

**Clinical Practice Guideline:**      **Acupuncture Services Medical Policy/Guideline**

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**Related Policies:**

CPG 12: Medical Necessity Decision Assist Guide for Rehabilitative Care  
 CPG 30: Laser Therapy  
 CPG 48: Moxibustion  
 CPG 89: Instrument-Assisted Soft Tissue Mobilization  
 CPG 111: Patient Assessments: Medical Necessity Decision Assist Guideline for Evaluations, Re-evaluations, and Consultations  
 CPG 112: Exercise Treatment for Non-Specific Low Back Pain  
 CPG 113: Exercise Treatment for Neck Pain  
 CPG 121: Passive Physiotherapy (Therapeutic) Modalities  
 CPG 133: Techniques and Procedures not Widely Supported as Evidence-Based  
 CPG 135: Physical Therapy Medical Policy Guideline  
 CPG 155: Occupational Therapy Medical Policy Guidelines  
 CPG 157: Lymphedema  
 CPG 167: Therapeutic Massage Medical Policy Guideline  
 CPG 175: Extraplinal Joint Manipulation, Mobilization Upper Extremities  
 CPG 177: Extraplinal Joint Manipulation, Mobilization Lower Extremities  
 CPG 272: Electric Stimulation for Pain, Swelling and Function in the Clinic Setting  
 CPG 273: Superficial Heat and Cold  
 CPG 274: Deep Heating Modalities (Therapeutic Ultrasound and Diathermy)  
 CPG 298: Telehealth, Digital and Phone-based Evaluation / Assessment and Management Services  
 QM 20: Facility Standards

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## DESCRIPTION OF THIS CLINICAL PRACTICE GUIDELINE

This document addresses Acupuncture services which may be delivered by an Acupuncture practitioner acting within the scope of a professional license. This document also addresses the processes associated with Medical Necessity Determinations performed by American Specialty Health (ASH) Clinical Quality Evaluators (CQEs) on Acupuncture services submitted for review.

The availability of coverage for Acupuncture services will vary by benefit design as well as by State and Federal regulatory requirements. Benefit plans may include a maximum allowable Acupuncture benefit, defined by any combination of duration of course of treatment, number of visits, conditions covered, or type of services covered. When the maximum allowable benefit is exhausted or if the condition or service is not covered, coverage will no longer be provided even if the medical necessity criteria described below are met.

The determination of medically necessary care, as outlined in this guideline, protects against inappropriate care that may be wasteful, unsafe, and harmful to the patient, while assuring approved care is safe, appropriate, and improves the patient's symptoms, function, and quality of life. To protect the health and safety of patients, American Specialty Health (ASH) has implemented medical necessity review strategies to educate practitioners of the need to implement methods to reduce clinical errors and improve patient safety. These medical necessity review strategies include encouraging practitioners to adopt evidence-based health care approaches to patient care, implement professional standards of care, and follow applicable care management guidelines. Conducting risk management procedures via medical necessity review minimizes potential adverse outcomes and harm to the patient and prevents wasteful, unsafe, and inappropriate care.

Medical necessity review protects the safety of patients. The application of acupuncture to a patient must be appropriate and safe. Cases where it is not safe to administer acupuncture may pose significant health and safety risk to a patient, for example:

- A patient with a history of breast cancer, lymph node resection, and resultant severe arm lymphedema is treated with acupuncture in the affected arm. This puts the patient at an increased risk of infection in the affected arm.
- A thin, frail patient who presents with shoulder and neck pain reports shortness of breath and chest pain after acupuncture is performed in the scapular area. Failure to recognize risk factors and symptoms of pneumothorax could lead to life-threatening complications.
- A patient reports acute low back pain, loss of sensory perception in the lower extremities and bladder dysfunction. Failure to recognize and diagnose classic signs of Cauda Equina syndrome may have serious harmful effects including permanent neurological dysfunction as this condition requires immediate surgical intervention.

Care approved through medical necessity review is safe, appropriate, and directed at specific treatment goal resolution to ensure clinical benefit and improvement to the patient's quality of life.

- For risk-reduction and the protection of patients, the review process does not approve treatment when a condition should be referred to a medical physician, the treatment is unsafe, or when treatment is not providing measurable health improvement.
- For the benefit of patients, the review process approves services when the evidence and practitioner treatment plan support the use of conservative treatment for conditions known to be amenable to the services provided. This allows patients to recover from conditions without the need for more costly or high-risk treatments such as prescription opioids, injections, or surgery.

## **GUIDELINES**

### **1. PROVIDERS OF ACUPUNCTURE SERVICES**

Covered, medically necessary Acupuncture services must be delivered by a qualified acupuncture practitioner acting within the scope of their license as regulated by the Federal and State governments. Only those healthcare practitioners who hold an active license, certification, or registration with the applicable state board or agency may provide such services.

Aides and other non-qualified personnel are limited to the provision of non-skilled services such as preparing the individual, treatment area, equipment, or supplies.

## 2. ACUPUNCTURE SERVICES

### 2.1 Medically Necessary

For individuals not covered by Medicare, (see section 2.5 for information about Medicare policy) Acupuncture Services are considered medically necessary for treatment of any of the following:

- Tension-type Headache; Migraine Headache with or without Aura;
- Hip or Knee Joint Pain associated with Osteoarthritis (OA);
- Other Extremity Joint Pain associated with OA or mechanical irritation/inflammation when chronic and unresponsive to standard medical care;
- Other Pain Syndromes involving the joints and associated soft tissues;
- Musculoskeletal Cervical Spine, Thoracic Spine, and Lumbar Spine Pain;
- Nausea Associated with Pregnancy (only when co-managed);
- Post-Operative Nausea/Vomiting (within the first 24 hours after surgery) or Post-Discharge Nausea/Vomiting (within a few days after post-operative discharge); (only when co-managed);
- Nausea Associated with Chemotherapy; (only when co-managed).

#### **AND when ALL of the following criteria are met**

1. The services are delivered by a qualified practitioner of acupuncture services; and
2. The services require the judgment, knowledge, and skills of a qualified practitioner of acupuncture services due to the complexity and sophistication of the therapy and the clinical condition of the individual; and
3. The service is aimed at treatment of disorders for which coverage is available; and
4. The service is for conditions that require the unique knowledge, skills, and judgment of an acupuncture practitioner for education and training of the patient that is part of an active skilled plan of treatment; and
5. There is a clinically supported expectation that the service will result in a clinically significant level of functional improvement within a **reasonable and predictable period of time**<sup>1</sup>; and
  - Improvement or restoration of function could not be reasonably expected as the individual gradually resumes normal activities without continued care.
  - The documentation objectively verifies progressive functional improvement over specific time frames and clinically justifies the continuation of acupuncture services; and

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<sup>1</sup> **Reasonable and predictable period of time:** The specific time frames for which one would expect practical functional improvement is dependent on various factors. A reasonable trial of care to determine the patient's potential for improvement in, or restoration of, function is generally up to 4 weeks, and is influenced by the patient's condition; clinical evaluation findings; stage of the condition (acute, sub-acute, chronic); severity of the condition; and patient-specific elements (age, sex, past and current medical history, family history, and any relevant psychosocial factors).

6. There are no diagnostic red flags<sup>2</sup> or red flags that are present are being addressed appropriately, including, as needed, co-management:
  - Examples of red flags may include but are not limited to new or progressing neurological deficits; history of malignancy; long term steroid use; sudden weight loss; and
7. Any present yellow flags<sup>3</sup> are being evaluated and managed appropriately:
  - Examples of yellow flags may include but are not limited to fear-avoidance behaviors; low self-efficacy; delayed return to work; and
8. No absolute contraindications are present including, but not limited to:
  - The use of acupuncture with patients who have uncontrolled movements that pose a safety risk for needle usage;
  - Needling of body area exhibiting lymphedema or at risk of lymphedema;
  - Needling of areas of spinal instability where relaxation of the surrounding muscles could potentially give rise to spinal cord compression;
  - Needling of scars, keloids
  - Compromised skin such as cellulitis, burns, cutaneous malignancies, other wounds, sensory deficits, etc. in the area of needling;
  - Needling the umbilicus area; infant fontanelles; the breast; or implants/artificial joints;
  - Hemophilia/hemorrhagic diseases; thrombocytopenia;
  - Severe neutropenia and or lymphopenia;
  - Psychosis, delusions, intoxications, cognitive or developmental impairments, uncontrolled seizure disorders, or other conditions that would disallow safe, appropriate patient participation in the treatment;
  - Generalized/widespread skin conditions that would render acupuncture inappropriate;
  - Emergent health conditions where acupuncture might delay or impede life-saving care, for example:
    - Mechanical obstruction (i.e., foreign body in throat, bowel obstruction);
    - Clear indications for surgical intervention (i.e., fractures, bleeding wounds);
    - Fulminant infections/sepsis;
    - Damaged or prosthetic heart valves; history of endocarditis;
    - Electromagnetic stimulation if internal defibrillator, pacemaker, or other medical electronic devices are present; and
  - Recent hemorrhagic stroke

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<sup>2</sup> Red Flag(s): Signs and symptoms presented through history or examination/assessment that warrant more detailed and immediate medical assessment and/or intervention.

<sup>3</sup> Yellow Flag(s): Adverse prognostic indicators with a psychosocial predominance associated with chronic pain and disability. Yellow flags signal the potential need for more intensive and complex treatment and/or earlier specialist referral.

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9. Any relative contraindications for acupuncture or electro-acupuncture therapy have been addressed and managed appropriately. Relative contraindications may include but are not limited to anticoagulant therapy; generalized frailty, febrile illnesses, pregnancy (avoiding professionally recognized areas of inappropriate needling); diabetes; and
10. Treatment planning and outcomes meet the criteria defined below.

## **2.2 Not Medically Necessary**

1. Acupuncture for any conditions other than those noted above is considered **not medically necessary**.
2. Maintenance care (e.g., elective care, wellness care) is considered **not** medically necessary and is often a specific benefit exclusion.
3. Acupuncture services are considered **not** medically necessary if **any** of the following is determined:
  - a. The service is not aimed at treatment of disorders for which coverage is available.
  - b. The service is for conditions for which therapy would be considered routine educational, training, conditioning, or fitness. This includes treatments or activities that require only routine supervision.
  - c. The expectation does **not** exist that the service(s) will result in a clinically significant improvement in the level of functioning within a reasonable and predictable period of time (up to 4 weeks).
    - If, absent supervised care, function could reasonably be expected to improve at the same / similar rate as the individual gradually resumes normal activities, then the service is considered not medically necessary.
    - If an individual's expected restoration potential would not produce a meaningful improvement in relation to the extent and duration of the service required to achieve such potential, the service(s) would be considered not medically necessary.
    - The documentation fails to objectively verify functional progress over a reasonable period of time (up to 4 weeks).
    - The patient has reached maximum therapeutic benefit.
  - d. A passive modality is **not** preparatory or adjunctive to other skilled treatment procedures or is not necessary in order to provide other skilled treatment procedures safely and effectively.
  - e. A passive modality has insufficient published evidence to support a clinically meaningful physiological effect on the target tissue or improve the potential for a positive response to care for the condition being treated.
  - f. Services do **not** require the skills of a qualified practitioner of acupuncture services. Examples include but are not limited to:

- Practitioner recommended activities and services that can be practiced independently and can be self-administered safely and effectively.
- Home exercise programs that can be performed safely and independently to continue therapy without skilled supervision.
- Activities for the general health and welfare of the individual such as:
  - General exercises (basic aerobic, strength, flexibility, or aquatic programs) to promote overall fitness/conditioning.
  - Services/programs for the primary purpose of enhancing or returning to athletic or recreational sports.
  - Massages and whirlpools for relaxation.
  - General public education/instruction sessions.
- g. Re-evaluations or assessments of a patient's status that are incorporated within the definition of the work components included within the acupuncture services Current Procedural Terminology (CPT®) codebook codes. (See chart below)
- h. Re-evaluations or assessments of a patient's status that are not necessary to continue a course of therapy nor related to a new condition, new or changed health status for which the evaluation will likely result in a change in the treatment plan.
- i. The treatments/services are **not** supported by and are **not** performed in accordance with nationally recognized clinical standards or peer-reviewed literature as documented in applicable ASH CPGs or other literature accepted by ASH Clinical Quality committees.
- 4. The following treatments are considered not medically necessary because they are educational, or training in nature. In addition, these treatments/programs may be specifically excluded under benefit plans:
  - Back school.
  - Group therapy (because it is not one-on-one, individualized to the specific patient's needs).
  - Vocational rehabilitation programs and any program or evaluation with the primary goal of returning a patient to work.
  - Work hardening programs.
  - Nutrition wellness education or similar wellness interventions.
- 5. The use of therapeutic magnets as a replacement for acupuncture needling services is not considered medically necessary. Magnet therapy is scientifically unproven for the treatment of pain, including when it is applied to acupuncture points. (*CPG 133 Techniques and procedures not Widely Supported as Evidence-Based and CPG 54 -Magnet Therapy - Static*).



### 2.3 Co-Management Requirements

Conditions that require medical co-management in order for treatment with acupuncture to be considered medically necessary include:

- Paralyzes/Plegias
- Abdominal/Pelvic Pain
- Nausea/Vomiting
- Pregnancy
- Post-Surgical Conditions
- Ear/Eye Pain
- Cancer
- Masses
- Pain Related to Other/Systemic Conditions (e.g., Ankylosing Spondylitis, Human Immunodeficiency Virus (HIV), Multiple Sclerosis, Chest Pain).

#### Children 3 years of age and under:

Evidence of co-management with a medical practitioner must be documented for all conditions before the medical necessity review (MNR) can be completed. Documentation only that the child has a medical practitioner is not adequate.

#### Children 4-11 years of age:

Co-management with the child's medical practitioner is required. If documentation of co-management is not provided, response codes may be used as appropriate with medical necessity review to notify the acupuncture practitioner of the need to report the co-management information on the next medical necessity review submission. Documentation only that the child has a medical practitioner is not adequate.

The main objective of co-management requirements for children receiving acupuncture is to ensure the medical practitioner is aware of the child's condition, knows that acupuncture treatment is being sought, and has had the opportunity to coordinate care as needed.

Verification of medical necessity is required after the initial evaluation for all children under 12 years of age.

### 2.4 Medical Referral for Acupuncture

If acupuncture services are part of a referral-required program, they may be considered medically necessary only if the patient history, physical exam findings, diagnosis and treatment plan are consistent with the diagnosis provided by the referring physician.

## 2.5 Centers for Medicare and Medicaid Services (CMS) Medical Necessity

For individuals covered by Medicare, ASH manages CMS Required and Supplemental benefits for Medicare Advantage Plans. Required (Traditional) Medicare benefits are covered based on CMS guidelines and regulations, CMS approved ICD defined conditions and CPT® defined services. ASH practitioners are required to follow CMS clinical requirements for the appropriate delivery and documentation of services rendered to Medicare beneficiaries who are served by ASH Medicare Advantage health plan clients.

Medicare coverage based on a National Coverage Determination (NCD 30.3.3) is limited to the following indications and limitations exist:

1. Acupuncture is only covered or medically necessary for chronic low back pain.
  - a. Up to 12 visits in 90 days
  - b. For this coverage, chronic low back pain is defined as:
    - i. Lasting 12 weeks or longer
    - ii. Non-specific with no identifiable systemic cause (e.g., not metastatic, inflammatory, infectious)
    - iii. Not associated with surgery
    - iv. Not associated with pregnancy
  - c. An additional 8 sessions will be covered for those patients demonstrating an improvement
  - d. No more than 20 acupuncture treatments may be administered annually
  - e. Treatment must be discontinued if the patient is not improving or is regressing

ASH will not cover, per CMS guidance, acupuncture treatment for low back pain when the patient has: experienced surgery of any kind to the lumbar spine region (low back); low back pain associated with systemic disease (e.g., metastatic, inflammatory, infectious); or low back pain associated with pregnancy when is less than 12 weeks post-partum.

ASH will cover, per CMS guidance, acupuncture treatment for low back pain that is nonspecific with no identifiable systemic cause including: non-specific chronic low back pain if the patient has unrelated co-morbid symptoms due to other pain conditions; or non-specific chronic low back pain for patients who have had hip or pelvic surgery as long as the low back pain is not related to the surgery.

Required Medicare benefits only cover the acupuncture needling services for chronic low back pain as defined in NCD 30.3.3. There are no Local Coverage Determinations (LCD) or Local Coverage Articles (LCA) that provide guidance regarding medical necessity other than the limited guidance provided by NCD 30.3.3. When Medicare policy guidance for medical necessity is sufficient and clear to guide medical necessity decisions, the applicable Medicare guidance should be used in medical necessity review determinations. If the Medicare guidance for medical necessity review determinations is not clear or is

insufficient in providing adequate guidance for a medical necessity determination for acupuncture services, the next policy in line used in making medical necessity review decisions would be the ASH *Acupuncture Services Medical Policy Guideline (CPG 264 – S)* clinical practice guideline.

If applicable this policy will provide guidance for medical necessity review determinations of the Medicare covered service of acupuncture and dry needle therapy for non-specific chronic low back pain. The determination of medically necessary care as outlined in this guideline protects against inappropriate care that may be wasteful, unsafe, and harmful to the patient. The clinical benefit of insuring services is medically necessary highly outweighs the risk from clinical harms, including the possibility of limitations from delayed or decreased access to services. These additional criteria are implemented by clinical quality evaluators to determine medical necessity consistently to ensure all appropriate care is provided to Medicare Advantage (MA) beneficiaries.

The clinical evidence to support the delivery of services for covered conditions is supported by the guidelines and primary research references noted below. In summary, the evidence supports the use of acupuncture and dry needle therapy for the treatment of non-specific chronic low back pain when the patient is correctly diagnosed with those conditions, there are not contraindications for the treatment, and the course of care produces a favorable outcome following an appropriate frequency of treatment encounters.

### 3. CURRENT PROCEDURAL TERMINOLOGY (CPT®) CODES AND DESCRIPTIONS FOR ACUPUNCTURE

CPT® Code	CPT® Code Description
97810	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97811	Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)
97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)

In addition to the CPT® codes above, the following are covered for Center for Medicare and Medicaid Services (CMS) Acupuncture Chronic Low Back Pain programs. These CPT® codes may be covered under other benefit plans. Check the applicable client summary for further information.

CPT® Code	CPT® Code Description
20560	Needle insertion(s) without injection(s); 1 or 2 muscle(s)
20561	Needle insertion(s) without injection(s); 3 or more muscles

### **3.1 General CPT Guidelines for Acupuncture**

1. Only one CPT® code may be reported for each 15-minute increment.
2. Only one initial acupuncture code is reported per date of service as these services include both the treatment, set-up, and evaluation necessary to identify the specific acupuncture service(s) necessary for the patient. Therefore, when reporting this service, only one initial code is reported per date of service to identify the complete initial service provided.
3. For the initial increment, either code 97810, *or* code 97813 for the initial 15 minutes of personal one-on-one contact with the patient, should be reported.
4. For each additional increment of "personal one-on-one contact with the patient with re-insertion of needle(s) " performed, either 97811 or 97814 is reported, depending on the use or non-use of electrical stimulation during that increment.
5. Re-insertion of the needle(s) is required for the use of add-on codes 97811 and 97814.
6. "Reinsertion" does not imply removing and replacing the same needles as would be contraindicated by related guidelines.
7. Acupuncture services performed without electrical stimulation and with electrical stimulation may be reported at the same session, provided separate 15-minute increments are spent performing each of the services.
8. Acupuncture is reported based on 15-minute increments of personal (face-to-face) contact with the patient and not the duration of acupuncture needle(s) retention.

9. One or two 15-minute episodes of acupuncture would be the most common pattern of practice and CPT® code usage. More than two CPT® codes would require documentation of special circumstances necessitating that level of acupuncture treatment.

10. Evaluation and management (E/M) services may be reported separately by appending modifier -25. Significant, separately identifiable evaluation and management service by the same practitioner on the same day of the procedure or other service may be utilized, if the patient's condition requires a significant separately identifiable E/M service, above and beyond the usual preservice and post-service work associated with the acupuncture services. The time of the E/M service is not included in the time of the acupuncture service.

#### 4. ACUPUNCTURE ADJUNCTIVE THERAPIES

Therapies may be used as adjuncts to, but not independently of, needle acupuncture. Adjunctive therapies must only be performed on the same date of service as needle acupuncture. Depending upon benefit design therapies may include, but are not limited to:

CPT® Code	CPT® Code Description
97010	Application of a modality to one or more areas; hot or cold packs
97014	Application of a modality to one or more areas; electrical stimulation (unattended)
97018	Application of a modality to one or more areas; paraffin bath
97022	Application of a modality to one or more areas; whirlpool
97024	Application of a modality to one or more areas; diathermy (e.g., microwave)
97026	Application of a modality to one or more areas; infrared
97032	Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes
97034	Application of a modality to one or more areas; contrast baths, each 15 minutes
97035	Application of a modality to one or more areas; ultrasound, each 15 minutes
97039	Unlisted modality (specify type and time if constant attendance)*

CPT® Code	CPT® Code Description
97110	Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97124	Therapeutic procedure, one or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)
97139	Unlisted therapeutic procedure (specify)*
97140	Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), one or more regions, each 15 minutes
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
97799	Unlisted physical medicine/rehabilitation service or procedure*
G0283	Electrical Stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

\*Procedures listed under the “unlisted” CPT® codes (97039, 97139 & 97799) will not be covered without documentation of medical necessity.

#### **4.1 Adjunctive Modalities**

The CPT® codebook defines a modality as “any physical agent applied to produce therapeutic changes to biologic tissue; includes but is not limited to thermal, acoustic, light, mechanical, or electric energy.” Modalities may be supervised, which means that the application of the modality does not require direct one-on-one patient contact by the practitioner; or modalities may involve constant attendance, which indicates that the modality requires direct one-on-one patient contact by the practitioner.

Supervised modalities are untimed therapies. Untimed therapies are usually reported only once for each date of service regardless of the number of minutes spent providing this service or the number of body areas to which they were applied. Untimed services billed as more than one unit will require significant documentation to justify treatment greater than one session per day. Examples of supervised modalities include:

- Hot or cold packs
- Unattended electrical stimulation
- Paraffin bath
- Infrared light

Modalities that require constant attendance, are timed, and reported in 15-minute increments (one unit) regardless of the number of body areas to which they are applied. Examples of modalities that require constant attendance include:

- Ultrasound
- Massage
- Manual electrical stimulation

#### **4.2 Adjunctive Therapeutic Procedures**

The CPT® codebook defines therapeutic procedures as "A manner of effecting change through the application of clinical skills and/or services that attempt to improve function." Therapeutic procedures that may be utilized by acupuncture practitioners require direct (one-on-one) patient contact (constant attendance) by the practitioner, are timed therapies, and must be reported in units of 15-minute increments. Only the actual time that the acupuncture practitioner is directly working with the patient performing exercises/activities, instruction, or assessments is counted as treatment time. The time that the patient spends not being treated because of a need for rest or equipment set up is not considered treatment time. Any exercise/activity that does not require, or no longer requires, the skilled assessment and intervention of a health care practitioner is not considered a medically necessary therapeutic procedure. Exercises often can be taught to the patient or a caregiver as part of a home/self-care program. Examples of therapeutic procedures that require the practitioner to have direct (one-on-one) patient contact include:

- Therapeutic exercises
- Manual therapy (e.g., soft tissue mobilization)

#### **4.3 Documentation Requirements to Substantiate Medical Necessity of Therapeutic Modalities and Procedures**

Proper and sufficient documentation is essential to establish the clinical necessity and effectiveness of each modality and procedure, aid in the determination of patient outcomes management, and support continuity of patient care. At a minimum, documentation is required for every treatment day and for each therapy performed. Each daily record should include: the date of service, the name of each modality and/or procedure performed, the parameters for each modality (e.g., amperage/voltage, location of pads/electrodes), area of treatment, total treatment time spent for each therapy (mandatory for timed services), the total treatment time for each date of service, and the identity of the person(s) providing the services. Failure to properly identify and sufficiently document the parameters for each therapy on a daily progress note may result in an adverse determination (partial approval or denial).

## 4.4 Passive Care and Active Care

### Passive Care

Passive care are those interventions applied to a patient with no active participation on the part of the patient. Passive care includes various skilled *therapeutic procedures* (e.g., acupuncture, manual therapy, chiropractic manipulation) as well as *passive therapeutic modalities*, such as heat, cold, electrical stimulation, and ultrasound. The following guidelines are relevant to the use of *passive therapeutic modalities*:

- Generally used to manage the acute inflammatory response, pain, and/or muscle tightness or spasm in the early stages of musculoskeletal and related condition management (e.g., short term and dependent upon patient condition and presentation; a few weeks). When the symptoms that prompted the use of certain passive therapeutic modalities begin to subside (e.g., reduction of pain, inflammation, and muscle tightness) and function improves, the medical record should reflect the discontinuation of those modalities, so as to determine the patient's ability to self-manage any residual symptoms.
- In Acupuncture Medicine passive therapeutic modalities may also be used for pain management longer term past the acute inflammatory response. (e.g. passive heating modalities for chronic cold conditions). Passive therapeutic modalities can be appropriate in these situations when they are adjunctive to delivery of other skilled therapeutic procedures (e.g., therapeutic exercise, acupuncture) that are considered medically necessary.
- Used as a stand-alone treatment is rarely therapeutic, and thus not required or indicated as the sole treatment approach to a patient's condition. Therefore, a treatment plan should not consist solely of passive therapeutic modalities but should also include skilled therapeutic procedures (e.g., acupuncture, therapeutic exercise).
- Should be based on the most effective and efficient means of achieving the patient's functional goals. Seldom should a patient require more than one (1) or two (2) passive therapeutic modalities to the same body part during the therapy session. Use of more than 2 passive therapeutic modalities on a single visit date and for a prolonged period is unusual and should be justified in the documentation for consideration of medical necessity.

### Active Care

Active care involves therapeutic interventions that require patients to engage in specific exercises, movements, or activities to improve their health. Unlike passive care, which relies on external treatments (such as passive therapeutic modalities), active care emphasizes patient involvement and responsibility. Examples of active care include



- Therapeutic Exercise Prescription (CPT® Code 97110): This service may be considered when healthcare professionals are present and supervising tailored exercises performed by the patient based on the patient's condition, goals, and limitations. These exercises may be considered medically necessary to restore/develop strength, endurance, range of motion and flexibility which has been lost or limited as a result of a disease or injury. (Refer to the "Treatment Interventions" section of this CPG for further information)
- Independent Exercise Programs: Patients are provided with appropriate exercise routines to perform on their own (e.g., home exercise programs [HEP]). Supervised skilled care is provided in the development, modifications, and progressions of the HEP.
- Education and Self-Management: Patients receive education about their condition, proper body mechanics, and strategies to prevent recurrence. Empowering patients with knowledge helps them actively manage their health.

Use of various forms of active care should be started as soon as treatment is initiated and documented in the medical record, including instructions supporting independent exercise, education and self-management. Patients should progress from active therapeutic procedures requiring the supervision of a skilled practitioner to solely an independent exercise program as soon as reasonably possible.

The goal for active therapeutic procedures requiring the supervision of a skilled practitioner is to provide the necessary skilled support (e.g., assessment, exercise technique and movement correction and feedback, modification and/or exercise progression) to empower patients to successfully adopt and maintain an independent exercise program more efficiently and effectively than if they tried to do it on their own.

The length of time per session and the duration for medically necessary, active therapeutic procedures requiring the supervision of a skilled practitioner will vary depending upon multiple factors including but not limited to the patient's knowledge of exercise techniques and health status of the patient, the diagnosis, co-morbidities, phase of care, chronicity, and exam findings, the nature and severity of complaints, and functional impairments.

When is supportive documentation required?:

- For most patients, the length of time per visit for medically necessary active therapeutic procedures typically does not exceed one to two (1-2) timed units of CPT® codes such as 97110. A longer time per visit requires documentation to support this level of supervision and activity.
- More than two (2) (e.g., 97110) sessions per week is expected to be a rare occurrence. Frequency of greater than two (2) times per week requires documentation to support this level of supervision.

## **4.5 Treatment Interventions**

Below are descriptions and medical necessity criteria, as applicable, for different treatment interventions, including specific modalities and therapeutic procedures associated with Acupuncture services. This material is for informational purposes only and is not indicative of coverage, nor is it an exhaustive list of services provided.

### **Hot/Cold Packs**

Hot packs increase blood flow, relieve pain, and increase flexibility. Cold packs decrease blood flow to an area for reduction of pain and swelling. They may be considered medically necessary for musculoskeletal conditions that include significant pain and or swelling.

### **Paraffin Bath**

This modality uses hot wax for application of heat. It is indicated for use to relieve pain and increase range of motion of extremities (typically wrists and hands) in post-surgical patients or patients with chronic joint dysfunction.

### **Infrared Light Therapy**

Infrared light therapy is a form of heat therapy used to increase circulation to relieve muscle spasm. Other heating modalities are considered superior to infrared lamps and should be considered unless there is a contraindication to those other forms of heat. Utilization of the Infrared light therapy CPT® code is not appropriate for low level laser treatment.

### **Electrical Stimulation**

Various types and frequencies of electrical stimulation are used to relieve pain, reduce swelling, and improve muscle function.

### **Ultrasound**

This modality provides deep heating and possibly micro-massage to a localized area through high frequency sound wave application. Ultrasound may be considered medically necessary to relieve pain and improve healing.

### **Therapeutic Exercises**

Therapeutic exercise includes instruction, feedback, and supervision of a person in an exercise program specific to their condition. Therapeutic exercise may be considered medically necessary to restore/develop strength, endurance, range of motion and flexibility which has been lost or limited as a result of illness, injury, loss of a body part, or congenital abnormality. Exercising done by the patient within a clinic facility or other location (e.g., home; gym) without a practitioner present and supervising would be considered not medically necessary.

## **4.6 Precautions and Contraindications to Therapeutic Modalities and Procedures**

### **Thermotherapy**

The use of thermotherapy is contraindicated for the following:

- Recent or potential hemorrhage
- Thrombophlebitis
- Impaired sensation
- Impaired mentation
- Local malignant tumor
- IR irradiation of the eyes
- Infected areas

Precautions for use of thermotherapy include:

- Acute injury or inflammation
- Pregnancy
- Impaired circulation
- Poor thermal regulation
- Edema
- Cardiac insufficiency
- Metal in the area
- Over an open wound
- Large scars
- Over areas where topical counterirritants have recently been applied
- Demyelinated nerve

### **Cryotherapy**

The use of cryotherapy is contraindicated for the following:

- Cold hypersensitivity
- Cold intolerance
- Cryoglobulinemia
- Paroxysmal cold hemoglobinuria
- Raynaud disease or phenomenon
- Over regenerating peripheral nerves
- Over an area with circulatory compromise or peripheral vascular disease

Precautions for cryotherapy include:

- Over the superficial branch of a nerve
- Neuropathy

- Over an open wound
- Hypertension
- Poor sensation or mentation

## **Electrical Currents**

Contraindications for use of electrical currents:

- Demand pacemakers, implantable defibrillator, or unstable arrhythmia
- Placement of electrodes over carotid sinus and heart
- Areas where venous or arterial thrombosis or thrombophlebitis is present
- Pregnancy (over or around the abdomen or low back)
- Infected areas

Precautions for electrical current use:

- Cardiac disease
- Impaired mentation
- Impaired sensation
- Malignant tumors
- Areas of skin irritation or open wounds

## **Ultrasound**

Contraindications to the use of ultrasound include:

- Malignant tumor
- Pregnant uterus
- Central Nervous Tissue
- Joint cement
- Plastic components
- Pacemaker or implantable cardiac rhythm device
- Thrombophlebitis
- Eyes
- Reproductive organs
- Impaired sensation
- Impaired mentation
- Infected areas

Precautions for ultrasound include:

- Acute inflammation
- Epiphyseal plates
- Fractures
- Breast implants

## **Pediatric Patients**

The use of electrical muscle stimulation, thermotherapy, cryotherapy, ultrasound, laser/light therapy, and mechanical traction is contraindicated if the patient cannot provide the proper feedback necessary for safe application.

## **Unproven**

In addition to the contraindications listed above, there are a wide range of services which are considered unproven, pose a significant health and safety risk, are scientifically implausible and/or are not widely supported as evidence based. Such services would be considered not medically necessary and include, but are not limited to:

- Dry needling
- Laser therapy
- Cupping
- Direct moxibustion
- Manual muscle testing to diagnosis non-neuromusculoskeletal conditions
- Microcurrent Electrical Nerve Stimulation (MENS)
- Other unproven procedures (see the *Techniques and Procedures Not Widely Supported as Evidence-Based (CPG 133 – S)* clinical practice guideline for complete list)

## **4.7 Redundant Therapeutic Effects and Services by Different Healthcare Practitioners/Specialties**

Certain therapeutic modalities and procedures are considered redundant in nature, and it would be inappropriate to provide these services to the same body region during the same treatment session. This includes treatments, such as but not limited to:

- More than one heating modality
- Massage therapy and myofascial release

Duplicate services provided by different healthcare practitioners/specialties for the same condition(s) are considered **not** medically necessary. When patients receive acupuncture services, physical therapy services, occupational therapy services, or other healthcare specialty services for the same condition(s), the healthcare practitioners should provide different treatments that reflect each healthcare discipline's unique perspective on the patient's impairments and functional deficits and not duplicate the same treatment. Each healthcare specialty practitioner must also have separate and distinct evaluations, treatment plans, and goals.

## 5. CLINICAL DOCUMENTATION

For more information, see the *Medical Record Maintenance and Documentation Practices* (CPG 110 – S) clinical practice guideline.

Medical record keeping is an essential component of patient evaluation and management. Medical records should be legible and should contain, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment. Good medical record keeping improves the likelihood of a positive outcome and reduces the risk of treatment errors. It also provides a resource to review cases for opportunities to improve care, provides evidence for legal records, and offers necessary information for third parties who need to review and understand the rationale and type of services rendered (e.g., medical billers and auditors/reviewers).

Outcome measures are important in determining effectiveness of a patient's care. The use of standardized tests and measures early in an episode of care establishes the baseline status of the patient, providing a means to quantify change in the patient's functioning. Outcome measures provide information about whether predicted outcomes are being realized. When comparing follow-up with baseline outcome metrics does not demonstrate minimal clinically important difference (MCID) (minimal amount of change in a score of a valid outcome assessment tool) the treatment plan should be changed or be discontinued. Failure to use Functional Outcome Measures (FOMs) / Outcome Assessment Tools (OATs) may result in insufficient documentation of patient progress and may result in an adverse determination (partial approval or denial) of continued care.

### **5.1 Evaluation and Re-evaluation**

As a best practice, all the following should be clearly described in the submitted records:

- Historical information including a clear description of the current complaint(s);
- Prior and current levels of function;
- Tests performed and the results (e.g., evaluation findings);
- Valid diagnosis(es);
- Therapeutic goals and treatment plan (e.g., specific treatments, number of office visits);
- Response to care, progress, and prognosis; and
- Self – Care advice, including home exercise program.

An initial evaluation service is essential to determine whether any services that may be recommended by the evaluating practitioner are medically necessary, to determine if referral to another clinical setting or another type of evaluation is necessary, to gather

baseline data, establish a treatment plan, and develop goals based on the data. The initial evaluation is usually completed in a single session. An evaluation is needed before implementing any acupuncture treatment. Initial evaluations include an Evaluation and Management (New Patient or Established Patient E/M) history and physical examination service and may be supported by, as necessary, imaging, laboratory studies, and/or other diagnostic tests and measures in accordance with scope of practice rules and regulations.

The acupuncture service CPT® codes 97810 and 97813 include a brief interval history and examination of the patient's condition, as well as documentation of the patient's response to the treatment and any changes to goals or treatment plan. Routine use of E/M services is not medically necessary. A re-evaluation is considered medically necessary following:

- a trial of care to determine whether that care resulted in significant clinical improvement and
- for documenting the need to continue a course of therapy
- a need for referral to other healthcare practitioner(s)/specialist(s), or
- that discontinuance of treatment is warranted.

A re-evaluation (an Established Patient E/M service) is considered medically necessary when **all** the following conditions are met:

- The re-evaluation exceeds the recurring routine assessment of patient status included in the Acupuncture CPT® codes work-value; and
- The documentation of the reevaluation includes **all** of the following elements:
  - Evaluation of progress toward current goals; and
  - Professional judgment about continued care; and
  - Professional judgment about revising goals and/or treatment or terminating services; and
- Any **one** of the following indications is documented:
  - An exacerbation, a new condition(s), or new clinical findings.
  - Significant change in the patient's condition(s).
  - Failure to respond to the therapeutic interventions outlined in the current plan of care.

A re-evaluation is considered **not** medically necessary once it has been determined that the patient has reached maximum therapeutic benefit from the services provided unless there is/are medically necessary reason(s) documented for the reevaluation service.

## 5.2 New and Established Patient Definitions

The CPT® codebook provides the following definitions:

**New Patient:** Is one who **has not** received any professional services from the physician/qualified health care professional or another physician/qualified health care professional of the exact same special and subspecialty who belongs to the same group practice, within the past three (3) years.

**Established Patient:** Is one who **has** received professional services from the physician/qualified health care professional or another physician/qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past three (3) years.

## 5.3 Treatment Sessions

Acupuncture treatment can vary from acupuncture alone (CPT® codes 97810, 97811, 97813, 97814) to the use of a variety of adjunctive modalities and procedures depending on the patient's condition, response to care and treatment tolerance. All services must be supported in the treatment plan and be based on an individual's clinical condition. An acupuncture treatment session may include:

- A brief evaluation of the patient's progress and response to previous treatment(s);
- Acupuncture.
- Adjunctive modalities (e.g., moxa, Tui Na, hot/cold packs, therapeutic exercise);
- Recommendations for self-care and home management.
- Skilled reassessment of the individual's problems, plan, and goals as part of the treatment session.
- Coordination, communication, and documentation.
- Reevaluation, if there is a significant change in the individual's condition or there is a need to update and modify the treatment plan.

Documentation of treatment should include:

- Date of treatment.
- Subjective complaints and current status (including functional deficits and ADL restrictions).
- Description/name of each specific treatment intervention provided, including Acupuncture points used, total numbers of needles inserted and removed
  - The parameters for each therapy provided (e.g., voltage/amperage, pad/electrode placement, area of treatment, types of exercises/activities, and intended goal of each therapy);
  - Treatment time for each therapy and total treatment time per date of service;
- The patient's response to each service and to the entire treatment session;



- Any progress toward the goals in objective, measurable terms using consistent and comparable methods;
- Any changes to the plan of care;
- Recommendations for follow-up visit(s);
- Signature/electronic identifier, name, and credentials of the treating clinician.

#### **5.4 Duplicated / Insufficient Information**

Entries in the medical record should be contemporaneous, individualized, appropriately comprehensive, and made in a chronological, systematic, and organized manner. Duplicated/nearly duplicated medical records (a.k.a. cloned records) are not acceptable. It is not clinically reasonable or physiologically feasible that a patient's condition will be identical on multiple encounters. (Should the findings be identical for multiple encounters, it would be expected that treatment would change or end because the patient is not making progress toward current goals.)

This includes, but is not limited to:

- Duplication of information from one treatment session to another (for the same or different patient[s]).
- Duplication of information from one evaluation to another (for the same or different patient[s]).

Duplicated medical records do not meet professional standards of medical record keeping and may result in an adverse determination (partial approval or denial) of those services.

The use of a system of record keeping that does not provide sufficient information (e.g., checking boxes, circling items from lists, arrows, travel cards with only dates of visit and listings) may result in an adverse determination (partial approval or denial) of those services.

Effective and appropriate record keeping that meets professional standards documents with adequate detail, a proper assessment of the patient's status, the nature and severity of his/her complaint(s) or condition(s), and/or other relevant clinical information (e.g., history, parameters of each therapy performed, objective findings, progress towards treatment goals, response to care, prognosis).

#### **5.5 Centers for Medicare and Medicaid Services (CMS)**

For Medicare and Medicaid services, medical records keeping must follow and be in accordance with Medicare and any additional state Medicaid required documentation guidelines.

## 6. CLINICAL REVIEW PROCESS

Medical necessity evaluations require approaching the clinical data and scientific evidence from a global perspective and synthesizing the various elements into a congruent picture of the patient's condition and need for skilled treatment intervention. Clinical review decisions made by the CQEs are based upon the information provided by the treating practitioner in the submitted documentation and other related findings and information. Failure to appropriately document pertinent clinical information may result in adverse determinations (partial approval or denial) of those services. Therefore, thorough documentation of all clinical information that established the diagnosis/diagnoses and supports the intended treatment is essential.

### 6.1 Definition of Key Terminology used in Clinical Reviews

#### **Elective/Convenience Services**

Examples of elective/convenience services include: (a) preventive services; (b) wellness services; (c) services not necessary to return the patient to pre-illness/pre-injury functional status and level of activity; (d) services provided after the patient has reached MTB. (Elective/convenience services may not be covered through specific client or ASH benefits.)

#### **Minimal Clinically Important Difference (MCID)**

The MCID is the minimal amount of change in a score of a valid outcome assessment tool that indicates an actual improvement in the patient's function or pain. Actual significance of outcome assessment tool findings requires correlation with the overall clinical presentation, including updated subjective and objective examination/evaluation findings.

#### **Maximum Therapeutic Benefit (MTB)**

MTB is the patient's health status when the application of skilled therapeutic services has achieved its full potential (which may or may not be the complete resolution of the patient's condition.) At the point of MTB, continuation of the same or similar skilled treatment approach will not significantly improve the patient's impairments and function during this episode of care.

If the patient continues to have significant complaints, impairments, and documented functional limitations, one should consider the following:

- Altering the treatment regimen such as utilizing a different physiological approach to the treatment of the condition, or decreasing the use of passive care (modalities, massage, etc.) and increasing the active care (therapeutic exercise) aspects of treatment to attain greater functional gains.
- Reviewing self-management program including home exercise programs; and/or
- Referring the patient for consultation by another health care practitioner for possible co-management or a different therapeutic approach.

## **Preventive Services**

Preventive services are designed to reduce the incidence or prevalence of illness, impairment, and risk factors, and to promote optimal health, wellness, and function. These services are not designed or performed to treat or manage a specific health condition. (Preventive services may or may not be covered under specific clients or through ASH benefits.)

## **Acute**

The stage of an injury, illness, or disease, in which the presence of clinical signs and symptoms is less than six weeks in duration, typically characterized by the presence of one or more signs of inflammation or other adaptive response.

## **Sub-Acute**

The stage of an injury, illness, or disease, in which the presence of clinical signs and symptoms is greater than six weeks, but not greater than twelve weeks in duration.

## **Chronic**

The stage of a pain condition in which the presence of clinical signs and symptoms is greater than 12 weeks in duration.

## **Red Flag(s)**

Signs and symptoms presented through history or examination/assessment that warrant more detailed and immediate medical assessment and/or intervention.

## **Yellow Flag(s)**

Adverse prognostic indicators with a psychosocial predominance associated with chronic pain and disability. Yellow flags signal the potential need for more intensive and complex treatment and/or earlier specialist referral.

## **Co-Morbid Condition(s)**

The presence of a concomitant condition, that may inhibit, lengthen, or alter in some way the expected response or approach to care.

## **Health Equity (HE)**

The attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes (Centers for Medicare & Medicaid Services, 2024).

## **Social Determinants of Health (SDoH)**

The conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. Five domains: 1) Economic stability; 2) Education access and quality; 3) Health care access and quality; 4) Neighborhood and built environment; 5) Social and community context (Office of Disease Prevention and Health Promotion [ODPHP], n.d.).

### **6.2 Clinical Review for Medical Necessity**

The goal of the CQEs during the review and decision-making process is to approve, as appropriate, those clinical services necessary to return the patient to pre-clinical/pre-morbid health status, stabilize, or functionally improve a chronic condition, as supported by the documentation presented. The CQE is to evaluate if the documentation and other clinical information presented by the practitioner has appropriately substantiated the patient's condition and justifies the treatment plan that is presented.

### **Approval**

ASH CQEs have the responsibility to approve appropriate care for all services that are medically necessary. The CQEs assess the clinical data supplied by the practitioner in order to determine whether submitted services and/or the initiation or continuation of care has been documented as medically necessary. The practitioner is accountable to document the medical necessity of all services submitted/provided. It is the responsibility of the peer CQE to evaluate the documentation in accordance with their training, understanding of practice parameters, and review criteria adopted by ASH through its clinical committees.

### **Partial Approval**

Occurs when only a portion of the submitted services are determined to be medically necessary services. The partial approval may refer to a decrease in treatment frequency, treatment duration, number of therapies, or other services from the original amount/length submitted for review. This decision may be due to any number of reasons, such as:

- The practitioner's documentation of the history and exam findings are inconsistent with the clinical conclusion(s).
- The treatment dosage (frequency/duration) submitted for review is not supported by the underlying diagnostic or clinical features.
- The need to initiate only a limited episode of care in order to monitor the patient's response to care.

Additional services may be submitted and reviewed for evaluation of the patient's response to the initial trial of care. If the practitioner or patient disagrees with the partial approval of services, they may contact the CQE listed on their response form to discuss the case, submit additional documentation through the Reopen process, or submit additional documentation to appeal the decision through the clinical appeal process.

## 1 **Non-approval / Denial**

2 Occurs when none of the services submitted for review are determined to be medically  
 3 necessary services. The most common causes for a non-approval/denial of all services are  
 4 administrative or contractual in nature (e.g., ineligibility, reached plan benefit limits, non-  
 5 coverage). Clinically, it is appropriate to deny continued/ongoing care if the patient's  
 6 condition(s) are not, or are no longer, responding favorably to the services being rendered  
 7 by the treating practitioner, or the patient has reached maximum therapeutic benefit.

## 9 **Additional / Continued Care**

10 Approval of an additional treatment/services requires submission of additional  
 11 information, including the patient's response to care and updated clinical findings. In cases  
 12 where an additional course of care is submitted, the decision to approve additional  
 13 treatment/services will be based upon the following criteria:

- 14 • The patient has made clinically significant progress under the initial treatment  
 15 plan/program based on a reliable and valid outcome tool or updated subjective,  
 16 functional, and objective examination findings.
- 17 • Additional clinically significant progress can be reasonably expected by continued  
 18 treatment. (The patient has not reached MTB or maximum medical improvement.)
- 19 • There is no indication that immediate care/evaluation is required by other health  
 20 care professionals.

21  
 22 Any exacerbation or flare-up of the condition that contributes to the need for additional  
 23 treatment/services must be clearly documented.

24 Ancillary diagnostic procedures should be selected based on clinical history and  
 25 examination findings that suggest the necessity to rule out underlying pathology or to  
 26 confirm a diagnosis that cannot be verified through less invasive methods.

- 27 • Information is expected to directly impact the treatment/services and course of care.
- 28 • The benefit of the procedure outweighs the risk to the patient's health (short and  
 29 long term).
- 30 • The procedure is sensitive and specific for the condition being evaluated (e.g., an  
 31 appropriate procedure is utilized to evaluate for pathology).

32  
 33 The clinical information documented and submitted to support medical necessity review  
 34 should be commensurate with the nature and severity of the presenting complaint(s), the  
 35 scope of the services being requested, the scope of practice of the practitioner performing  
 36 the services, and may include but is not limited to:

- 37 • History
- 38 • Physical examination/evaluation
- 39 • Documented treatment plan and goals
- 40 • Estimated time of discharge

In general, the initiation of care is warranted if there are no contraindications to the care, there is reasonable evidence to suggest the efficacy of the intervention, and the intervention is within the scope of services permitted by state or federal law. The treatment submission for a disorder is typically structured in time-limited increments depending on clinical presentation. Dosage (frequency and duration of service) should be appropriately correlated with clinical findings, potential complications/barriers to recovery and clinical evidence. When the practitioner discovers that a patient is nonresponsive to the applied interventions within a reasonable time frame, re-assessment and treatment modification should be implemented and documented. If the patient's condition(s) worsen, the practitioner should take immediate and appropriate action to discontinue or modify care and/or make an appropriate healthcare referral.

Services that do not require the professional skills of a practitioner to perform or supervise are not medically necessary. If a patient's recovery can proceed safely and effectively through a home exercise program or self-management program, services are not indicated or medically necessary.

### **6.3 Critical Factors During Clinical Reviews**

The complexity and/or severity of historical factors, symptoms, examination findings, and functional deficits play an essential role to help quantify the patient's clinical status and assess the effectiveness of planned interventions over time. CQEs consider patient-specific variables as part of the medical necessity verification process. The entire clinical picture must be taken into consideration with each case evaluated based upon unique patient and condition characteristics.

Such variables may include but not be limited to co-morbid conditions and other barriers to recovery, the stage(s) of the condition(s), mechanism of injury, severity of the symptoms, functional deficits, and exam findings, as well as social and psychological status of the patient and the available support systems for self-care. In addition, the patient's age, symptom severity, and the extent of positive clinical findings may influence duration, intensity, and frequency of services approved as medically necessary. For example:

- Severe symptomatology, exam findings, and/or functional deficits may require more care overall (e.g., longer duration, more services per encounter than the average); these patients may require a higher frequency of care; but may require short-term trials of care initially to assess the patient response to care.
- Less severe symptomatology, exam findings and/or functional deficits usually require less care overall (e.g., shorter duration, fewer services per encounter, and frequency of encounters than the average); but may allow for less oversight and a longer initial trial of care.

- As patients age, they may have a slower response to care, and this may affect the approval of a trial of care.
- Because pediatric patients (under the age of 12) have not reached musculoskeletal maturity, it may be necessary to modify the types of therapies approved as well as shorten the initial trial of care.
- Complicating and/or co-morbid condition factors vary depending upon individual patient characteristics, the nature of the condition/complaints, historical and examination elements, and may require appropriate coordination of care and/or more timely re-evaluations.

Health equity is the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health. Factors that can impede health equity include, but are not limited to, race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, and preferred language. Social Determinants of Health (SDoH) are important influences on health equity status. SDoH are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. There are typically five domains of SDoH: 1) Economic stability; 2) Education access and quality; 3) Health care access and quality; 4) Neighborhood and built environment; 5) Social and community context. These barriers to health equity may impact health care access, the patient presentation, clinical evaluations, treatment planning, and patient outcomes which may in turn influence medical necessity considerations.

The following are examples of the factors CQEs consider when verifying the medical necessity of rehabilitative services for musculoskeletal conditions and pain disorders.

#### **6.4 General Factors**

Multiple patient-specific historical and clinical findings may influence clinical decisions, such as but not limited to:

- Red flags
- Yellow flags (psychosocial factors)
- Co-morbid conditions (e.g., diabetes, inflammatory conditions, joint instability)
- Age (older or younger)
- Non-adherence to treatment and/or self-care recommendations
- Lack of response to appropriate care
- Lifestyle factors (e.g., smoking, diet, stress, deconditioning)
- Work and recreational activities
- Pre-operative/post-operative care
- Medication use (type and adherence)

## Nature of Complaint(s)

- Acute and severe symptoms
- Functional testing results that display severe disability/dysfunction
- Pain that radiates below the knee or elbow (for spinal conditions)

## History

- Trauma resulting in significant injury or functional deficits
- Pre-existing pathologies/surgery(ies)
- Congenital anomalies (e.g., severe scoliosis)
- Recurring exacerbations
- Prior episodes (e.g., >3 for spinal conditions)
- Multiple new conditions which introduce concerns regarding the cause of these conditions

## Examination

- Severe signs/findings
- Results from diagnostic testing that are likely to impact coordination of care and response to care (e.g., fracture, joint instability, neurological deficits)

## Assessment of Red Flags

At any time the patient is under care, the practitioner is responsible for seeking and recognizing signs and symptoms that require additional diagnostics, treatment/service, and/or referral. A careful and adequately comprehensive history and evaluation in addition to ongoing monitoring during the course of treatment is necessary to discover potential serious underlying conditions that may need urgent attention. Red flags can present themselves at several points during the patient encounter and can appear in many different forms. If a red flag is identified during a medical necessity review, the CQE should communicate with the practitioner of services as soon as possible by telephone and/or through standardized communication methods. When a red flag is identified, the CQE may not approve services and recommend returning the patient back to the referring healthcare practitioner or referring the patient to other appropriate health care practitioner/specialist with the measure of urgency as warranted by the history and clinical findings.

Due to the uncommon presence of actual red flag diagnoses in clinical practice, it is emphasized that the practitioner does not need to perform expensive or invasive diagnostic procedures (e.g., x-ray, advanced imaging, laboratory studies) in the absence of suspicious clinical characteristics. Important red flags and events as well as the times during the clinical encounter at which they are likely to appear include but may not be limited to:



1 Past or Current History

- 2 • Personal or family history of cancer
- 3 • Current or recent urinary tract, respiratory tract, or other infection
- 4 • Anticoagulant therapy or blood clotting disorder
- 5 • Metabolic bone disorder (osteopenia and osteoporosis)
- 6 • Unintended weight loss
- 7 • Significant trauma sufficient to cause fracture or internal injury
- 8 • Unexplained dizziness or hearing loss
- 9 • Trauma with skin penetration
- 10 • Immunosuppression (e.g., AIDS/HIV/ARC)
- 11 • Intravenous drug abuse, alcoholism
- 12 • Prolonged corticosteroid use
- 13 • Previous adverse reaction to substances or other treatment modalities
- 14 • Use of substances or treatment which may contraindicate proposed services
- 15 • Uncontrolled health condition (e.g., diabetes, hypertension, asthma)

16  
17 Present Complaint

- 18 • Writhing or cramping pain
- 19 • Precipitation by significant trauma
- 20 • Pain that is worse at night or not relieved by any position
- 21 • Suspicion of vascular/cerebrovascular compromise
- 22 • Symptom's indicative of progressive neurological disorder
- 23 • Unexplained dizziness or hearing loss
- 24 • Complaint inconsistent with reported mechanism of injury and/or evaluation findings
- 25 • Signs of psychological distress

26  
27  
28 Physical Examination/Assessment

- 29 • Inability to reproduce symptoms of musculoskeletal diagnosis or complaints
- 30 • Fever, chills, or sweats without other obvious source
- 31 • New or recent neurologic deficit (e.g., special senses, peripheral sensory, motor, language, and cognitive)
- 32 • Positive vascular screening tests (e.g., carotid stenosis, vertebrobasilar insufficiency, abdominal aortic aneurysm)
- 33 • Abnormal vital signs.
- 34 • Uncontrolled hypertension
- 35 • Signs of nutritional deficiency
- 36 • Signs of allergic reaction requiring immediate attention
- 37 • Surface lesions or infections in area to be treated
- 38
- 39

- Widespread or multiple contusions
- Unexplained severe tenderness or pain
- Signs of abuse/neglect
- Signs of psychological distress

#### Pattern of Symptoms Not Consistent with Benign Disorder

- Chest tightness, difficulty breathing, chest pain
- Headache of morbid proportion
- Rapidly progressive neurological deficit
- Significant, unexplained extremity weakness or clumsiness
- Change in bladder or bowel function
- New or worsening numbness or paresthesia
- Saddle anesthesia
- New or recent bilateral radiculopathy

#### Lack of Response to Appropriate Care

- History of consultation/care from a series of practitioners or a variety of health care approaches without resolving the patient's complaint
- Unsatisfactory clinical progress, especially when compared to apparently similar cases or natural progression of the condition
- Signs and symptoms that do not fit the normal pattern and are not resolving

### Assessment of Yellow Flags

When yellow flags are present, clinicians need to be vigilant for deviations from the normal course of illness and recovery. Examples of yellow flags include depressive symptoms, injuries still in litigation, signs, and symptoms not consistent with pain severity, and behaviors incongruent with underlying anatomical and physiological principles.

If a yellow flag is identified during a medical necessity review, the reviewer will communicate with the practitioner of services as soon as possible by telephone and/or through standardized communication methods. CQE may recommend returning the patient back to the referring healthcare practitioner or referring the patient to other health care practitioner/specialist as appropriate.

### Health Equity Factors

Health Equity factors may be barriers to clinical progress when reviewing practitioner submissions for medical necessity. If the clinical quality evaluator notes a related health equity factor, they may communicate with the specialty practitioner regarding the patient's situation and any possible relationship to medical necessity. Standardized referral recommendations or resources for assisting with the patient's health-related needs may also

be provided. If the clinical quality evaluator notes a related health and safety issue, they will utilize the current HSIT guidelines.

### **Assessment of Historical Information**

The following factors are assessed in review and determination if the services are medically necessary:

- The mechanism of onset and date of onset are congruent with the stated condition's etiology.
- The patient's past medical history and response to care do not pose contraindication(s) for the services submitted for review.
- The patient's past medical history of pertinent related and unrelated conditions does not pose contraindication(s) for the services submitted for review.
- The patient's complaint(s) have component(s) that are likely to respond favorably to services submitted for review.
- Provocative and palliative factors identified on examination indicate the presence of a musculoskeletal condition as expected per diagnosis(es) or complaints, or as consistent with other type of diagnosis(es).
- The patient's severity of limitations to activities of daily living (ADLs) are appropriate and commensurate for the presence of the condition(s) or disorder(s).
- The quality, radiation, severity, and timing of pain are congruent with the documented condition(s) or disorder(s).
- The patient's past medical history of having the same or similar condition(s) indicates a favorable response to care.
- The absence or presence of co-morbid condition(s) may or may not present absolute or relative contraindications to care.

### **Assessment of Examination Findings**

- The exam procedures, level of complexity, and intensity are appropriate for the patient's complaint(s) and historical findings.
- Physical examination findings are current, clearly defined, qualified, and quantified, including the nature, extent, severity, character, professional interpretation, and significance of the finding(s) in relation to the patient's complaint(s) and diagnosis(es).
- Exam findings provide evidence justifying the condition(s) is/are likely to respond favorably to services submitted for review.
- Exam findings provide a reasonable and reliable basis for the stated diagnosis(es).
- Exam findings provide a reasonable and reliable basis for treatment planning; accounting for variables such as age, sex, physical condition, occupational and recreational activities, co-morbid conditions, etc.

- The patient's progress is being appropriately monitored each visit (as noted within daily chart notes and during periodic re-exams) to ensure that acceptable clinical progress is realized.

### **Assessment of Treatment / Treatment Planning**

- Treatment dosage (frequency and duration of service) is appropriately correlated with the nature and severity of the subjective complaints, potential complications/barriers to recovery, and objective clinical evidence.
- Services that do not require the professional skills of a practitioner to perform or supervise are not medically necessary, even if they are performed or supervised by an acupuncture practitioner. Therefore, if the continuation of a patient's care can proceed safely and effectively through a home exercise program or self-management program, services are not indicated or medically necessary.
- The treatment plan includes the use of therapeutic procedures to address functional deficits and ADL restrictions.
- The set therapeutic goals are functionally oriented, realistic, measurable, and evidence based.
- The proposed date of release/discharge from treatment is clearly defined.
- The selected treatment/therapies are appropriately correlated with the nature and severity of the patient's condition(s) and treatment goals.
- Functional Outcome Measures (FOM) demonstrate minimal clinically important difference (MCID) from baseline results through periodic reevaluations during the course of care. This is important to determine the need for continued care, the appropriate frequency of visits, estimated date of release from care, and if a change in the treatment plan or a referral to an appropriate health care practitioner/specialist is indicated.
- Home care, self-care, and active-care instructions are documented.

### **Assessment of Diagnostic Testing**

- Laboratory tests are performed only when medically necessary to improve diagnostic accuracy and treatment planning. Abnormal values are professionally interpreted as they relate to the patient's complaint(s) or to unrelated co-morbid conditions that may or may not impact the patient's prognosis and proposed treatment.
- X-ray procedures are performed only when medically necessary to improve diagnostic accuracy and treatment planning. (Indicators from history and physical examination indicating the need for x-ray procedures are described in the *X-Ray Guidelines (CPG 1 - S)* clinical practice guideline.)

- Advanced imaging studies, when medically necessary and/or available, are used to evaluate for structural integrity and to rule out osseous, related soft tissue pathology, or other pathology.
- Imaging or special studies must be appropriate given the nature and severity of the patient's condition(s) and the findings obtained from those studies are likely to influence the basis for and character of the proposed treatment.

## **6.5 Factors that Influence Adverse Determinations of Clinical Services (Partial Approvals/Denials)**

Factors that influence adverse determinations of clinical services may include but are not limited to these specific considerations and other guidelines and factors identified elsewhere in this policy. Topics/factors covered elsewhere in this guideline are also applicable in this section and may result in an adverse determination on medical necessity review. To avoid redundancy, many of those factors have not been listed below.

### **Additional Factors Considered in Determination of Medical Necessity**

#### **History / Complaints / Patient Reported Outcome Measures**

- The patient's complaint(s) and/or symptom(s) are not clearly described.
- There is poor correlation and/or a significant discrepancy between the complaint(s) and/or symptom(s) as documented by the treating practitioner and as described by the patient.
- The patient's complaint(s) and/or symptom(s) have not demonstrated clinically significant improvement.
- The nature and severity of the patient's complaint(s) and/or symptom(s) are insufficient to substantiate the medical necessity of any/all submitted services.
- The patient has little, or no pain as measured on a valid pain scale.
- The patient has little or no functional deficits using a valid functional outcome measure or as otherwise documented by the practitioner.

#### **Evaluation Findings**

- There is poor correlation and/or a significant discrepancy in any of the following:
  - Patient's history
  - Subjective complaints
  - Objective findings
  - Diagnosis
  - Treatment plan
- The application of various exam findings to diagnostic or treatment decisions are not clearly described or measured. (e.g., severity, intensity, professional interpretation of results, significance).

- 1 • The patient's objective findings have not demonstrated clinically significant
- 2 improvement.
- 3 • The objective findings are essentially normal or are insufficient to support the
- 4 medical necessity of any/all submitted services.
- 5 • The submitted objective findings are insufficient due to any of, but not limited to,
- 6 the following reasons:
  - 7 ○ Old or outdated relative to the requested dates of service
  - 8 ○ Do not properly describe the patient's current status
  - 9 ○ Do not substantiate the medical necessity of the current treatment plan
  - 10 ○ Do not support the patient's diagnosis/diagnoses
  - 11 ○ Do not correlate with the patient's subjective complaint(s) and/or
  - 12 symptom(s)
- 13 • Not all of the patient's presenting complaints were properly examined.
- 14 • The patient does not have any demonstrable functional deficits or impairments.
- 15 • The patient has not made reasonable progress toward pre-clinical status or
- 16 functional outcomes under the initial treatment/services.
- 17 • Clinically significant therapeutic progress is not evident through a review of the
- 18 submitted records. This may indicate that the patient has reached maximum
- 19 therapeutic benefit.
- 20 • The patient is approaching or has reached maximum therapeutic benefit.
- 21 • The patient's exam findings have returned to pre-injury status or prior level of
- 22 function.
- 23 • There is inaccurate reporting of clinical findings.
- 24 • The exam performed is for any of the following:
  - 25 ○ Wellness
  - 26 ○ Pre-employment
  - 27 ○ Sports pre-participation
- 28 • The exam performed is non-standard and solely technique/protocol based.
- 29

### 30 **Assessment/Diagnosis**

- 31 • The assessment/diagnosis is not supported by one or more of the following:
  - 32 ○ Patient's history (e.g., date/mechanism of onset)
  - 33 ○ Subjective complaints (e.g., nature and severity, location)
  - 34 ○ Objective findings (e.g., not clearly defined and/or quantified, not
  - 35 professionally interpreted, significance not noted)
  - 36 ○ Referral diagnosis when a referral is required

## Submitted Medical Records

- The submitted records are insufficient to reliably verify pertinent clinical information, such as (but not limited to):
  - Patient's clinical health status
  - The nature and severity of the patient's complaint(s) and/or symptom(s)
  - Date/mechanism of onset
  - Objective findings
  - Diagnosis/diagnoses
  - Response to care
  - Functional deficits/limitations
- There are daily notes submitted for the same dates of service with different/altere findings without an explanation.
- There is evidence of duplicated or nearly duplicated records for the same patient for different dates of service, or for different patients.
- There is poor correlation and/or a significant discrepancy between the information presented in the submitted records with the information presented during a verbal communication between the reviewing CQE and treating practitioner.
- The treatment time (in minutes) and/or the number of units used in the performance of a timed service (e.g., modality, procedure) during each encounter/office visit was not documented.
- Some or all of the service(s) submitted for review are not documented as having been performed in the daily treatment notes.
- There is poor correlation and/or a significant discrepancy between the information presented in the submitted records with the information presented on a medical necessity review submission.

## Treatment / Treatment Planning

- The submitted records show that the nature and severity of the patient's complaint(s) and/or symptom(s) require a limited, short trial of care in order to monitor the patient's response to care and determine the efficacy of the current treatment plan. This may include, but not limited to, any of the following:
  - Significant trauma affecting function
  - Acute/sub-acute stage of condition
  - Moderate-to-severe or severe subjective and objective findings
  - Possible neurological involvement
  - Presence of co-morbidities that may significantly affect the treatment plan and/or the patient's response to care
- There is poor correlation of the treatment plan with the nature and severity of the patient's complaint(s) and/or symptom(s), such as (but not limited to):
  - Use of acute care protocols for chronic condition(s)

- Prolonged reliance on passive care
- Active care and reduction of passive care are not included in treatment plan
- Use of passive modalities in the treatment of sub-acute or chronic conditions beyond the acute, inflammatory response time frame
- Use of passive modalities as stand-alone treatments (which is rarely therapeutic) or as the sole treatment approach to the patient's condition(s)
- There is evidence from the submitted records that the patient's treatment can proceed safely and effectively through a home exercise program or self-management program.
- The patient's function has improved, complaints and symptoms have decreased, and patient requires less treatment (e.g., lesser units of services per office visit, lesser frequency, and/or shorter total duration to discharge).
- The patient's symptoms and/or exam findings are mild and the patient's treatment plan requires a lesser frequency (e.g., units of services, office visits per week) and/or total duration.
- Therapeutic goals have not been documented. Goals should be measurable and written in terms of function and include specific parameters.
- Therapeutic goals have not been reassessed in a timely manner to determine if the patient is making expected progress.
- Failure to make progress or respond to care as documented within subjective complaints, objective findings and/or functional outcome measures.
- The patient's condition(s) is/are not amenable to the proposed treatment plan.
- Additional significant improvement cannot be reasonably expected by continued treatment and treatment must be changed or discontinued.
- The patient has had ongoing care without any documented lasting therapeutic benefits.
- The condition requires an appropriate referral and/or coordination with other appropriate health care services.
- The patient is not adhering to the treatment plan that includes lifestyle changes to help reduce frequency and intensity of symptoms.
- The patient is not adhering to treatment plan that includes medically necessary frequency and intensity of services without documented extenuating circumstances.
- The use of multiple passive modalities with the same or similar physiological effects to the identical region is considered a duplication of services and not reasonable or medically necessary.
- Home care, self-care, and active-care instructions are not implemented or documented in the submitted records.
- Uncomplicated diagnoses do not require services beyond the initial treatment plan before discharging the patient to active home/self-care (e.g., mild knee pain that can be managed with a home exercise program).



- As symptoms and clinical findings improve the frequency of services (e.g., visits per week/month) did not decrease.
- The submitted services do not or no longer require the professional skills of the treating practitioner.
- The treatment plan is for any of the following:
  - Maintenance therapy
  - Preventive care
  - Elective/convenience/wellness care
  - Back school
  - Group therapy (not one-on-one)
  - Vocational rehabilitation or return to work programs
  - Work hardening programs
  - Routine education, training, conditioning, return to sport, or fitness.
  - Non-covered condition
- There is duplication of services with other healthcare practitioners/specialties.
- The treatment plan is not supported due to, but not limited to, any of the following reasons:
  - Technique-/protocol-based instead of individualized and evidence based
  - Generic and not individualized for the patient's specific needs
  - Does not correlate with the set therapeutic goals
  - Not supported in the clinical literature (e.g., proprietary, unproven)
  - Not considered evidence-based and/or professionally accepted
- The treatment plan includes services that are considered not evidence-based, not widely accepted, unproven and/or not reasonable or medically necessary, or inappropriate or unrelated to the patient's complaint(s) and/or diagnosis/diagnoses. (e.g., Low level laser therapy, select forms of EMS such as microcurrent) Also see the *Techniques and Procedures Not Widely Supported as Evidence-Based (CPG 133 – S)* clinical practice guideline for complete list).

### Health and Safety

- There are signs, symptoms and/or other pertinent information presented through the patient's history, exam findings, and/or response to care that require urgent attention, further testing, and/or referral to and/or coordination with other healthcare practitioners/specialists.
- There is evidence of the presence of Yellow and/or Red Flags. (See section on Red and Yellow Flags above.)
- There are historical, subjective, and/or objective findings which present as contraindications for the plan of care.

## 6.6 Referral / Coordination of Services

When a potential health and safety issue is identified, the CQE must communicate with the practitioner of services as soon as possible by telephone and/or through standardized communication methods to recommend returning the patient back to the referring health care practitioner or referring the patient to other appropriate health care practitioner/specialist with the measure of urgency as warranted by the history and clinical findings. Such referral does not preclude coordinated cotreatment if / when applicable and documented as such.

Clinical factors that may require referral or coordination of services include, but are not limited to:

- Symptoms worsening following treatment
- Deteriorating condition (e.g., orthopedic, or neurologic findings, function)
- Reoccurring exacerbations despite continued treatment
- No progress despite treatment
- Unexplained diagnostic findings (e.g., suspicion of fracture)
- Identification of Red Flags
- Identification of co-morbid conditions that do not appear to have been addressed previously that represent absolute contraindications to services
- Constitutional signs and symptoms indicative of systemic condition (e.g., unintended weight loss of greater than 4.5 kg/10 lbs. over 6-month period)
- Inability to provoke symptoms with standard exam
- Treatment needed outside of scope of practice

The Clinical Policy is reviewed and approved by the ASH Clinical Quality committees that are comprised of contracted network practitioners including practitioners of the same clinical discipline as the practitioners for whom compliance with the practices articulated in this document is required. Guidelines are updated at least annually, or as new information is identified that result in material changes to one or more of these policies.

## 7. DESCRIPTION AND BACKGROUND

The practice of traditional acupuncture is predicated upon several fundamental underlying principles. The existence of a series of meridians that course through the body along which are located discrete points that correspond to specific organs and/or have particular clinical significance; a vital energy, “chi,” flows through the meridians and the acupuncture points regulating bodily functions; it is the disruption of this flow of energy that therapeutic acupuncture is said to address.

Medical acupuncturists choose 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 (e.g., muscle rather than skin) and the type and amount of stimulation given" (White, 2009). Western medical acupuncture has been an available treatment modality in the UK and other countries for many years.

Acupuncture typically utilizes unique diagnostic procedures to evaluate the meridian/chi system. This includes an evaluation of the patient's chief complaint and related health status through standardized diagnostic interviewing and examination techniques. Interviews are based on the traditional "Ten Questions" and examinations include, but are not limited to, evaluation of meridians, points, general vitality and behavior, the radial pulses and the tongue. Based upon the patient's complaint and the findings of these diagnostic procedures, individualized treatment regimens are developed that specify treatment variables such as the acupuncture points to be utilized, needle placement, and type of needle stimulation. There are several variations on the use of acupuncture needles for treatment, including acupuncture and dry needling. Individuals may feel different sensations during acupuncture treatments. The "De Qi" often thought of as the "arrival of qi" energy at the needle insertion site can be experienced in various ways such as numbness, tingling, electrical sensation, fullness, distension, soreness, warmth, tenseness, pulling or itching. Acupuncturists may additionally facilitate this qi sensation 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.

Depending upon the jurisdiction, those licensed to administer acupuncture may vary. Depending upon the practitioner's training, different systems of acupuncture diagnosis and treatment may be used.

Multiple different biological mechanisms have been proposed and studied to explain acupuncture. The mechanism of action of analgesia secondary to acupuncture remains unclear, and likely multimodal. However, there are some physiological effects that have been noted with its use. Many of these proposed mechanisms are centrally mediated and others are local physiological responses. For example, it is thought that the immediate analgesic effects of acupuncture may be dependent on neural (nerve) innervation. Most commonly it is thought that the stimulation of the acupuncture needle triggers the release of endogenous opioids (endorphins) in various parts of the brain. This effect seems the most pronounced in electro-acupuncture. Another possible mechanism is through the diffuse noxious inhibitory control pathway (DNIC). According to DNIC, a noxious stimulus applied to any region of the body can induce immediate suppression of pain transmission in neurons of the trigeminal caudalis and/or the spinal dorsal horn. Another theory proposes that the descending serotonergic inhibitory pathway is key to acupuncture analgesia. In addition, there is some preliminary evidence that acupuncture

may have effects on the inflammatory response mediated through the autonomic nervous system. 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, extra-segmental pain effects, and central regulatory effects (White et al., 2008). Current available evidence indicates that insertion of acupuncture needles has an effect above waiting list controls but there is limited available evidence to define whether exact needle placement on established “Traditional” Acupuncture points is necessary to produce a result. Specific treatment parameters of acupoint selections, number of points needed, depth of insertion, responses elicited, needle stimulation- method and strength, needle retention time, needle types and the relevance of experience of the acupuncturist have not been adequately determined. Future trials are needed to establish the standardization of these characteristics as well as to compare the effectiveness of different acupuncture techniques.

None of the mechanisms of action postulated for acupuncture effects are sufficiently well understood to have established a dispositive answer to describe the exact physiological mechanism by which acupuncture produces its analgesic and antiemetic effects.

## 8. EVIDENCE REVIEW

Evaluating the clinical efficacy of acupuncture in the context of clinical trials is challenging primarily because of the difficulty of designing randomized trials with appropriate blinding of both subjects and providers. Many studies lack appropriate controls, adequate study size, randomization and/or consistent outcome measures.

Study controls for comparing real acupuncture (also referred to as verum acupuncture) typically include a placebo, sham acupuncture, standard treatment, or no treatment. Sham acupuncture is the most often used control in studies evaluating the efficacy of acupuncture. However, there is no standardized method for employing sham acupuncture and no consensus on needle placement, making it difficult to generalize findings across studies. The goal of applying sham acupuncture is to refrain from stimulating acupuncture points. In many studies, sham is done at irrelevant acupuncture sites; however, evidence has shown sham acupuncture evokes physiological responses. Because the evidence suggests that sham acupuncture is not truly a physiologically neutral event, its use as a control in clinical trials is debatable. It is difficult to distinguish between the specific effects of treatment versus that of the placebo. It has been reported that the ratio of improvement in sham groups was substantially higher than in truly inert placebo groups (Madsen, et al., 2009; Ezzo, et al., 2000). Although initially believed to have no effect, some researchers contend that needle placement in any position invokes a biological response that may interfere with the interpretation of findings.

There are now several thousand RCTs evaluating the effectiveness of acupuncture for hundreds of different conditions. The literature is examined below.

### **8.1 Acute Pain**

Nielsen et al. (2022) updated the evidence base for acupuncture therapy for acute pain with a review of systematic reviews and meta-analyses on postsurgical/perioperative pain with opioid sparing and acute nonsurgical/trauma pain, including acute pain in the emergency department. There are 22 systematic reviews, 17 with meta-analyses of acupuncture in acute pain settings, and a review for acute pain in the intensive care unit. There are additional studies of acupuncture in acute pain settings. The majority of reviews found acupuncture therapy to be an efficacious strategy for acute pain, with potential to avoid or reduce opioid reliance. Future multicenter trials are needed to clarify the dosage and generalizability of acupuncture for acute pain in the emergency department. With an extremely low risk profile, acupuncture therapy is an important strategy in comprehensive acute pain care.

### **8.2 Chronic Pain**

There are several Cochrane Reviews of acupuncture for pain that are inconclusive due to the small number of studies and/or the low quality of studies. Conditions reviewed include menstrual pain (Smith et al., 2011), elbow pain (Green et al., 2002), cancer pain (Paley et al., 2011), rheumatoid arthritis (Casimiro et al., 2005) and acute ankle sprain (Kim et al., 2014).

In 2009 BMJ published a systematic review of acupuncture for pain that came to a largely negative conclusion (Madsen et al., 2009). The review focused on trials that included both sham acupuncture and no acupuncture controls. Thirteen trials with 3,025 patients were identified. Conditions included OA of the knee, tension-type headaches, migraine headache, low back pain, fibromyalgia, abdominal scar pain, and postoperative pain. A small difference was found between acupuncture and placebo acupuncture, comparable to 4 mm on a 100 mm visual analog scale. A larger effect equal to 10 mm was found between placebo acupuncture and no acupuncture. This 10 mm difference is considered to be at the margin of clinical significance. They find that overall, the analgesic effects of acupuncture are small and that methodological limitations of the trials make it impossible to determine whether any of these results can be attributed to specific treatment effects rather than placebo. They conclude, “Whether needling at acupuncture points, or at any site, reduces pain independently of the psychological impact of the treatment ritual is unclear.”

Hopton and Macpherson (2010) conducted a systematic review of meta-analyses of acupuncture compared to placebo for acute and chronic pain. The review criteria yielded 8 studies; 2 for low back pain, 4 on knee pain, and 2 for headaches. The review found that

for knee osteoarthritis and headache, acupuncture was more effective than placebo both in the short term and long term. For low back pain, short term treatment effects were greater than placebo, but for long term, there was an inconclusive finding. Authors concluded that acupuncture has specific effects beyond placebo for a wide range of pain syndromes. They further noted this conclusion is now broadly reflected in the scientific literature and that more salient research should shift focus from placebo-related questions to more practical questions about whether the overall benefit is clinically meaningful and cost-effective.

Vickers et al. conducted a meta-analysis of trials of acupuncture for chronic pain (Vickers et al., 2012). Eligible trials included those for mechanical low back and neck pain, shoulder pain, headache, and osteoarthritis. Study subjects were required to have pain for a minimum of 4 weeks and be followed for at least 4 weeks after the end of treatment. There were no restrictions on what outcomes measures could be used. The analysis identified 29 trials that met these criteria with a total of 17,922 individual patients analyzed. The analysis found acupuncture to be superior to both sham and no acupuncture control for each of the four conditions studied (all  $p < 0.001$ ). The effect sizes were similar across all pain conditions. Patients receiving acupuncture had less pain, with scores 0.23 and 0.15 standard deviations lower than sham controls for back and neck pain, osteoarthritis, and chronic headache respectively; the effect sizes in comparison to no acupuncture controls were 0.55, 0.57 and 0.42. It is worth noting that the differences between acupuncture and sham are quite modest when compared to the differences between acupuncture and no acupuncture. Sensitivity analyses including for publication bias did not change these findings. The authors concluded, “Our results from individual patient data meta-analyses of nearly 18,000 randomized patients on high quality trials provide the most robust evidence to date that acupuncture is a reasonable referral option for patients with chronic pain.”

A 2013 Cochrane Review examined acupuncture for the treatment of fibromyalgia (Deare et al., 2013). Nine trials with 395 subjects were included. These included both needle acupuncture and electro-acupuncture therapies. The overall conclusion was that there was low to moderate quality evidence that acupuncture improves pain and stiffness in people with fibromyalgia. Sham acupuncture had similar effects. The effects of electro-acupuncture are somewhat greater than needle acupuncture and both are considered safe. These findings are qualified due to the low number and quality of studies.

MacPherson et al. (2017) aimed to determine the trajectory of pain scores over time after acupuncture, using a large individual patient data set from high-quality randomized trials of acupuncture for chronic pain. The available patient data set included 29 trials and 17,922 patients. The chronic pain conditions included musculoskeletal pain (low back, neck, and shoulder), osteoarthritis of the knee, and headache/migraine. Authors used meta-analytic techniques to determine the trajectory of posttreatment pain scores. Data on long term

1 follow-up were available for 20 trials, including 6,376 patients. The central estimate  
 2 suggests that approximately 90% of the benefit of acupuncture relative to controls would  
 3 be sustained at 12 months. Authors suggest that the effects of a course of acupuncture  
 4 treatment for patients with chronic pain do not seem to decrease notably over 12 months.

5  
 6 AHRQ published a systematic review by Skelly et al. (2018) on Noninvasive  
 7 Nonpharmacological Treatment for Chronic Pain. Acupuncture that improved function  
 8 and/or pain for at least 1 month was found for chronic low back, chronic neck pain, and  
 9 fibromyalgia. Skelly et al. (2020) updated the evidence from their 2018 report assessing  
 10 persistent improvement in outcomes following completion of therapy for noninvasive  
 11 nonpharmacological treatment for selected chronic pain conditions. For chronic low back  
 12 pain, function improved over short and/or intermediate term for acupuncture (SOE low).  
 13 Improvements in pain at short term were seen for acupuncture (SOE: moderate). For  
 14 chronic neck pain, acupuncture improved function short and intermediate term, but there  
 15 was no pain improvement compared with sham acupuncture (SOE: low). Functional  
 16 improvements for fibromyalgia were seen with acupuncture (SOE: moderate) short term  
 17 compared with usual care, attention control, or sham treatment. At intermediate term, there  
 18 was functional improvement with acupuncture (SOE: moderate).

19  
 20 National Institute for Health and Care Excellence (NICE) guideline (2021) examined the  
 21 literature on acupuncture and chronic pain. Findings included the following:

- 22 • Acupuncture versus sham acupuncture
  - 23 ○ Pain reduction
    - 24 ■ Very low quality evidence from 13 studies with 1230 participants showed a  
 25 clinically important benefit of acupuncture compared to sham acupuncture  
 26 at  $\leq 3$  months.
    - 27 ■ Low quality evidence from 2 studies with 159 participants showed a  
 28 clinically important benefit of acupuncture compared to sham acupuncture  
 29 at  $\leq 3$  months.
    - 30 ■ Low quality evidence from 4 studies with 376 participants showed no  
 31 clinically important difference between acupuncture and sham acupuncture  
 32 at  $> 3$  months.
    - 33 ■ Moderate quality evidence from 2 studies with 159 participants showed a  
 34 clinically important benefit of acupuncture compared to sham acupuncture  
 35 at  $> 3$  months.
    - 36 ■ Low quality evidence from 1 study with 61 participants showed no  
 37 clinically important difference between acupuncture and sham acupuncture  
 38 at  $> 3$  months

○ Quality of life

- Low to moderate quality evidence from 2 studies with 210 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at  $\leq 3$  months.
- Moderate quality evidence from 1 study with 158 participants showed sham acupuncture to have a clinically important improvement compared to acupuncture at  $\leq 3$  months.
- Very low quality evidence from 3 studies with 244 participants showed no clinically important difference between acupuncture and sham acupuncture at  $\leq 3$  months.
- Very low quality evidence from 2 studies with 168 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at  $\leq 3$  months.
- Very low to low quality evidence from 1 study with 178 participants showed a clinically important benefit, clinically important harm and no clinically important difference of acupuncture compared to sham acupuncture at  $\leq 3$  months (various quality of life subscales).
- Moderate quality evidence from 2 studies with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at  $\leq 3$  months.
- Low quality evidence from 1 study with 72 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at  $\leq 3$  months.
- Very low quality evidence from 1 study with 76 participants showed a clinically important benefit of sham acupuncture compared to verum acupuncture at  $> 3$  months.
- Low quality evidence from 1 study with 96 participants showed no clinically important difference between acupuncture and sham acupuncture at  $> 3$  months.
- Low quality evidence from 1 study with 153 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at  $> 3$  months.
- Moderate quality evidence from 1 study with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at  $> 3$  months.



- Physical function
  - Very low quality evidence from 1 study with 118 participants showed no clinically important difference between acupuncture and sham acupuncture at  $\leq 3$  months.
  - Very low quality evidence from 1 study with 106 participants showed no clinically important difference between acupuncture and sham acupuncture at  $> 3$  months.
- Acupuncture versus usual care
  - Pain reduction
    - Low quality evidence from 5 studies with 234 participants showed a clinically important benefit of acupuncture compared to usual care at  $\leq 3$  months. Low quality evidence from 2 studies with 384 participants showed no clinically important difference between acupuncture and usual care at  $\leq 3$  months.
    - Moderate quality evidence from 1 study with 3162 participants showed a clinically important benefit of acupuncture compared to usual care at  $\leq 3$  months.
    - Moderate quality evidence from 1 study with 344 participants showed no clinically important difference between acupuncture and usual care at  $> 3$  months.
  - Quality of life
    - Moderate quality evidence from 1 study with 3213 participants showed a clinically important benefit of acupuncture compared to usual care at  $\leq 3$  months. Very low quality evidence from 1 study with 100 participants showed both a clinically important benefit and no clinically important difference between acupuncture and usual care at  $\leq 3$  months (various quality of life subscales).
    - Low quality evidence from 1 study with 204 participants showed a clinically important benefit of acupuncture compared to usual care at  $> 3$  months.
  - Physical function
    - Very low quality evidence from 1 study with 45 participants showed no clinically important difference between acupuncture and usual care at  $\leq 3$  months.
    - Very low quality evidence from 1 study with 100 participants showed a clinically important benefit of acupuncture compared to usual care at  $\leq 3$  months.
  - Pain self-efficacy
    - Very low quality evidence from 1 study with 294 participants showed a clinically important benefit of acupuncture compared to usual care at  $\leq 3$  months.

○ Pain interference

- Very low-quality evidence from 1 study with 100 participants showed a clinically important benefit of acupuncture compared to usual care at >3 months.

Busse et al. (2023) completed a comparative effectiveness study of available therapies for chronic pain associated with temporomandibular disorders (TMD). Because current clinical practice guidelines are largely consensus-based and provide inconsistent recommendations, they wanted to summarize the current evidence. Based on findings, patients living with chronic pain ( $\geq 3$  months) associated with TMD, and compared with placebo or sham procedures, the guideline panel issued conditional recommendations in favor of manipulation, supervised jaw exercise with mobilization, CBT with non-steroidal anti-inflammatory drugs (NSAIDs), manipulation with postural exercise, and acupuncture; (3) conditional recommendations against reversible occlusal splints (alone or in combination with other interventions), arthrocentesis (alone or in combination with other interventions), cartilage supplement with or without hyaluronic acid injection, low level laser therapy (alone or in combination with other interventions), transcutaneous electrical nerve stimulation, gabapentin, botulinum toxin injection, hyaluronic acid injection, relaxation therapy, trigger point injection, acetaminophen (with or without muscle relaxants or NSAIDs), topical capsaicin, biofeedback, corticosteroid injection (with or without NSAIDs), benzodiazepines, and  $\beta$  blockers; and (4) strong recommendations against irreversible oral splints, discectomy, and NSAIDs with opioids. These recommendations apply to patients living with chronic pain ( $\geq 3$  months duration) associated with TMD as a group of conditions, and do not apply to the management of acute TMD pain. When considering management options, clinicians and patients should first consider strongly recommended interventions, then those conditionally recommended in favor, then conditionally against. In doing so, shared decision making is essential to ensure patients make choices that reflect their values and preference, availability of interventions, and what they may have already tried. Further research is warranted and may alter recommendations in the future.

Park et al. (2023) aimed to assess the effectiveness and safety of acupuncture for TMD via a systematic review of randomized clinical trials. The qualitative analysis of randomized clinical trials with acupuncture as the intervention included 32 articles, 22 of which were included in the quantitative analysis (471 participants). Acupuncture significantly improved outcomes versus active controls. In the analysis of add-ons, acupuncture significantly improved the effect rate and pain intensity. However, the quality of evidence was determined to range from low to very low. Acupuncture in TMD significantly

improved outcomes versus active controls and when add-on treatments were applied. However, as the quality of evidence was determined to be low, well-designed clinical trials should be conducted in the future.

Yu et al. (2023) assessed the effect of sham acupuncture (SA) on chronic musculoskeletal pain syndrome (MPS). SA included superficial acupuncture on non-acupoints (SANAs), non-penetration on acupoints (NPAs), and non-penetration on non-acupoints (NPANAs). The pain-related indicators were set as primary outcomes. Forty-two RCTs were included in this study, encompassing a total of 6,876 patients and incorporating 3 types of SA procedures. In the traditional meta-analysis, true acupuncture (TA) was more effective than SANAs, NPAs, and NPANAs concerning MPS. The quality of the evidence for outcomes ranged from "low" to "moderate." Authors concluded that compared with SA, TA was effective in treating MPS. The effects produced by different SA procedures were different, and the order of effects from greatest to least was as follows: SANA, NPA, and NPANA.

Di Francisco et al. (2024) performed a qualitative and quantitative analysis of the scientific literature regarding the use of acupuncture and laser acupuncture in the treatment of pain associated with temporomandibular disorders (TMDs). The aim of this article was to assess the clinical evidence for acupuncture and laser acupuncture therapies as treatment for temporomandibular joint disorder (TMD). This systematic review includes randomized clinical trials (RCTs) of acupuncture and laser acupuncture as a treatment for TMD compared to other treatments. A total of 11 RCTs met inclusion criteria. The findings show that acupuncture is short-term helpful for reducing the severity of TMD pain with muscle origin. Meta-analysis revealed that the Acupuncture group and Laser Acupuncture group had a higher efficacy rate than the Placebo control group, showing a high efficacy of Acupuncture and Laser Acupuncture group in the treatment of temporomandibular. In conclusion, this systematic review demonstrated that the evidence for acupuncture as a symptomatic treatment of TMD is limited. Further rigorous studies are required to establish whether acupuncture has therapeutic value.

### **8.3 Osteoarthritis**

A Cochrane Review of acupuncture for peripheral joint arthritis identified sixteen trials (3498 individual patients) of adequate quality for review (Manheimer et al., 2010). Twelve of these trials included only people with OA of the knee, three were for OA of the hip and one trial included both hip and knee. Acupuncture showed statistically significant, short-term improvements in OA pain and function. However, these differences were not considered to be clinically significant. Using only studies with sham controls deemed adequate to blind participants, these differences were small and not statistically significant. On a pain scale of 0-20, these differences were in the range of 3-4 points. On a functional

scale of 0-68, improvements ranged from 3 to 11 points. However, greater effects were seen when compared to waiting list controls. The overall conclusion was that at both 8 and 26 week end points, acupuncture offered small benefits in pain and function. These benefits were deemed to be at least partially due to non-specific treatment effects. Atalay et al. (2021) sought to determine the effect of acupuncture treatment and physiotherapy on pain, physical function, and quality of life (QOL) in patients with knee osteoarthritis (KOA). One hundred patients with KOA were randomly divided into the acupuncture group and the physiotherapy group. Both treatments were given in 12 sessions over 6 weeks. Thirteen acupuncture points were selected for the knee. Local points were GB34, SP10, SP9, ST36, ST35, ST34, EX-LE2, EX-LE5, EXLE4, and distal (distant) points were defined as KI3, SP6, LI4, and ST41. The Visual Analog Scale (VAS) was used to measure pain intensity. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the 36-Item Short Form Health Survey (SF-36) were used to determine functional status and health-related QOL, respectively. All patients were evaluated at baseline, after the last treatment, and at the 12-week follow-up period. There was no statistically significant difference between the acupuncture group and physiotherapy group in terms of pain, total WOMAC, and SF-36 levels at baseline, after treatment, and at the 12th week after treatment ( $P > 0.05$ ). Both treatments significantly improved functional status and decreased the level of pain assessed by VAS at the 12-week follow-up of the study. There was no adverse advent related to therapeutic methods. Authors concluded that the acupuncture and physiotherapy performed twice weekly for 6 weeks have similar effects with regard to pain, functional status, and QOL. There were no significant differences between the acupuncture and physiotherapy groups in relief of pain, improved functional status, and QOL in the treatment of KOA. Both acupuncture and physiotherapy treatments were found to yield significantly superior results when compared with baseline values.

Lin et al. (2022) systematically evaluated the efficacy and safety effectiveness of acupuncture inactivation of myofascial pain trigger points in the treatment of osteoarthritis of the knee. A total of 724 patients from 9 RCTs were finally included, and the results of meta-analysis showed that the acupuncture myofascial pain trigger point group was better than the control group in terms of total effective rate, cure rate, VAS score, Lysholm score, and WOMAC score. Authors concluded that the efficacy and safety of acupuncture myofascial pain trigger points in the treatment of knee osteoarthritis is positive, but due to the limited number of literature included in this study and the low quality of the included literature, there is still a need for high-quality and large sample size RCTs for the analysis of this treatment option.

Gibbs et al. (2023) appraised the quality and consistency in recommendations across higher-quality hip and knee osteoarthritis guidelines in a systematic review. Seven higher-quality and 18 lesser-quality guidelines were included. Higher-quality guidelines consistently recommended in favor of education, exercise, and weight management and

non-steroidal anti-inflammatory drugs (hip and knee), and intra-articular corticosteroid injections (knee). Higher quality guidelines consistently recommended against hyaluronic acid (hip) and stem cell (hip and knee) injections. Other pharmacological recommendations in higher-quality guidelines (e.g., paracetamol, intra-articular corticosteroid (hip), hyaluronic acid (knee)) and adjunctive treatments (e.g., acupuncture) were less consistent. Arthroscopy was consistently recommended against in higher-quality guidelines. No higher-quality guidelines considered arthroplasty.

Chen et al. (2023) investigated the clinical efficacy of acupuncture combined with active exercise training in improving pain and function of knee osteoarthritis (KOA) individuals. Authors analyzed trials of acupuncture combined with active exercise training for KOA. They performed systematic analyses based on different outcome measures, including total efficiency rate, visual analogue scale (VAS), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the Lysholm Knee Scale (LKS) and range of motion (ROM). A total of 11 high-quality studies including 774 KOA individuals were included in this review for meta-analysis. The results showed that acupuncture combined with active exercise training (combined group) was superior to the acupuncture group in improving the total effective rate, reducing the pain level (VAS), improving knee joint function (WOMAC) and improving joint range of motion (ROM). Similarly, the combined group showed significant improvements in the total effective rate, pain (VAS) and knee function (WOMAC) compared with the non-acupuncture group. Authors concluded that the combined effect of all studies showed significant benefits of acupuncture combined with active exercise training in improving the total effective rate, reducing pain, promoting recovery of knee function and expanding range of motion. However, some evaluation indicators are highly subjective and need to be further confirmed by more objective and evidence-based high-quality RCTs in future.

Kwak et al. (2023) aimed to find out whether the combined treatment of acupuncture and oral medication is more effective than sole oral medication in reducing pain and improving knee function at the end of treatment and after short-term period (4-6 weeks after treatment). Second, if it is effective, they investigated whether the effect surpasses the minimal clinically important difference. The combined treatment of oral medication and adjuvant acupuncture showed statistically significant improvement in VAS and WOMAC scores at the end of acupuncture treatment and short-term follow-up time (between 4 and 6 weeks after acupuncture). In addition, the degree of improvement of VAS and WOMAC index showed effects beyond minimal clinically important differences compared to pretreatment at both the end of acupuncture treatment and the short-term follow-up of acupuncture treatment. Authors concluded that the existing evidence suggests that adjuvant acupuncture may play a role in the treatment of knee osteoarthritis. However, physicians should be aware of adverse effects such as hematoma in adjuvant acupuncture treatment.

Chen et al. (2024) investigated the durability of efficacy after completion of acupuncture treatment of knee osteoarthritis. Primary outcomes were changes from baseline in pain and function measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain and function subscales. Secondary outcomes included response rate, overall pain, the WOMAC stiffness subscale, total WOMAC index, and physical and mental health components of 12/36-item Short-Form Health Survey. A total of 10 randomized controlled trials (RCTs) involving 3221 participants were included. Pooled estimates suggested that acupuncture may offer potential improvements in function and overall pain for 4.5 months post-treatment versus sham acupuncture (SA). Acupuncture may provide durable clinically important pain relief and functional improvement up to 5 months post-treatment versus usual care, and up to 6 months post-treatment versus diclofenac. For acupuncture versus no treatment, one trial with large sample size indicated that improvements in pain and function persisted for 3 months post-treatment, while the other trial reported that significant pain reduction and functional improvement were only observed at the end of the treatment, not at 9 months post-treatment. However, acupuncture as adjunct to exercise-based physical therapy (EPT) showed no superiority to SA as an adjunct to EPT or EPT alone up to 11.25 months after completion of treatment. Acupuncture may provide pain alleviation and functional improvements in KOA patients for 3 to 6 months after completion of treatment with a good safety profile.

Liu et al. (2024) aimed to evaluate (1) the effect and safety of acupuncture in patients with knee osteoarthritis (KOA) and explore (2) whether the effect of acupuncture differed according to acupuncture type, acupuncture dose and follow-up time in a systematic review and pairwise and exploratory network meta-analysis. Randomized controlled trials comparing acupuncture with sham acupuncture, non-steroidal anti-inflammatory drugs (NSAIDs), usual care or waiting list groups, intra-articular (IA) injection and blank groups in patients with KOA. Eligible interventions included manual acupuncture (MA) and electroacupuncture (EA). The primary outcome was pain intensity at the end of treatment. Eighty trials (9933 participants) were included. Very low certainty evidence suggested that acupuncture may reduce pain intensity compared with sham acupuncture, NSAIDs, usual care or waiting list groups and blank groups, but not IA injection. Similar results were also found in other outcomes. For most of the subgroup analyses, acupuncture type, acupuncture dose and follow-up time did not show a significant relative effect. Only when compared with NSAIDs, a higher dose of acupuncture may provide greater pain relief. The network meta-analysis revealed that electroacupuncture had a greater effect on pain relief in patients with KOA compared with manual acupuncture. The findings suggest that acupuncture may provide clinically important effects in reducing pain and improving physical function in patients with KOA, but the certainty of evidence was very low.

## 8.4 Headache

Linde et al. conducted a Cochrane Review of acupuncture for tension-type headaches (Linde et al., 2009). Eleven trials with 2,317 subjects met the inclusion criteria. Two of the trials compared acupuncture to routine care (including self-care) and found clinically and statistically significant benefits to acupuncture for both headache frequency and pain intensity. In these two trials 47% of patients receiving acupuncture reported a decrease in the number of headache days by at least 50%, compared to 16% of patients in the control groups. Six of the trials compared acupuncture to some form of sham acupuncture where needle placement was not guided by any specific acupuncture findings. In this comparison, 50% of the “true” acupuncture patients experienced a greater than 50% reduction in headache pain compared to 41% in the sham controls. Three trials compared acupuncture to massage, physiotherapy, or relaxation. The methodological quality of these studies was poor and the results difficult to interpret, but overall, there appeared to be a slight benefit to acupuncture compared to these interventions. A previous Cochrane review of this topic yielded inconclusive results. However, the addition of six newer trials in this review led the authors to conclude that acupuncture could be “a valuable non-pharmacological tool in patients with frequent episodic or chronic tension-type headaches.”

Another Cochrane Review examined acupuncture for migraine headache prophylaxis (Linde et al., 2009). Twenty-two trials with 4,419 participants met the inclusion criteria. Six of the trials compared acupuncture to no treatment or routine care. The acupuncture care resulted in fewer headaches than in the controls over 3-4 months. One of the trials followed patients for nine months and the treatment effects were undiminished. Fourteen trials compared acupuncture to some form of sham intervention. The results of single trials varied considerably, but the pooled results did not show any clinically or statistically significant benefit to the “true” acupuncture. Four trials compared acupuncture to drug prophylaxis and demonstrated slightly better outcomes and fewer side effects in the acupuncture groups. Overall, the authors conclude that acupuncture should be considered a valid treatment option for migraine prophylaxis.

Turkistani et al. (2021) evaluated the effectiveness of acupuncture and manual therapy in tension-type headaches. Eight articles involving 3,846 participants showed evidence that acupuncture and manual therapy can be valuable non-pharmacological treatment options for tension-type headaches. Acupuncture was compared to routine care or sham intervention. Acupuncture was not found to be superior to physiotherapy, exercise, and massage therapy. Randomized controlled trials done in various countries showed manual therapy also significantly decreased headache intensity. Manual therapy has an efficacy that equals prophylactic medication and tricyclic antidepressants in treating tension-type headaches. The available data suggests that both acupuncture and manual therapy have beneficial effects on treating symptoms of tension-type headache. However, further clinical trials looking at long-term benefits and risks are needed.

Zheng et al. (2022) examined the effectiveness of acupuncture with a follow-up period of 32 weeks. They conducted a randomized controlled trial with 218 participants who were diagnosed with chronic tension-type headache (CTTH). The participants in the intervention group received 20 sessions of true acupuncture (TA group) over 8 weeks. The acupuncture treatments were standardized across participants, and each acupuncture site was needled to achieve deqi sensation. Each treatment session lasted 30 minutes. The participants in the control group received the same sessions and treatment frequency of superficial acupuncture (SA group) defined as a type of sham control by avoiding deqi sensation at each acupuncture site. A responder was defined as a participant who reported at least a 50% reduction in the monthly number of headache days (MHD's). The responder rate was 68.2% in the TA group (n= 110) versus 48.1% in the SA group (n=108) at week 16; and it was 68.2% in the TA group versus 50% in the SA group at week 32. The reduction in MHDs was  $13.1 \pm 9.8$  days in the TA group versus  $8.8 \pm 9.6$  days in the SA group at week 16, and the reduction was  $14 \pm 10.5$  days in the TA group versus  $9.5 \pm 9.3$  days in the SA group at week 32. Four mild adverse events were reported; three in the TA group versus one in the SA group. Authors concluded that the 8-week TA treatment was effective for the prophylaxis of CTTH. Further studies might focus on the cost-effectiveness of the treatment.

### **8.5 Low Back and Neck Pain**

The Cochrane Review of acupuncture for low back pain (Furlan et al., 2005) has not been updated and is considered obsolete at this point. A systematic review and meta-analysis of acupuncture for non-specific low back pain by Lam et al. was published in Spine (Lam et al., 2013). They identified 32 relevant studies, 25 of which had usable data for a meta-analysis. They found clinically significant benefits to acupuncture when compared to sham acupuncture and no treatment in both pain and function. They also compared acupuncture to other common treatment modalities including NSAIDS, muscle relaxants and analgesics and found acupuncture to offer comparable relief. However, these findings were qualified because of the low overall quality of the studies.

The Cochrane Review for neck pain (Trinh et al., 2006) found 10 clinical trials that met inclusion criteria. All these trials were for chronic neck pain. The overall quality of these trials was judged to be poor. They found that for short term follow-up, acupuncture was more effective than inactive controls. And they found limited evidence that acupuncture was more effective than massage therapy. Also, for neck pain with radiculopathy there was moderate evidence that acupuncture was more effective than waiting list control.



Under the aegis of the Agency for Healthcare Research and Quality (AHRQ), Furlan et al. evaluated the entire range of complementary and alternative therapies, including acupuncture, for back and neck pain (Furlan et al., 2010). For acupuncture, a total of 105 clinical trials were evaluated. Acupuncture was found to be superior to placebo for chronic nonspecific low back pain, but only immediately post-treatment. But acupuncture was not different from placebo in post-treatment disability, pain medication intake, or global improvement in chronic nonspecific low back pain. Acupuncture and sham acupuncture were similar in reducing chronic non-specific neck pain immediately after treatment. Both were superior to no treatment in improving pain intensity, disability, well-being (SF-36), and range of motion immediately after the treatment. In general, trials that applied sham-acupuncture tended to produce negative results (i.e., statistically non-significant) compared to trials that applied other types of placebo (e.g., TENS, medication, laser). This can be interpreted as sham acupuncture having greater treatment effects than the other comparators.

Cho et al. evaluated the effects of acupuncture for chronic low back pain (Cho et al., 2013). One hundred thirty adults aged 18 to 65 years with chronic, nonspecific low back pain (cLBP) of at least three months duration were randomized to either individualized, traditional acupuncture, or to a sham needling procedure. The sham consisted of using non-penetrating, semi-blunt needles at non-acupuncture points. The primary outcome measure was a visual analog scale (VAS) for bothersomeness, and the secondary outcome measure was function (Oswestry). Patients were treated twice weekly for six weeks. VAS for “bothersomeness” scores for the real acupuncture groups decreased by 3.36 points, compared with 2.27 points for participants receiving sham acupuncture at the primary end point. There were no significant differences in disability scores and other secondary outcomes measures between the two treatment groups.

Yuan et al. (2015) reviewed and analyzed the existing data about pain and disability in TCM treatments for NP and LBP. Seventy-five randomized controlled trials ( $n = 11,077$ ) were included. Almost all of the studies investigated individuals experiencing chronic NP (CNP) or chronic LBP (CLBP). Authors concluded that acupuncture, acupressure, and cupping could be efficacious in treating the pain and disability associated with CNP or CLBP in the immediate term. Zeng and Chung (2015) aimed to summarize and evaluate the available systematic reviews on the clinical effectiveness and cost-effectiveness of acupuncture for the management of chronic nonspecific low back pain (cnLBP), and to identify the safety of acupuncture for the management of cnLBP. Seventeen systematic reviews were included. Five found that acupuncture was more effective when compared with a no treatment/waiting list control, as there were eight systematic reviews and meta-analysis providing positive and consistent findings. Seven systematic reviews providing positive findings of the comparison of acupuncture to sham acupuncture/passive modality treatment. Three systematic reviews of multiple RCTs also indicated positive and

consistent findings of the comparison of acupuncture plus an intervention vs an intervention alone. Overall, findings on the effectiveness of acupuncture for cnLBP were consistent.

Liu et al. (2015) examined the set of systematic reviews of acupuncture for low back pain. They identified 16 systematic reviews, the overall quality of which they judged to be low. They found inconclusive evidence of a benefit for acupuncture compared to a sham for acute low back pain. For chronic low back pain there was consistent evidence of a benefit for short term pain relief and functional improvement when compared to sham or to no treatment. This benefit was found both when acupuncture was used in isolation and when used as an adjunct treatment.

Zeng and Chung (2015) aimed to summarize and evaluate the available systematic reviews on the clinical effectiveness and cost-effectiveness of acupuncture for the management of chronic nonspecific low back pain (cnLBP), and to identify the safety of acupuncture for the management of cnLBP. Seventeen systematic reviews were included. Five found that acupuncture was more effective when compared with a no treatment/waiting list control, as there were eight systematic reviews and meta-analysis providing positive and consistent findings. Seven systematic reviews providing positive findings of the comparison of acupuncture to sham acupuncture/passive modality treatment. Three systematic reviews of multiple RCTs also indicated positive and consistent findings of the comparison of acupuncture plus an intervention vs an intervention alone. Overall, findings on the effectiveness of acupuncture for cnLBP were consistent.

In another AHRQ publication by Chou et al. (2016) titled Noninvasive Treatments for Low Back Pain, noted the following key points:

- For acute low back pain, a systematic review found acupuncture associated with lower pain intensity versus sham acupuncture using nonpenetrating needles; three other trials reported effects consistent with these findings. One trial of sham acupuncture using penetrating needles to non-acupuncture points found no effect on pain. These were no clear effects on function in 5 trials (Strength of Evidence (SOE): low for pain and function).
- For chronic low back pain, a systematic review found acupuncture associated with lower pain intensity versus sham acupuncture (superficial needling at acupuncture or non-acupuncture points, or nonpenetrating pressure at acupuncture points) immediately at the end of treatment and at up to 12 weeks, but there were no differences in function. Four additional trials reported results consistent with these findings (SOE: moderate for pain and function).

- For chronic low back pain, a systematic review found acupuncture associated with lower pain intensity and better function immediately after treatment versus no acupuncture. Mean effects on pain ranged from 7 to 24 points on a 0- to 100-point scale; for function one trial reported a difference of 8 points on a 0- to 100-point scale and the other two trials; two trials showed small or no clear differences at longer-term follow up (SOE: moderate for pain and function).
- For acute low back pain, a systematic review found acupuncture associated with slightly greater likelihood of overall improvement versus NSAIDs at the end of treatment (SOE: low).
- For chronic low back pain, a systematic review found acupuncture associated with better pain relief and improvement in function immediately postintervention (SOE: low).
- Harms of acupuncture were poorly reported in the trials, though no serious adverse events were reported (SOE: low).

Qaseem et al. (2017) provided clinical recommendations on noninvasive treatment of low back pain (LBP): Recommendation 1: Given that most patients with acute or subacute LBP improve over time regardless of treatment, clinicians and patients should select nonpharmacologic treatment with superficial heat (moderate-quality evidence), massage, acupuncture, or spinal manipulation (low-quality evidence). (Grade: strong recommendation). Recommendation 2: For patients with chronic LBP, clinicians and patients should initially select nonpharmacologic treatment with exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction (moderate-quality evidence), tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, or spinal manipulation (low-quality evidence). (Grade: strong recommendation).

Chou et al. (2017) updated the 2007 American College of Physicians guideline that addressed nonpharmacologic treatment options for LBP. New evidence was available. Authors systematically reviewed the current evidence on nonpharmacologic therapies for acute or chronic non radicular or radicular LBP. Randomized trials of 9 nonpharmacologic options versus sham treatment, wait list, or usual care, or of 1 nonpharmacologic option versus another were included. New evidence indicated that tai chi (SOE, low) and mindfulness-based stress reduction (SOE, moderate) are effective for chronic LBP and strengthens previous findings regarding the effectiveness of yoga (SOE, moderate). Evidence continues to support the effectiveness of exercise, psychological therapies, multidisciplinary rehabilitation, spinal manipulation, massage, and acupuncture for chronic LBP (SOE, low to moderate). Limited evidence shows that acupuncture is modestly effective for acute LBP (SOE, low). The magnitude of pain benefits was small to moderate and generally short term; effects on function generally were smaller than effects on pain.

Wong et al. (2017) authored a systematic review for the Ontario Protocol for Traffic Injury Management (OPTIMA) Collaboration. According to high-quality guidelines: (1) all patients with acute or chronic LBP should receive education, reassurance and instruction on self-management options; (2) patients with acute LBP should be encouraged to return to activity and may benefit from paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs), or spinal manipulation; (3) the management of chronic LBP may include exercise, paracetamol or NSAIDs, manual therapy, acupuncture, and multimodal rehabilitation (combined physical and psychological treatment); and (4) patients with lumbar disc herniation with radiculopathy may benefit from spinal manipulation. According to Tice et al. (2017), the strength of evidence appears adequate to support coverage of acupuncture, CBT, MBSR, and yoga for chronic low back pain. Evidence-based boundaries on duration of therapy and on repetitive courses of therapy are reasonable given the potential for inappropriate overuse of services. Authors reported that there was no evidence on the concurrent use of multiple modalities, so concurrent treatment should be treated on a case-by-case basis.

Xiang et al. (2017) sought to establish whether sham acupuncture (SA) or placebo acupuncture (PA) was more efficacious for reducing low back pain (LBP) than other routine treatments and to discuss whether SA or PA is appropriate for RCTs of acupuncture for LBP. Review identified 7 trials (1,768 participants); all were included in the meta-analysis. They found statistically significant differences in pain reduction post-intervention between SA or PA and routine care or a waiting list, however, no significant difference was observed between SA or PA and routine care or no treatment for post-intervention function. Authors concluded that compared with routine care or a waiting list, SA or PA was more efficacious for pain relief post-intervention. Concluding that SA or PA is appropriate for acupuncture research would be premature. Guidelines evaluating SA or PA control methods are needed to determine the specific effect of acupuncture over placebo.

Mu et al. (2020) authored an updated Cochrane review. This review is a split from an earlier Cochrane review, and it focuses on chronic LBP. Mu et al. (2020) assessed the effects of acupuncture compared to sham intervention, no treatment, or usual care for chronic nonspecific LBP. Authors included only RCTs of acupuncture for chronic nonspecific LBP in adults. They excluded RCTs that investigated LBP with a specific etiology. Trials comparing acupuncture with sham intervention, no treatment, and usual care were included. The primary outcomes were pain, back-specific functional status, and quality of life; the secondary outcomes were pain-related disability, global assessment, or adverse events. Authors included 33 studies (37 articles) with 8,270 participants. Most studies were carried out in Europe, Asia, North and South America. Seven studies (5,572 participants) conducted in Germany accounted for 67% of the participants. Sixteen trials compared acupuncture with sham intervention, usual care, or no treatment. Most studies had high risk of performance bias due to lack of blinding of the acupuncturist. A few studies were found

to have high risk of detection, attrition, reporting or selection bias. Mu et al. (2020) found low-certainty evidence (7 trials, 1,403 participants) that acupuncture may relieve pain in the immediate term (up to 7 days) compared to sham intervention, visual analogue scale (VAS) 0-100. The difference did not meet the clinically important threshold of 15 points or 30% relative change. Very low-certainty evidence from 5 trials (1,481 participants) showed that acupuncture was not more effective than sham in improving back-specific function in the immediate term; corresponding to the Hannover Function Ability Questionnaire (HFAQ, 0 to 100, higher values better) change. Three trials (1,068 participants) yielded low-certainty evidence that acupuncture seemed not to be more effective clinically in the short term for quality of life; corresponding to the physical 12-item Short Form Health Survey (SF-12, 0-100, higher values better) change. The reasons for downgrading the certainty of the evidence to either low to very low were risk of bias, inconsistency, and imprecision. We found moderate-certainty evidence that acupuncture produced greater and clinically important pain relief; (VAS, 0 to 100), and improved back function; 5 trials, 2,960 participants; corresponding to the HFAQ change in the immediate term compared to no treatment. The evidence was downgraded to moderate certainty due to risk of bias. No studies reported on QoL in the short term or adverse events. Low-certainty evidence (5 trials, 1,054 participants) suggested that acupuncture may reduce pain; not clinically important on 0 to 100 VAS and improve back-specific function immediately after treatment; 5 trials, 1,381 participants; corresponding to the HFAQ change compared to usual care. Moderate-certainty evidence from 1 trial (731 participants) found that acupuncture was more effective in improving physical quality of life but not mental QoL in the short term. The certainty of evidence was downgraded to moderate to low because of risk of bias, inconsistency, and imprecision. Low-certainty evidence suggested a similar incidence of adverse events immediately after treatment in the acupuncture and sham intervention groups (4 trials, 465 participants), and the acupuncture and usual care groups (1 trial, 74 participants). The certainty of the evidence was downgraded due to risk of bias and imprecision. No trial reported adverse events for acupuncture when compared to no treatment. The most reported adverse events in the acupuncture groups were insertion point pain, bruising, hematoma, bleeding, worsening of LBP, and pain other than LBP (pain in leg and shoulder). Authors concluded that acupuncture may not play a more clinically meaningful role than sham in relieving pain immediately after treatment or in improving quality of life in the short term, and acupuncture possibly did not improve back function compared to sham in the immediate term. However, acupuncture was more effective than no treatment. Trials with usual care as the control showed acupuncture may not reduce pain clinically, but the therapy may improve function immediately after sessions as well as physical but not mental QoL in the short term. The evidence was downgraded to moderate to very low certainty considering most of studies had high risk of bias, inconsistency, and small sample size introducing imprecision. The decision to use acupuncture to treat chronic LBP might depend on the availability, cost, and patient's preferences.

Su et al. (2021) critically evaluated the evidence for acupuncture as an effective treatment for acute LBP (ALBP). Of the 13 eligible RCTs identified, 11 RCTs (involving 707 patients) provided moderate-quality evidence that acupuncture has a statistically significant association with improvements in VAS (visual analog scale) score. Two studies indicated that acupuncture did not influence the RMDQ (Roland-Morris Disability Questionnaire) scores more than the control treatment. Three studies suggested that acupuncture influenced the ODI (Oswestry Disability Index) scores more than the control treatment. Two studies suggested that acupuncture influenced the number of medications taken more than the control treatment. Authors conclude that acupuncture treatment of acute LBP was associated with modest improvements in the VAS score, ODI score, and the number of pills, but not the RMDQ score. However, findings should be considered with caution due to the low power original studies. High-quality trials are needed to assess further the role of acupuncture in the treatment of acute LBP.

Wu et al. (2021) evaluated and compared the efficacy and safety of different acupuncture therapies for ALBP. In total, nineteen randomized controlled trials (RCTs) comprising 1,427 participants were included. Results showed the following: (I) compared with placebo, motion style acupuncture (MSA), manual acupuncture (MA), and electroacupuncture (EA) were found to be more effective for decreasing VAS score; (II) compared with pharmacotherapy, MSA and MA were found to be more effective in reducing ROM score. Results of the surface under the cumulative ranking curve indicated that all acupuncture types were superior to placebo or pharmacotherapy in lowering VAS and ROM score. It was noted that MSA was the most effective treatment. Authors concluded that this study indicated that acupuncture therapy achieved good therapeutic effects in the treatment of ALBP, especially MSA therapy. Nevertheless, due to the low quality of the included trials, the credibility of conclusions is low. Further well-designed RCTs with high quality and large samples are still needed to evaluate the efficacy and safety of acupuncture therapy for ALBP.

Huang et al. (2021) investigated the effect and safety of acupuncture for the treatment of chronic spinal pain. Data was extracted from 22 RCTs including 2,588 patients. Pooled analysis revealed that acupuncture can reduce chronic spinal pain compared to sham acupuncture, medication control, usual care control, and no treatment control. In terms of functional disability, acupuncture can improve physical function at immediate-term follow-up, short-term follow-up, and long-term follow-up. In summary, compared to no treatment, sham acupuncture, or conventional therapy such as medication, massage, and physical exercise, acupuncture has a significantly superior effect on the reduction in chronic spinal pain and function improvement. Acupuncture might be an effective treatment for patients with chronic spinal pain and it is a safe therapy.

Baroncini et al. (2022) investigated the available randomized control trials (RCTs) to point out which acupuncture protocol is the most effective for chronic aspecific low back pain (LBP). Efficacy was measured in terms of pain (Visual Analogic Scale, VAS) and disability (Roland Morris Disability Questionnaire, RMQ), Transcutaneous Electrical Nerve Stimulation (TENS). Data from 44 RCTs (8338 procedures) were retrieved. 56% of patients were women. The mean age of the patients was  $48 \pm 10.6$  years. The mean BMI was  $26.3 \pm 2.2$  kg/m<sup>2</sup>. Authors concluded that verum acupuncture is more effective than sham treatment for the non-pharmacological management of LBP. Among the verum protocols, individualized acupuncture and standard acupuncture with TENS were the protocols that resulted in the highest improvement in pain and quality of life.

Feise et al. (2023) compared the benefits and harms of treatments for the management of chronic low back pain without radiculopathy. Systematic review and meta-analysis of randomized controlled trials were evaluated. Adults with chronic nonspecific low back pain, excluding radicular pain, in any clinical setting were included. Outcome measures included comparison of pain at immediate-term ( $\leq 2$  weeks) and short-term ( $> 2$  weeks to  $\leq 12$  weeks) and serious adverse events. Three studies provided data on the benefits of interventions, and 30 provided data on harms. Studies included interventions of acupuncture (n=8); manipulation (n=2); pharmacological therapies (n=9), including NSAIDs and opioid analgesics; surgery (n=8); and epidural corticosteroid injections (n=3). Acupuncture (moderate quality of evidence, benefit rating of 3) and manipulation (moderate quality of evidence, benefit rating of 5) were effective in reducing pain intensity compared to sham. The benefit of the other interventions was scored as uncertain due to not being effective, statistical heterogeneity preventing pooling of effect sizes, or the absence of relevant trials. The harms level warnings were at the lowest (e.g., indicating rarer risk of events) for acupuncture, spinal manipulation, NSAIDs, combination ingredient opioids, and steroid injections, while they were higher for single ingredient opioid analgesics (level 4) and surgery (level 6). Authors concluded that there is uncertainty about the benefits and harms of all the interventions reviewed due to the lack of trials conducted in patients with chronic nonspecific low back pain without radiculopathy. From the limited trials conducted, nonpharmacological interventions of acupuncture and spinal manipulation provide safer benefits than pharmacological or invasive interventions. However, more research is needed. There were high harms ratings for opioids and surgery.

Yu et al. (2023) evaluated benefits and harms of needling therapies (NT) for chronic primary low back pain (CPLBP) in adults to inform a World Health Organization (WHO) standard clinical guideline. Authors screened 1831 citations and 109 full text RCTs, yielding 37 RCTs. The certainty of evidence was low or very low across all included outcomes. There was little or no difference between NT and comparisons across most outcomes; there may be some benefits for certain outcomes. Compared with sham, NT improved health-related quality of life (HRQoL) (physical) at 6 months. Compared with

no intervention, NT reduced pain at 2 weeks and 3 months; and reduced functional limitations at 2 weeks and 3 months. In older adults, NT reduced functional limitations at 2 weeks and 3 months. Compared with usual care, NT reduced pain and functional limitations. Authors concluded that based on low to very low certainty evidence, adults with CPLBP experienced some benefits in pain, functioning, or HRQoL with NT; however, evidence showed little to no differences for other outcomes.

Yan et al. (2023) reevaluated the methodological quality, report quality, and evidence quality of systematic reviews (SRs)/meta-analyses (MAs) of acupuncture for low back pain to determine whether acupuncture effectively treats LBP. Twenty-three SRs/MAs were deemed eligible for the present overview. Results from the GRADE evaluation indicated that 13 of 255 outcomes were rated as moderate, 88 were low, and 154 were very low. Acupuncture effectively treated LBP in the SRs/MAs included in the reevaluation. However, the methodological, report, and evidence-based quality of the SRs/MAs on acupuncture for LBP was low. Therefore, further rigorous and comprehensive studies are warranted to improve the quality of SRs/MAs in this field.

Plener et al. (2023) assessed the effectiveness and safety of conservative interventions compared with other interventions, placebo/sham interventions, or no intervention on disability, pain, function, quality of life, and psychological impact in adults with cervical radiculopathy (CR). Of the 2561 records identified, 59 trials met inclusion criteria (n = 4108 participants). Due to clinical and statistical heterogeneity, the findings were synthesized narratively. There is very-low certainty evidence supporting the use of acupuncture, prednisolone, cervical manipulation, and low-level laser therapy for pain and disability in the immediate to short-term, and thoracic manipulation and low-level laser therapy for improvements in cervical range of motion in the immediate term. There is low to very-low certainty evidence for multimodal interventions, providing inconclusive evidence for pain, disability, and range of motion. There is inconclusive evidence for pain reduction after conservative management compared with surgery, rated as very-low certainty. Authors concluded that there is a lack of high-quality evidence, limiting their ability to make any meaningful conclusions.

Takakura et al. (2023) assessed whether acupuncture treatment with superficial skin piercing is superior to placebo treatment. Four hundred patients with essential neck/shoulder stiffness were randomly assigned to penetrating needle treatment (acupuncture ritual and skin penetration), skin-touch needle treatment (acupuncture ritual and skin touch), no-touch needle treatment (acupuncture ritual alone), and no-treatment control. Each of the six acupuncturists applied a needle to each of the four acupoints in the neck/shoulder of 50 patients. Each of the three treatments significantly improved neck/shoulder stiffness compared with the no-treatment control immediately and 24 h after treatment. There was a significant improvement in penetrating needle treatment over no-



1 touch needle treatment 24 h later. However, there was no significant difference between  
 2 the penetrating and skin-touch and skin-touch vs. no-touch. Authors concluded that all  
 3 treatments that received the ritual of acupuncture were better than the no-treatment control.  
 4 Only genuine acupuncture involves the specific effects of needle insertion into the body.  
 5 The acupuncture ritual had a significant impact on the subjective improvement of  
 6 neck/shoulder stiffness; however, improvement with ritual alone versions of placebo  
 7 acupuncture was not maintained as with superficial skin piercing. Authors suggest that this  
 8 study provides important evidence of acupuncture efficacy and information regarding inert  
 9 no-touch placebo control in acupuncture research.

10  
 11 Lee et al. (2024) aimed to establish clinical evidence for acupuncture by analyzing data  
 12 from trials that demonstrated the efficacy of acupuncture for whiplash-associated disorder  
 13 (WAD) with the following research question: Is acupuncture treatment effective for  
 14 symptom alleviation in patients with WAD compared with other usual care? Authors  
 15 included RCTs using acupuncture on patients with WAD. The outcomes were the pain  
 16 visual analogue scale (VAS) score or numerical rating scale score for neck pain, the range  
 17 of motion (ROM) of the neck, the Neck Disability Index and safety. A total of 525 patients  
 18 with WAD from eight RCTs were included in this study. The meta-analysis revealed that  
 19 the outcomes showed significant differences in the pain VAS score and ROM-extension.  
 20 Authors concluded that acupuncture may have clinical value in pain reduction and  
 21 increasing the ROM for patients with WAD. High-quality RCTs must be conducted to  
 22 confirm the efficacy of acupuncture in patients with WAD.

23  
 24 Fang, et al. (2024) aimed to evaluate the durable effects of acupuncture on chronic neck  
 25 pain in a systematic review and meta-analysis. Eighteen randomized controlled trials were  
 26 included in this meta-analysis. Acupuncture as an adjunct therapy provided sustained pain  
 27 relief at 3 and 6 months post-treatment. Compared to sham acupuncture, acupuncture did  
 28 not show a statistically significant difference in pain alleviation. However, it significantly  
 29 improved functional outcomes as evidenced by Northwick Park Neck Pain Questionnaire  
 30 scores 3 months post-treatment. Although nine studies reported an 8.5%-13.8% probability  
 31 of adverse events, these were mild and transitory adverse events. Authors concluded that  
 32 acupuncture as an adjunct therapy may provide post-treatment pain relief lasting at least 3  
 33 months for patients with chronic neck pain, although it is not superior to sham acupuncture,  
 34 shows sustained efficacy in improving functional impairment for over 3 months, with a  
 35 good safety profile.

36  
 37 Lin et al. (2024) assessed efficacy and safety of acupuncture for acute/subacute NSLBP as  
 38 alternative treatment. A total of 6,784 records were identified, and 14 studies were included  
 39 (1,263 participants) in this review. The results of the meta-analysis indicated that  
 40 acupuncture therapy was slightly more effective than oral medication in improving pain.  
 41 exhibited a significant improvement in disability as measured by the Roland-Morris

Disability Questionnaire (RMDQ). Based on the results of the meta-analysis, acupuncture therapy was associated with a 12% improvement rate compared to oral medication in patients with acute/subacute NSLBP. Authors conclude that acupuncture is more effective and safer than oral medication in treating acute/subacute NSLBP.

Zhang et al. (2024) compared the effects of different acupuncture methods on chronic nonspecific low back pain (CNLBP) in a network meta-analysis. A total of 27 articles were included, involving 2,579 patients. The results of the network meta-analysis showed that the top three treatment schemes were warm needle acupuncture, intensive silver needle therapy and meridian-sinew theory-based treatment. In terms of relieving pain, the top three treatments were electrical warm needling, intensive silver needle therapy and warm needle acupuncture. In improving mobility, the top three were meridian-sinew theory-based treatment, routine acupuncture and electroacupuncture. Authors concluded that for CNLBP patients, warm needle acupuncture, electrical warm needling and meridian-sinew theory-based treatment are mainly recommended. If patients have significant pain, electroacupuncture is strongly suggested. On the contrary, for patients with decreased joint mobility, meridian-sinew theory-based treatment is advocated.

Macedo et al. (2024) note that acupuncture may be helpful for CLBP in a Synopsis of the 2021 US Department of Veterans Affairs and US Department of Defense Clinical Practice Guideline. Evidence favored acupuncture over sham for reduction of pain intensity. Evidence for improvement of function and disability was mixed. Small improvements in back-specific function compared with sham and small improvements in function compared with usual care were seen in one study. Impacts on disability were mixed and there was no clinically meaningful change in QoL.

Zhao et al. (2024) evaluated the efficacy and safety of pressure pain, sensory-based individualized acupuncture for relieving CNP. 716 participants with CNP were randomly assigned to a waiting list (WL) group or to 1 of 3 interventions, which consisted of 10 sessions over 4 weeks: higher sensitive acupoints (HSA), lower sensitive acupoints (LSA), and sham acupoints (SA) acupuncture groups. The primary outcome was the change in the visual analogue scale (VAS) score for neck pain (range, 0 to 100) from baseline to 4 weeks, with a difference of 10 points considered the minimum clinically important threshold. The VAS was also assessed every 4 weeks through 24 weeks. The modified intention-to-treat population included 683 participants. The mean baseline VAS was 50.36, 50.10, 49.24, and 49.16 for HSA, LSA, SA, and WL, respectively. Compared with a mean baseline to week 4 change of -12.16 in the HSA group, the mean changes were -10.19 in the LSA group (net difference [ND], -1.97 [95% CI, -5.03 to 1.09]), -6.11 in the SA group (ND, -6.05 [CI, -9.10 to -3.00]), and -2.24 in the WL group (ND, -9.93 [CI, -12.95 to -6.90]). The intervention effects persisted at 24-week follow-up. Authors concluded that individualized acupuncture interventions using high- or low-sensitivity acupuncture points were more

effective in reducing CNP than SA and WL control groups sustained through 24 weeks, but the magnitude of relative improvement did not reach a minimal clinically important difference.

Yu et al. (2024) investigated the efficacy and safety of acupuncture in the treatment of stiff neck. This study evaluated 10 clinical randomized controlled trials comparing acupuncture therapy with conventional treatment, involving 754 patients. The treatment group received acupuncture alone or in combination with conventional treatment, whereas the control group received only conventional treatment. The analysis results showed that the treatment group was significantly superior to the control group in improving the total effective rate, reducing visual analog scale scores, reducing neck disability index scores, and restoring cervical range of motion. Authors concluded that acupuncture is an effective and safe method for treating stiff neck. However, to validate this conclusion, more rigorously designed and higher-quality studies are needed in the future.

## **8.6 Cancer Pain**

A Cochrane Review by Paley et al. reviewed the trials of acupuncture for cancer pain in adults (Paley et al., 2011). Three RCTs with 204 patients met the inclusion criteria. One study compared traditional auricular acupuncture with auricular acupuncture at non-acupuncture points and with a control using non-invasive “ear seeds,” at non-acupuncture points. The remaining two studies compared acupuncture with pain medication. The reviewers concluded that while there was some evidence of acupuncture effectiveness there was a high risk of bias in all studies and no conclusions could be reached regarding acupuncture effectiveness. Paley et al. (2015) updated the Cochrane review. They found five studies (with a total of 285 participants) that compared acupuncture against either sham acupuncture or pain-killing medicines. All five identified studies had small sample sizes, which reduces the quality of their evidence. Authors reported that none of the studies described in this review were big enough to produce reliable results. None of the studies reported any harm to the participants. They concluded that there was insufficient evidence to judge whether acupuncture is elective in relieving cancer pain in adults and that larger, well-designed studies are needed to provide evidence in this area.

Yang et al. (2021) analyzed currently available publications regarding the use of acupuncture for pain management among patients with cancer in palliative care settings. Five studies ( $n=189$ ) were included in this systematic review. Results indicated a favorable effect of acupuncture on pain relief in palliative care for patients with cancer. Authors concluded that acupuncture may be an effective and safe treatment associated with pain reduction in the palliative care of patients with cancer. Further high-quality, adequately powered studies are needed in the future.

Li et al. (2021) evaluated the effect of acupuncture on treatment-related symptoms among breast cancer survivors. The primary outcomes were pain, hot flashes, sleep disturbance, fatigue, depression, lymphedema, and neuropathy as individual symptoms. They also evaluated adverse events reported in acupuncture studies. Of 26 selected trials (2,055 patients), 20 (1,709 patients) were included in the meta-analysis. Acupuncture was more effective than control groups in improving pain intensity, fatigue, and hot flash severity. The subgroup analysis indicated that acupuncture showed trends but not significant effects on all the treatment-related symptoms compared with the sham acupuncture groups. Compared with waitlist control and usual care groups, the acupuncture groups showed significant reductions in pain intensity, fatigue, depression, hot flash severity, and neuropathy. No serious adverse events were reported related to acupuncture intervention. Mild adverse events (i.e., bruising, pain, swelling, skin infection, hematoma, headache, menstrual bleeding) were reported in 11 studies. This systematic review and meta-analysis suggest that acupuncture significantly reduces multiple treatment-related symptoms compared with the usual care or waitlist control group among breast cancer survivors. The safety of acupuncture was inadequately reported in the included studies. Based on the available data, acupuncture seems to be generally a safe treatment with some mild adverse events. These findings provide evidence-based recommendations for incorporating acupuncture into clinical breast cancer symptom management. Due to the high risk of bias and blinding issues in some RCTs, more rigorous trials are needed to confirm the efficacy of acupuncture in reducing multiple treatment-related symptoms among breast cancer survivors.

Zhang et al. (2021) evaluated the effects of acupuncture in women with breast cancer (BC), focusing on patient-reported outcomes (PROs). Out of the two, 524 identified studies, 29 studies representing 33 articles were included in this meta-analysis. At the end of treatment (EOT), the acupuncture patients' quality of life (QoL) was measured by the QLQ-C30 QoL subscale, the Functional Assessment of Cancer Therapy-Endocrine Symptoms (FACT-ES), the Functional Assessment of Cancer Therapy-General/Breast (FACT-G/B), and the Menopause-Specific Quality of Life Questionnaire (MENQOL), which depicted a significant improvement. The use of acupuncture in BC patients lead to a considerable reduction in the scores of all subscales of the Brief Pain Inventory-Short Form (BPI-SF) and Visual Analog Scale (VAS) measuring pain. Moreover, patients treated with acupuncture were more likely to experience improvements in hot flashes scores, fatigue, sleep disturbance, and anxiety compared to those in the control group, while the improvements in depression were comparable across both groups. Long-term follow-up results were similar to the EOT results. Authors concluded that current evidence suggests that acupuncture might improve BC treatment-related symptoms measured with PROs including QoL, pain, fatigue, hot flashes, sleep disturbance and anxiety. However, a number of included studies report limited amounts of certain subgroup settings, thus more rigorous, well-designed and larger RCTs are needed to confirm our results.

Ge et al. (2022) developed an evidence-based clinical practice guideline of acupuncture in the treatment of patients with moderate and severe cancer pain. Recommendations were developed through a Delphi consensus of an international multidisciplinary panel including 13 western medicine oncologists, Chinese medicine/acupuncture clinical practitioners, and two patient representatives. The certainty of evidence, patient preferences and values, resources, and other factors were fully considered in formulating the recommendations. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach was employed to rate the certainty of evidence and the strength of recommendations. The guideline proposed three recommendations: (1) a strong recommendation for the treatment of acupuncture rather than no treatment to relieve pain in patients with moderate to severe cancer pain; (2) a weak recommendation for the combination treatments with acupuncture/acupressure to reduce pain intensity, decrease the opioid dose, and alleviate opioid-related side effects in moderate to severe cancer pain patients who are using analgesics; and (3) a strong recommendation for acupuncture in breast cancer patients to relieve their aromatase inhibitor-induced arthralgia. This proposed guideline provides recommendations for the management of patients with cancer pain. The small sample sizes of evidence limit the strength of the recommendations and highlights the need for additional research.

Zhang et al. (2022) evaluated and summarized the systematic reviews (SRs) that assess the effects and safety of acupuncture for cancer-related conditions, and to inform clinical practice and future studies. Fifty-one SRs of RCTs on acupuncture for cancer-related conditions were included and synthesized. The methodological quality of SRs included 1 "high", 5 "low" and 45 "very low" by AMSTAR 2. Acupuncture showed effectiveness on systemic conditions in relation to different cancers, including cancer-related pain (17 SRs, 80 RCTs), fatigue (7 SRs, 18 RCTs), insomnia (4 SRs, 10 RCTs), quality of life (2 SRs, 15 RCTs); conditions in relation to chemo-radiotherapy, including nausea and vomiting (3 SRs, 36 RCTs) and bone marrow suppression (2 SRs, 21 RCTs); and conditions in relation to specific cancers, including breast cancer-related menopause (3 SRs, 6 RCTs), hot flashes (12 SRs, 13 RCTs), arthralgia (5 SRs, 10 RCTs), and nasopharyngeal cancer-related dysphagia (1 SRs, 7 RCTs). Acupuncture appeared to have benefit for patients with lymphoedema (3 SRs, 3 RCTs), gastrointestinal function (5 SRs, 27 RCTs), and xerostomia (4 SRs, 7 RCTs). Limited evidence showed inconsistent results on acupuncture for chemotherapy-induced peripheral neuropathy (3 SRs, 6 RCTs), depression and anxiety (3 SRs, 9 RCTs). Acupuncture was regarded as a safe therapy for cancer patients as no severe adverse events related were reported. Authors concluded that evidence from SRs showed that acupuncture is beneficial to cancer survivors with cancer-related pain, fatigue, insomnia, improved quality of life, nausea and vomiting, bone marrow suppression, menopausal symptoms, arthralgia, and dysphagia, and may also be potential for lymphoedema, gastrointestinal function, and xerostomia. For neuropathy, depression and anxiety, acupuncture should be used as an option based on individual conditions.

Acupuncture is relatively safe without serious adverse events. More well-designed clinical trials of acupuncture are recommended on cancer-related depression and anxiety, arthralgia, xerostomia, gastrointestinal dysfunction and dysphagia.

Abe et al. (2022) aimed to identify the current treatment options for pain and numbness in cancer survivors and to evaluate their effects. Cancer survivors were defined as patients diagnosed with cancer who had completed active cancer treatment, whose conditions were stable, and who had no evidence of recurrent or progressive disease. A meta-analysis was conducted using the random-effects model to obtain the effect sizes of 7 types of treatments: opioid therapy, nonopioid pharmacotherapy, interventional therapy, acupuncture, education/cognitive behavioral therapy (CBT), physical exercise, and alternative medicine. A total of 36 studies involving 2,870 cancer survivors were included. Among them, 35 (n=2,813) were included in the meta-analysis for pain. The analysis suggested that physical exercise, acupuncture, and alternative medicine could significantly reduce pain. Nonopioid pharmacotherapy and education/CBT did not demonstrate significant effects. No studies were identified that investigated the effects of opioid therapy or interventional therapy on pain. Regarding numbness, 5 studies (n=566) were included in the meta-analysis. Acupuncture (n=99; 2 studies) did not demonstrate significant effects on numbness, and the effects of nonopioid pharmacotherapy, education/CBT, and physical exercise could not be determined due to the small number of included studies. No studies were identified that investigated the effects of opioid therapy, interventional therapy, or alternative medicine on numbness. Authors concluded that this meta-analysis suggested that physical exercise, acupuncture, and alternative medicine may reduce pain in cancer survivors, with a very small to moderate amount of evidence.

Mao et al. (2022) authored a joint guideline to provide evidence-based recommendations to practicing physicians and other health care providers on integrative approaches to managing pain in patients with cancer. The Society for Integrative Oncology and ASCO convened an expert panel of integrative oncology, medical oncology, radiation oncology, surgical oncology, palliative oncology, social sciences, mind-body medicine, nursing, and patient advocacy representatives. The literature search included systematic reviews, meta-analyses, and randomized controlled trials published from 1990 through 2021. Outcomes of interest included pain intensity, symptom relief, and adverse events. Expert panel members used this evidence and informal consensus to develop evidence-based guideline recommendations. The literature search identified 227 relevant studies to inform the evidence base for this guideline. Recommendations included the following:

- Among adult patients, acupuncture should be recommended for aromatase inhibitor-related joint pain.
- Acupuncture or reflexology or acupressure may be recommended for general cancer pain or musculoskeletal pain.

These recommendations are based on an intermediate level of evidence, benefit

1 outweighing risk, and with moderate strength of recommendation. There is insufficient or  
2 inconclusive evidence to make recommendations for pediatric patients.

3  
4 Hershman et al. (2022) examined the effect of acupuncture in reducing AI-related joint  
5 pain through 52 weeks. A randomized clinical trial was conducted at 11 sites in the US  
6 from May 1, 2012, to February 29, 2016, with a scheduled final date of follow-up of  
7 September 5, 2017, to compare true acupuncture (TA) with sham acupuncture (SA) or  
8 waiting list control (WC). Participants were randomized 2:1:1 to the TA (n = 110), SA (n  
9 = 59), or WC (n = 57) group. The TA and SA protocols were composed of 6 weeks of  
10 intervention at 2 sessions per week (12 sessions overall), followed by 6 additional weeks  
11 of intervention with 1 session per week. Participants randomized to WC received no  
12 intervention. All participants were offered 10 acupuncture sessions to be used between  
13 weeks 24 and 52. Among 226 randomized, 191 (84.5%) completed the trial. In this  
14 randomized clinical trial, women with AI-related joint pain receiving 12 weeks of TA had  
15 reduced pain at 52 weeks compared with controls, suggesting long-term benefits of this  
16 therapy.

17  
18 de Sousa et al. (2023) described the main acupuncture techniques and parameters that have  
19 been used in the most varied symptoms of different types of cancer in a systematic review.  
20 After the selection and evaluation phase, 23 studies were included and analyzed. Authors  
21 concluded that based on this analysis, it is concluded that acupuncture is safe and there is  
22 evidence of the reduction of gastrointestinal symptoms, chemotherapy-induced peripheral  
23 neuropathy, pain, dry mouth, fatigue, insomnia, and improvement of cognitive capacity.

24  
25 Frenkel et al. (2023) reviewed research findings on the beneficial effect of use of CIM  
26 modalities in regard to pancreatic cancer, with emphasis on pancreatic ductal  
27 adenocarcinoma (PDAC). This data reveal that nutrition counselling; digestive enzyme  
28 therapy; microbiome support; dietary supplements; lifestyle interventions (physical  
29 activity and circadian health/sleep hygiene) appear to improve QoL of these patients  
30 through reduced symptom burden and meeting psychological needs, such as distress and  
31 fatigue. Acupuncture, mindfulness, yoga, reflexology, massage, and homeopathy may also  
32 contribute to symptom reduction, both physical and psychological, in all stages of the  
33 disease. There is supporting evidence that some CIM modalities may alleviate side effects  
34 and symptoms related to pancreatic cancer and its treatment, suggesting that practitioners  
35 might consider integrating these modalities in certain situations encountered in the  
36 treatment of pancreatic cancer. Further investigation is needed to define the optimal  
37 integration of CIM into the treatment and supportive care of patients affected by pancreatic  
38 cancer.

39  
40 Epstein et al. (2023) compared the effects of acupuncture and massage on musculoskeletal  
41 pain among patients with advanced cancer. Participants included patients with advanced

cancer with moderate to severe pain and clinician-estimated life expectancy of 6 months or more. The intervention included weekly acupuncture or massage for 10 weeks with monthly booster sessions up to 26 weeks. The primary end point was the change in worst pain intensity score from baseline to 26 weeks. The secondary outcomes included fatigue, insomnia, and quality of life. The Brief Pain Inventory (range, 0-10; higher numbers indicate worse pain intensity or interference) was used to measure the primary outcome. The secondary outcomes included fatigue, insomnia, and quality of life. A total of 298 participants were enrolled were women, 33 [11.1%] Black, 220 [74.1%] White, 46 [15.4%] Hispanic, and 78.5% with solid tumors). The mean (SD) baseline worst pain score was 6.9 (1.5). During 26 weeks, acupuncture reduced the worst pain score, with a mean change of -2.53 points, and massage reduced the Brief Pain Inventory worst pain score, with a mean change of -3.01 points; the between-group difference was not significant. Both treatments also improved fatigue, insomnia, and quality of life without significant between-group differences. Adverse events were mild and included bruising (6.5% of patients receiving acupuncture) and transient soreness (15.1% patients receiving massage). Authors concluded that given results of this study, for patients with advanced cancer, both acupuncture and massage were associated with pain reduction and improved fatigue, insomnia, and quality of life over 26 weeks; however, there was no significant difference between the treatments. More research is needed to evaluate how best to integrate these approaches into pain treatment to optimize symptom management for the growing population of people living with advanced cancer.

Yang et al. (2023) performed a study aimed to investigate the historical development, recent hotspots, and research trends in cancer-related pain (CRP) in a bibliometric analysis. This analysis was conducted from 2000 to 2022. A total of 664 publications were included, with the number rising steadily over the past 20 years. The U.S. contributed the most articles (244). This study explored the application value of acupuncture in the management of CRP with bibliometric analysis, offering an intuitive understanding of this topic and revealing the hotspots and research trends. Overall, it demonstrates the prominent role of acupuncture as an integrated medicine and a complementary alternative medicine. Traditional acupuncture and electroacupuncture play an important role as alternative therapies to relieve pain and improve the quality of life of cancer patients. The main types of cancer pain treated with acupuncture are breast pain, neuralgia and low back pain, which are commonly characterized by chronic pain. These researchers provide sufficiently compelling evidence for acupuncture in the treatment of breast cancer-related pain. In addition, acupuncture is one of the important interventions that can help breast cancer patients improve their pain symptoms after surgery. Numerous experts in Evidence-based Clinical Practice Guidelines strongly recommend using acupuncture for the relief of aromatase inhibitor-induced arthralgia in breast cancer patients. Acupuncture is also one of the frontiers and hotspots in the treatment of post-chemotherapy peripheral neuropathy and neuropathic pain. This research is expanding in depth and breadth.



Qi et al. (2023) evaluated the efficacy and safety of acupuncture by systematically reviewing the literature on colorectal cancer resection. Twenty-two studies with 1878 patients were included. Results of the meta-analysis showed there was a low level evidence that acupuncture may improve early postoperative symptoms, such as time to first flatus, time to first bowel movement, time to first defecation, and nausea/vomiting compared with usual care and sham acupuncture. However, there were no statistically significant differences in postoperative pain. And there was no sufficient evidence of improving long-term functional outcomes. There was substantial heterogeneity across trials. The adverse events associated with acupuncture stimulation were minor in included studies. Authors concluded that there is currently low-level evidence supporting the use of acupuncture on postoperative symptoms for patients after colorectal cancer resection.

Faria et al. (2024) evaluated the current evidence regarding the efficacy of acupuncture for cancer in a systematic review and meta-analysis. Studies included randomized controlled trials (RCTs) where acupuncture was compared with no treatment, placebo acupuncture or usual care. The primary outcome was pain intensity, measured with the visual analog scale, numeric rating scale, or brief pain inventory. Secondary outcomes also assessed were quality of life, functionality, xerostomia, pain interference, and analgesic consumption. Sixteen RCTs with a total of 1,124 participants, were included in the meta-analysis, with the majority of the studies presenting a low or unclear risk of bias. Acupuncture was more effective in reducing pain than no treatment, sham acupuncture or usual care. Authors concluded that the results of this study suggest that acupuncture may be an effective intervention to reduce pain associated with cancer. Despite some limitations due to the low quality and small sample size of some included studies, as well as the different types and stages of cancer, acupuncture might provide an effective and safe treatment to reduce cancer pain.

### **8.7 Neuropathic Pain**

Ju et al. (2017) assessed the analgesic efficacy and adverse events of acupuncture treatments for chronic neuropathic pain in adults. Randomized controlled trials (RCTs) with treatment duration of 8 weeks or longer comparing acupuncture (either given alone or in combination with other therapies) with sham acupuncture, other active therapies, or treatment as usual, for neuropathic pain in adults were included in this review. The primary outcomes were pain intensity and pain relief. The secondary outcomes were any pain-related outcome indicating some improvement, withdrawals, participants experiencing any adverse event, serious adverse events, and quality of life. Authors included 6 studies involving 462 participants with chronic peripheral neuropathic pain (442 completers (251 male), mean ages 52 to 63 years). Most studies included a small sample size (fewer than 50 participants per treatment arm) and all studies were at high risk of bias for blinding of participants and personnel. Authors concluded that due to the limited data available, there was insufficient evidence to support or refute the use of acupuncture for neuropathic pain

in general, or for any specific neuropathic pain condition when compared with sham acupuncture or other active therapies. Yu et al. (2021) evaluated the clinical efficacy of acupuncture through a review and analysis of systematic reviews of acupuncture for the treatment of diabetic peripheral neuropathy. Eighty-eight reviews were retrieved. The inclusion criteria were a published systematic evaluation/meta-analysis/systematic review of acupuncture treatment for diabetic peripheral neuropathy, which included subjects meeting the diagnostic criteria for diabetic peripheral neuropathy, and which compared acupuncture treatment with non-acupuncture treatment. After the inclusion criteria had been applied, 18 reviews were finally included. Authors report that evidence shows that acupuncture improves diabetic peripheral neuropathy and increases nerve conduction velocity. However, the methodological quality of the reviews is generally extremely low, and most of the reviews had certain defects, showing that there is still much room for improvement in terms of the methodology and quality of the research reports.

Ben-Arye et al. (2022) explored the impact of acupuncture with other complementary and integrative medicine (CIM) modalities on chemotherapy-induced peripheral neuropathy (CIPN) and quality of life (QoL) in oncology patients. In this prospective, pragmatic, and patient-preference study, patients with CIPN were treated with acupuncture and CIM therapies (intervention group) or standard care alone (controls) for 6 weeks. Patients in the intervention arm were randomized to twice-weekly acupuncture-only (group A) or acupuncture with additional manual-movement or mind-body CIM therapies (group B). Severity of CIPN was assessed with various outcome measures. Of 168 participants, 136 underwent the study intervention (group A, 69; group B, 67), with 32 controls. Baseline-to-6-week assessment scores improved significantly in the intervention arm (vs controls) on FACT-Tax and emotional well-being scores; FACT-TAX scores for hand numbness/tingling and discomfort; and EORTC physical functioning. Intervention groups A and B showed improved FACT-Tax physical well-being, FACT-TAX total score, FACT-TAX feet discomfort, and EORTC pain scores. Authors concluded that acupuncture, with or without CIM modalities, can relieve CIPN-related symptoms during oncology treatment. This is most pronounced for hand numbness, tingling, pain, discomfort, and for physical functioning.

Pei et al. (2023) performed a systematic review to evaluate whether acupuncture is effective for treating chemotherapy-induced peripheral neuropathy (CIPN). Nine studies involving 582 patients were included in this review. Most of the studies exhibited unclear risk of bias because some details were not mentioned. As the clinical heterogeneity was significant, qualitative analysis was performed to describe nerve conduction velocity, effective rate for motor neuropathy, pain scores, quality of life and adverse events. Meta-analysis was performed on four studies to analyze the effective rate for sensory neuropathy due to inconspicuous heterogeneity. The results indicated that acupuncture may generate a better effect on sensory neuropathy than vitamin B. The efficacy of EA plus glutathione

(GSH) appeared to be better than that of GSH alone in alleviating sensory neurotoxicity and in improving nerve conduction velocity. Acupuncture plus methylcobalamin showed more favorable effects than methylcobalamin alone in relieving neuralgia, restoring nerve conduction velocity and improving quality of life. In terms of pain relief and improved CIPN-specific quality of life, acupuncture plus standard care was better than standard care alone. In terms of pain relief, EA was more effective than usual care. Authors concluded that acupuncture may be effective and safe in the treatment of CIPN according to the analyzed studies. However, more studies with higher methodological quality are warranted in order to be able to draw firmer conclusions. Future rigorous RCTs will be necessary to confirm the effectiveness and safety of acupuncture for CIPN.

Shi et al. (2023) summarized and evaluated the evidence from current systematic reviews/meta-analyses (SRs/MAs) on the effectiveness of acupuncture treatment for CIPN. This umbrella review includes 9 SRs/MAs, and their methodological quality, risk of bias, reporting quality, and evidence quality were all deemed unsatisfactory. Authors state that their updated meta-analysis suggests that CIPN patients can benefit from acupuncture therapy, as indicated by effectiveness in measures including BPI-SF, VAS, FACT-NTX, NRS, SCV, and NCI-CTCAE. Authors concluded that based on the existing evidence, acupuncture is effective and safe for patients with CIPN, as it can significantly improve effective rate, pain symptoms, quality of life, and nerve conduction velocity. However, given the low quality of current evidence, caution should be taken interpreting this conclusion.

Yeh et al. (2024) sought to determine the hierarchical effects of acupuncture-related interventions on symptoms, pain, and QoL associated with Chemotherapy-Induced Peripheral Neuropathy (CIPN) in cancer patients undergoing chemotherapy in a systematic review and network meta-analysis. A total of 33 studies involving 2,027 participants were included. Pairwise meta-analysis revealed that acupuncture-related interventions were superior to usual care, medication, or dietary supplements in improving CIPN symptoms, CIPN pain, and QoL. Furthermore, network meta-analysis indicated that acupuncture plus electrical stimulation (acupuncture-E) had the greatest overall effect among the various interventions. Acupuncture alone was most effective in reducing CIPN pain, and acupuncture plus moxibustion (acupuncture-M) ranked highest in enhancing QoL. This finding suggests that acupuncture-related interventions can provide patients with benefits in improving CIPN symptoms, pain, and QoL. In particular, acupuncture-E could be the most effective approach in which the provided evidence offers diverse options for cancer patients and healthcare professionals.

## **8.8 Musculoskeletal and Pain Disorders of the Extremities**

Green et al. (2008) reviewed the evidence for acupuncture in the treatment of shoulder pain via a Cochrane review. Nine trials of varying quality met the inclusion criteria. Acupuncture was found to improve shoulder function more than placebo at 4 weeks, but this benefit (a 3.53-point difference on a 100 point scale) was no longer considered clinical significant at 4 months. The authors concluded that there was insufficient evidence to either support or refute the use of acupuncture for shoulder pain.

Hinman et al. (2014) conducted a randomized clinical trial of acupuncture for knee pain. In total 282 patients, over 50 years of age, with chronic knee pain were randomized into one of four groups: No treatment control; Traditional needle acupuncture; Laser acupuncture; Sham laser (very low power). Subjects in the last 3 groups were treated once or twice a week for 12 weeks. Primary outcome measures were knee pain (0-10) and function as measure by the McMaster Universities Osteoarthritis Index (0-68). End points were 12 weeks and one year. There was no difference in pain at 12 weeks between needle acupuncture or laser acupuncture and sham laser. There was a small difference between needle and laser treatment and the no treatment control at 12 weeks but not at one year. Needle acupuncture resulted in modest improvement in function compared with control at 12 weeks but was not significantly different from sham and was not maintained at one year. The authors concluded, “In patients older than 50 years with moderate or severe chronic knee pain, neither laser nor needle demonstrate that acupuncture conferred benefit over sham for pain or function. Our findings do not support acupuncture for these patients.”

Cox et al. (2016) assessed the effectiveness and safety of acupuncture therapies for musculoskeletal disorders of the extremities. The search revealed 5,180 articles; 15 were included (10 with a low risk of bias, 5 with a high risk of bias). Authors concluded that the evidence for the effectiveness of acupuncture for musculoskeletal disorders of the extremities was inconsistent. Traditional needle acupuncture may be beneficial for CTS and Achilles tendinopathy, but not for nonspecific upper extremity pain and patellofemoral syndrome. Electroacupuncture may be effective for shoulder injuries and may show similar effectiveness to that of night wrist splinting for CTS. The effectiveness of dry needling for plantar fasciitis is equivocal. Leggit (2018) summarized the consensus on acupuncture as a musculoskeletal therapy. Evidence regarding efficacy in the management of musculoskeletal conditions is heterogeneous and subject to several limitations. Despite these limitations, acupuncture consistently has been shown to be more effective than no treatment and is relatively safe. For chronic back pain, it is recommended as a first-line noninvasive therapy. For neck pain, acupuncture provides benefits when it is combined with other treatments.

Babatunde et al. (2021) evaluated the comparative effectiveness of treatment options for relieving pain and improving function in patients with subacromial shoulder conditions

(SSCs). The review identified 177 eligible trials. Current evidence shows small to moderate effect sizes for most treatment options for SSCs. Six treatments had a high probability of being most effective, in the short term, for pain and function [acupuncture, manual therapy, exercise, exercise plus manual therapy, laser therapy and Microcurrent (MENS) (TENS)], but with low certainty for most treatment options. After accounting for risk of bias, there is evidence of moderate certainty for the comparative effects of exercise on function in patients with SSCs. Future large, high-quality pragmatic randomized trials or meta-analyses are needed to better understand whether specific subgroups of patients respond better to some treatments than others.

Fredy et al. (2022) described the role of acupuncture for myofascial pain syndrome (MPS) in interventional pain management. They summarized that acupuncture, combined with other therapies, is effective in reducing pain and improving physical function. Acupuncture can enhance endogenous opioids such as endorphins to relieve pain and enhance the healing process. Authors concluded that acupuncture could be considered as one of nonpharmacological options in Interventional Pain Management for MPS. Interventions with acupuncture are safe and have minimal side effects when performed by a trained and competent practitioner.

Zhan et al. (2023) assessed the efficacy of acupuncture versus rehabilitation therapy (RT) for post-stroke shoulder pain PSSP. Eighteen studies were included in qualitative synthesis, fifteen (83%) studies with 978 patients were included in meta-analysis (MA) because of the outcomes of 3 studies were inappropriate. Nine (50%) studies were considered as moderate to high quality. The effectiveness of acupuncture for patients with PSSP was similar to that of RT on shoulder pain alleviation, improvement of upper limb motor function, and ADL. Two (11%) studies reported no acupuncture-related AEs, and fourteen (78%) studies did not mention AEs resulting from acupuncture. Authors concluded that acupuncture is similar to RT in relieving shoulder pain, improving upper limb motor function and ADL in patients with PSSP. Either acupuncture or RT might be the optimal treatment of PSSP. More well-designed RCTs of this topic are needed in the future.

Luan et al. (2023) investigated the efficacy of acupuncture or similar needling therapy on pain, proprioception, balance, and self-reported function in individuals with chronic ankle instability (CAI). Twelve trials (n = 571) were found, of which the final meta-analysis was conducted with eight. Different studies employ varying treatments, including specific needle types, techniques, and therapeutic frameworks. Compared to control without acupuncture or similar needling therapy, acupuncture or similar needling intervention resulted in improved pain, proprioception, balance, and self-reported function (Cumberland Ankle Instability Tool); American Orthopedic Foot and Ankle; Foot and Ankle Ability Measure: activities of daily living for individuals with CAI. Authors concluded that the available evidence suggests that acupuncture or similar needling therapy

may improve pain, proprioception, balance, and self-reported function in individuals with CAI, but more trials are needed to verify these findings. Furthermore, various needles and techniques used in different studies have resulted in methodological limitations that should be addressed in the future.

An et al. (2024) examined the exclusive impact of manual acupuncture on shoulder impingement syndrome (SIS). This study included 5 randomized controlled trials. The primary outcome assessment revealed significantly reduced pain and improvements in shoulder function and disability. A subgroup analysis based on treatment duration indicated that short-term acupuncture treatment ( $\leq 4$  weeks) exhibited a high level of confidence with low heterogeneity. Manual acupuncture is effective for relieving pain and improving shoulder function and disability in patients with SIS. However, further research is necessary to validate these findings owing to the limited number of patients and heterogeneity among the studies reviewed.

### **8.9 Nausea and Vomiting**

Ezzo et al. (2006) conducted a Cochrane Review on the effects of acupuncture point stimulation for chemotherapy-induced nausea and vomiting. Eleven trials met the inclusion criteria. Different acupuncture modalities were used, and overall, acupuncture-point stimulation by all modalities reduced the incidence of acute vomiting, but not acute or delayed nausea severity compared to control. Electro-acupuncture reduced acute nausea, but manual acupuncture did not. Acupressure reduced acute nausea severity, but not acute vomiting or delayed nausea. Non-invasive electro-stimulation showed no benefits for any outcome. A more recent update of this review has been withdrawn for failure to complete on time.

A 2009 Cochrane Review (Lee and Fan, 2009) evaluated studies of the stimulation of wrist acupuncture point P6 for the prevention of postoperative nausea and vomiting. Forty trials were identified with 4,858 individual subjects. Overall, acupuncture was found to be equally effective as anti-emetic drugs. This was true for both adults and children. It was also found equally effective whether using invasive needles or non-invasive stimulation of the acupuncture point.

Garcia et al. (2013) conducted a systematic review of the use of acupuncture in cancer care for the relief of multiple different symptoms. They identified 41 RCTs that met inclusion criteria. In total, eight different symptoms were evaluated: pain, nausea, hot flashes, fatigue, radiation-induced xerostomia, prolonged postoperative ileus, anxiety/mood disorders, and sleep disturbance. They found evidence that acupuncture was an effective treatment for nausea and vomiting, but the evidence was inconclusive or negative for the remaining symptoms.

Lee et al. (2013) conducted a clinical trial testing the effectiveness acupuncture to prevent opioid-induced nausea. They randomized 178 patients to one of three groups: 1. Pre-operative electro-acupuncture at P6; 2. Post-operative electro-acupuncture at P6; 3. A no-treatment control. The incidence of nausea and vomiting was significantly lower in the pre-operative group than in the control group. Vomiting was also lower in the pre-operative group than in the post-operative group. Overall, pre-operative, but not post-operative electro-acupuncture was more effective than the control group.

The effectiveness of acupuncture in preventing chemotherapy-related nausea and vomiting in patients with gynecological cancers was tested in a 2014 randomized clinical trial (Rithirangsiroj et al., 2014). Seventy patients were randomized to either acupuncture at P6 prior to chemotherapy infusion, or to the anti-emetic drug ondansetron. All patients received dexamethasone orally twice daily. The acupuncture group had a statistically significantly higher rate of complete absence of nausea and vomiting; 52.6% compared to 35.7% in the medication group. Overall, the acupuncture group had lower rates of nausea, less severe nausea, and fewer side effects than the ondansetron group.

A second Cochrane Review (Matthews et al., 2015) evaluated a range of treatments, including acupuncture to treat nausea and vomiting in early pregnancy. Overall, the reviewers found that the low quality of evidence precluded any definitive conclusions. In addition, they noted that, “Acupuncture (P6 or traditional) showed no significant benefit to women in pregnancy.”

Shen et al. (2015) completed a trial of 103 liver cancer patients tested the effectiveness of acupuncture at point K1 to prevent chemotherapy induced nausea and vomiting. Fifty-one patients were randomized to receive electrostimulation at K1 acupoint for 20 minutes prior to the first administration of chemotherapy and then daily for the next five days. They also received anti-emetic drugs. The control group underwent the same regimen except that they received electrostimulation at a presumed placebo point in their heel. Outcome measures included the rate, intensity and duration of nausea and frequency of vomiting. There were no significant differences between the two groups on any of the outcome measures.

Zhang et al. (2015) performed a meta-analysis on the use of wristband at acupuncture points for postoperative nausea and vomiting. They found a significant reduction in post-operative vomiting through the use of the wrist band compared to controls. However, they found no difference in the rates of nausea between wrist band and control.

Lu et al. (2021) explored acupuncture’s clinical efficacy in treating hyperemesis gravidarum HG. A total of 16 trials covering 1,043 gravidas were included. Compared with the conventional treatment, acupuncture had a significantly higher effective rate, a higher conversion rate of urine ketone, an improvement rate of nausea and vomiting, and a

relatively higher improvement rate of food intake. Acupuncture also shortened hospitalization time and manifested with a lower pregnancy termination rate and fewer adverse events. Nevertheless, no statistical variation in the improvement of nausea intensity, vomiting episodes, and lassitude symptom, recurrence rate, and serum potassium was observed. Authors concluded suggested that acupuncture was effective in treating HG. However, as the potential inferior quality and underlying publication bias were found in the included studies, there is a need for more superior-quality RCTs to examine their effectiveness and safety.

Mora et al. (2022) performed a systematic review and meta-analysis about the use and effect of complementary and alternative medicine (CAM) modalities to treat adverse effects of conventional cancer treatment among children and young adults. Twenty RCTs comprising 1,069 participants were included in this review. The included studies investigated acupuncture, mind-body therapies, supplements, and vitamins for chemotherapy-induced nausea and vomiting (CINV), oral mucositis, and anxiety among children and young adults who underwent conventional cancer treatment. Seven studies (315 participants) were included in the meta-analysis. The overall effect of CAM (including acupuncture and hypnosis only) on chemotherapy-induced nausea and/or vomiting and controls was statistically significant. There was a significant difference between acupuncture and controls ( $n = 5$ ) for intensity and/or episodes of CINV. Authors concluded that current evidence from this meta-analysis of randomized controlled trials shows that CAM, including acupuncture and hypnosis only, is effective in reducing chemotherapy-induced nausea and vomiting in children and young adults. More rigorous trials and long-term effects should be investigated if acupuncture and hypnosis are to be recommended for clinical use.

Yan et al. (2023) assessed the effectiveness and safety of acupuncture for the prevention of chemotherapy-induced nausea and vomiting (CINV), with specific attention on exploring sources of between-study variation in treatment effects. Thirty-eight RCTs with a total of 2503 patients were evaluated. Acupuncture in addition to usual care (UC) may increase the complete control of acute vomiting and delayed vomiting when compared with UC only. No effects were found for all other review outcomes. The certainty of evidence was generally low or very low. Authors concluded that acupuncture in addition to usual care may increase the complete control of chemotherapy-induced acute vomiting and delayed vomiting, but the certainty of evidence was very low. Well-designed RCTs with larger sample sizes, standardized treatment regimens, and core outcome measures are needed.

Tan et al. (2023) performed a meta-analysis to assess the improvement provided by complementary and alternative medicine (CAM) therapies for nausea and vomiting during pregnancy (NVP). Thirty-three RCTs were included in this study. Specific to acupuncture



as CAM, acupuncture treatment was superior to conventional medicine; (low-quality evidence).

Jin et al. (2024) evaluated the effectiveness and safety of acupuncture in managing nausea and vomiting of pregnancy (NVP), considering the traditional meridian and acupoint theories. Twenty-four RCTs involving 2,390 women were included. Acupuncture plus western medicine (WM) significantly led to a reduction in Pregnancy-Unique Quantification of Emesis (PUQE) scores and ineffective rates compared with WM alone. It also resulted in a greater improvement in ketonuria, shorter length of stay, and lower scores on the NVP Quality of Life and Chinese Medicine Syndrome Scale. Acupuncture was superior to WM in terms of reduction in ineffective rates. Acupuncture and WM had comparable results in improvement in PUQE scores and ketonuria negative rates. The evidence is not clear regarding the impact of acupuncture on depression and anxiety compared with that of sham acupuncture. The incidence of severe adverse events was not significantly different between acupuncture and WM or sham acupuncture. Evidence certainty ranged from moderate to very low. Of the 24 RCTs, 19 used the Neiguan (PC6) acupoint, 16 used the Zusanli (ST36) acupoint, and 13 used the Zhongwan (CV12) acupoint. According to the current systematic review and meta-analysis, acupuncture combined with WM may be a more effective treatment for NVP than WM alone. Furthermore, acupuncture may be as effective as WM. PC6, ST36, and CV12 are the most commonly used acupoints. Although more robust and larger studies are required, the current evidence supports the use of acupuncture in NVP treatment, as it has been demonstrated to be safe.

Wang et al. (2025) evaluated the efficacy of non-pharmacological interventions in improving chemotherapy induced delayed nausea and vomiting symptoms using a network meta-analysis. A total of 58 RCTs 4,081 patients were selected, involving 14 non-pharmacological interventions. The results of meta-analysis showed that acupoint patch was identified as the most probable superior intervention in the improvement of chemotherapy induced delayed nausea and vomiting, and acupuncture was identified as the most probable superior intervention on the improvement of Karnofsky Performance Scale (KPS) scores. Non-pharmacological interventions can serve as an effective complementary approach to managing delayed chemotherapy-induced nausea and vomiting. In particular, acupoint application may be the optimal complementary therapy to mitigate the incidence of delayed nausea and vomiting, though more high-quality, large-scale evidence is required to conclusively demonstrate the efficacy of acupuncture in enhancing the quality of life for cancer patients.

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