidence reviews and the evidence report by the Institute for Clinical and Economic Review. CMS considers dry needling as a type of acupuncture. We note that private payers consider dry needling to be experimental and do not cover this therapy.

Comment: One commenter requested chiropractic doctors who have completed the 100 hour acupuncture course and examination approved by the American Chiropractic Association (ACA) and the National Board of Chiropractic Examiners (NBCE) be included in the list of personnel able to furnish acupuncture in the studies.

Response: CMS notes that the requirements for chiropractic acupuncturists vary widely from state to state. CMS also notes Medicare covers manual manipulation of the spine if medically necessary to correct a subluxation when provided by a chiropractor (or other qualified provider). Medicare does not cover other services or tests ordered by a chiropractor, including acupuncture. However, if a chiropractor fulfills the requirements in section I of this decision memo as auxiliary personnel, they would be eligible to furnish acupuncture “incident to” a physician’s service.

Comment: One commenter requested that provider requirements for acupuncture be equal for physicians and qualified licensed healthcare practitioners who are not physicians, and not have any requirements above applicable state requirements.

Response: To ensure the quality of services received by Medicare beneficiaries conforms to at least the requirements of private payers, 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), 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.

NCCAOM Requirement

Comment: Several comments requested that CMS not limit certification to the NCCAOM and that the California Acupuncture Licensing Exam (CALE) and other state licensing exams be accepted.

Response: While CMS believes NCCAOM certification would provide important standards in knowledge and experience, CMS is removing the NCCAOM certification requirement to allow equivalent access. We note there is variability across the country. To facilitate quality of care and better outcomes, we believe that requiring 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); meeting all state requirements and having a current, full, active, and unrestricted license to practice acupuncture in a State, Territory, or Commonwealth (e.g. Puerto Rico) of the United States, or District of Columbia will provide consistency and help ensure qualified practitioners will be furnishing acupuncture.

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)). 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, 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)).

When making national coverage determinations, we evaluate the evidence related to our analytic questions based on the quality, strength and totality of evidence presented in the reviewed literature. As part of this evaluation, it is important to consider whether the evidence is relevant to the Medicare beneficiary population. In determining the generalizability of the results of the body of evidence to the Medicare population, we consider, at minimum, the age, race and gender of the study participants.

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 a small number of adults 65 years of age or older have been enrolled in published acupuncture studies reviewed for this reconsideration, patients with chronic low back pain in these studies showed improvements in function and pain. The evidence supports clinical strategies that include nonpharmacologic therapies for chronic low back pain (Skelley, 2018; Eskander, 2019). The decision regarding coverage of an item or service also takes into account an assessment of benefits and harms (discussed further below) and the opioid public health emergency. We note too that while there is variation in covered indications and frequency of services, a number of large private payers provide some coverage of acupuncture for certain indications.

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).

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.

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.

The decision regarding coverage takes into account an assessment of benefits and harms and the opioid public health crisis. While a small number of adults 65 years of age or older have been enrolled in published acupuncture studies, patients with chronic low back pain in these studies showed improvements in function and pain. The evidence reviewed for this decision supports clinical strategies that include nonpharmacologic therapies for chronic low back pain. CMS notes too that while there is variation in covered indications and frequency of services, a number of large private payers provide some coverage of acupuncture for certain indications.

Opioid Public Health Emergency

In October 2017, President Trump declared the opioid crisis a public health emergency. In 2018, an initiative was outlined: Part 1 is reducing demand and over-prescription, including educating Americans about the dangers of opioid misuse. Part 2 is cutting down on the supply of illicit drugs by cracking down on the international and domestic drug supply chains that devastate American communities. Part 3 is helping those struggling with addiction through evidence-based treatment and recovery support services. (<https://www.whitehouse.gov/opioids/>).

Although opioid misuse is lower among older than younger individuals, the rate of opioid misuse among older adults nearly doubled between 2002 and 2014 (Weiss, Heslin, Barrett, Izar & Bierman, 2018). The largest relative increase in the deaths attributable to opioids over 2001-2016, occurred among adults aged 55 to 64 years (754% increase from 0.2% to 1.7%) and those aged 65 years and older (635% increase from 0.01% to 0.07%) (Gomes, Tadrous, Mamdani, Paterson & Juurlink, 2018). Between 2010 and 2015, the number of opioid related inpatient stays increased 54.4 percent among patients aged 65 years and older, from 80,500 stays in 2010 to 124,300 stays in 2015; in that same time period, the number of opioid related ED visits doubled among patients aged 65 years and older, from 18,100 visits in 2010 to 36,200 visits. Further, between 2005 and 2014, the rate of opioid related hospitalizations increased faster among patients aged 65 and older than that compared with all other age groups. Between 2010 and 2015, within this same age group of elderly patients, the rate of opioid related inpatient stays increased whereas the rate of nonopioid stays decreased and the rate of emergency room visits increased substantially more than did nonopioid related visits (Weiss et al., 2018).

Multimodal Non-Pharmacologic Approach to Chronic Pain

As with other complex diseases, Medicare recognizes the importance of having treatment options to allow an integrated approach that is tailored to the needs and preferences of Medicare patients. This is particularly important for multifaceted, multifactorial conditions such as chronic low back pain. In a recent publication, a multimodal approach produced benefits in pain scores and healthcare visits at 1 year (Eskander et al., 2019). By providing multiple evidence based nonpharmacologic treatment options, we believe the physician and patient are better equipped to manage this condition without use of opioids.

Consideration of Benefits and Harms

The AHRQ technology assessment (Number 209, 2018) noted that “[a]cupuncture was associated with slightly greater effects on short-term pain than sham acupuncture, usual care, an attention control, or a placebo intervention.” Since the studies included in the evidence review did not include adequate numbers of older adults, we noted a concern with generalizability in the proposed decision. While it would be helpful to see specific results from older patients, we recognize this evidence is forthcoming from NIH supported studies. For this consideration, we did not find clinical rationale to indicate that published study results would not be generalizable. The AHRQ technology assessment also noted that “[d]ata on harms were limited but indicated no clear difference between acupuncture versus control interventions in risk of withdrawal due to adverse events. Serious adverse events were rare with acupuncture and control interventions.”

Therefore, we believe that in light of the relative safety of the procedure and the grave consequences of the opioid crisis in the United States, there is sufficient rationale to provide this nonpharmacologic treatment to appropriate beneficiaries with chronic 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.

We have reviewed coverage policies of private payers including integrated health systems. A number of other payers such as Aetna, various Blue Cross Blue Shield plans, Cigna, Kaiser Permanente, and United Healthcare provide some coverage of acupuncture for certain indications or offer advantage plans that may provide coverage. There is

variation in covered indications and frequency of services.

The consideration of benefits and harms also is directly dependent on the qualifications of the provider. While most private payers did not specify provider requirements, there is variation in the ones that did. For example, one payer covers acupuncture only if administered by a legally qualified physician while another allowed specifically trained non-physician providers as well. To increase access due to the public health crisis and due to the statutory requirements requiring the involvement of an eligible Medicare provider or supplier regardless, CMS will include physicians and non-physician practitioners. To ensure the quality of services received by Medicare beneficiaries conforms to at least the requirements of private payers, 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), 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.

We recognize the need to be responsive to urgent health care issues and the evolving nature of the evidence on acupuncture and will closely monitor the situation, including how this decision interacts with state scope of practice requirements. If the consideration of benefits and harms change, we will reconsider and revise the decision accordingly.

Frequency of Acupuncture for Chronic Low Back Pain

The frequency and number of acupuncture treatments varied in the studies reviewed. With this variability, we reviewed coverage policies of private payers. The number of sessions that were covered by private payers ranged from 10-20 treatments per year. Based on a review of study protocols and the supporting documentation, we believe acupuncture for chronic low back pain should be initially applied in up to 12 visits over 90 days. In patients in whom acupuncture has not produced a resolution or plateau of their cLBP, but have shown measurable improvement within this time period, then 8 more visits are allowed. Treatment should be discontinued if the patient is not improving, or is regressing. No more than 20 acupuncture treatments may be provided in any 12 month period. Examples of a grouping of clinical characteristics that may describe the reasonable and necessary nature of this service include:

- Services are delivered toward well described and realistic goals aimed to significantly improve the patient's functional status over a reasonable and defined period of time;
- Treatment is based on clinical findings documented by the physician or practitioner who is managing or co-managing the care of the beneficiary's chronic low back pain.
- Continuation of treatment is contingent upon progression towards treatment goals as evidenced by specific and significant objective (i.e. measurable) improvements of function and clinical findings (e.g., outcome assessment scales, range of motion) and
- Treatment is discontinued if the patient is not improving or is regressing.

NIH Research

The NIH is 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). Under the coverage provided by this NCD, CMS can provide payment for acupuncture for chronic low back pain in these studies, if the coverage requirements specified in this decision are met.

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.

IX. Conclusion

A. The Centers for Medicare & Medicaid Services (CMS) will cover acupuncture for chronic low back pain under section 1862(a)(1)(A) of the Social Security Act. Up to 12 visits in 90 days are covered for Medicare beneficiaries under the following circumstances:

- 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; and
 - not associated with pregnancy.
- An additional eight sessions will be covered for those patients demonstrating an improvement. No more than 20 acupuncture treatments may be administered annually.
- Treatment must be discontinued if the patient is not improving or is regressing.

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); and
- current, full, active, and unrestricted license to practice acupuncture in a State, Territory, or Commonwealth (i.e. Puerto Rico) of the United States, or District of Columbia.

Auxiliary personnel furnishing acupuncture must be under the appropriate level of supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist required by our regulations at 42 CFR §§ 410.26 and 410.27.

B. Nationally Non-Covered Indications

All types of acupuncture including dry needling for any condition other than cLBP are non-covered by Medicare.

See Appendix B for the NCD manual language.

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 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 systematic 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

This draft NCD is subject to formal revisions and formatting changes prior to the release of the final NCD contractor instructions and publication in the Medicare National Coverage Determinations Manual.

Table of Contents (Rev.)

30.3.3 - ACUPUNCTURE

The Centers for Medicare & Medicaid Services (CMS) is finalizing 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, Acupuncture for Fibromyalgia and NCD 30.3.2, Acupuncture for Osteoarthritis.

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 January 21, 2020 CMS will cover acupuncture for Medicare patients with chronic low back pain. Up to 12 visits in 90 days are covered for Medicare beneficiaries under the following circumstances:

- *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; and*
 - *not associated with pregnancy.*
- *An additional eight sessions will be covered for those patients demonstrating an improvement. No more than 20 acupuncture treatments may be administered annually.*
- *Treatment must be discontinued if the patient is not improving or is regressing.*

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);*
- *and*
- *current, full, active, and unrestricted license to practice acupuncture in a State, Territory, or Commonwealth (i.e. Puerto Rico) of the United States, or District of Columbia.*

Auxiliary personnel furnishing acupuncture must be under the appropriate level of supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist required by our regulations at 42 CFR §§ 410.26 and 410.27.

C. Nationally Non-Covered Indications

All types of acupuncture including dry needling for any condition other than cLBP are non-covered by Medicare.

D. Other

N/A

30.3 - ACUPUNCTURE

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 claims with dates of service on and after January 21, 2020, acupuncture is only covered for chronic low back pain under section 1862(a)(1)(A) of the Social Security Act (the Act). See National Coverage Determination section 30.3.3 for specific coverage criteria.

C. Nationally Non-Covered Indications

Medicare reimbursement for acupuncture, as an anesthetic or as an analgesic or for other therapeutic purposes, may not be made unless the specific indication is excepted. Accordingly, acupuncture is not considered reasonable and necessary within the meaning of §1862(a)(1)(A) of the Act. All indications for acupuncture outsided of NCD section 30.3.3 remain non-covered.

D. Other

N/A

30.3.1 – ACUPUNCTURE FOR FIBROMYALGIA

A. General

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

B. Nationally Covered Indications

N/A for acupuncture for fibromyalgia.

C. Nationally Non-Covered Indications

Effective for claims with dates of service on and after April 16, 2004, after careful reconsideration of its initial non-coverage determination for acupuncture, the Centers for Medicare & Medicaid Services (CMS) concludes that there is no convincing evidence for the use of acupuncture for pain relief in patients with fibromyalgia. Study design flaws presently prohibit assessing acupuncture's utility for improving health outcomes. Accordingly, CMS determines that acupuncture is not considered reasonable and necessary for the treatment of fibromyalgia within the meaning of §1862(a)(1) of the Social Security Act, and the national non-coverage determination for acupuncture for fibromyalgia continues.

D. Other

N/A

(This NCD last reviewed April 2004.)

30.3.2 – ACUPUNCTURE FOR OSTEOARTHRITIS

A. General

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

B. Nationally Covered Indications

N/A for acupuncture for osteoarthritis.

C. Nationally Non-Covered Indications

Effective for claims with dates of service on and after April 16, 2004, after careful reconsideration of its initial non-coverage determination for acupuncture, the Centers for Medicare & Medicaid Services (CMS) concludes that there is no convincing evidence for the use of acupuncture for pain relief in patients with osteoarthritis. Study design flaws presently prohibit assessing acupuncture's utility for improving health outcomes. Accordingly, CMS determines that acupuncture is not considered reasonable and necessary for the treatment of osteoarthritis within the meaning of §1862(a)(1) of the Social Security Act, and the national non-coverage determination for acupuncture for osteoarthritis continues.

D. Other

N/A

(This NCD last reviewed April 2004.)

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