Clinical Policy Title: Hierarchy of chronic pain management

Clinical Policy Number: 18.04.02

Effective Date: September 1, 2014
Initial Review Date: April 16, 2014
Most Recent Review Date: April 10, 2018
Next Review Date: April 2019

Related policies:

- CP# 18.04.01 Hierarchy of strength of evidence
- CP# 14.02.08 Prolotherapy
- CP# 00.02.06 Infusible pharmaceuticals for bone pain management
- CP# 03.03.06 Biofeedback for chronic pain management
- CP# 03.03.01 Spinal cord stimulators for chronic pain
- CP# 03.03.02 Intrathecal opioid therapy for chronic pain
- CP# 03.03.04 Spine pain — epidural steroid injections
- CP# 03.02.02 Radiofrequency ablation treatment for spine pain
- CP# 03.03.08 Intravenous lidocaine infusion for neuropathic pain
- CP# 09.02.08 Cryoneurolysis

About this Policy: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies, along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage Policy

Prestige Health Choice considers the use of a hierarchy of clinical approaches for the management of chronic pain to be clinically proven and, therefore, medically necessary when applying the following evidence-based constructs (American Association of Nurse Anesthetists, 2011; Institute of Medicine, 2011;):

- Chronic pain is defined as patient-experienced pain of six months or greater.
Before initiating treatment, the treating provider must make a determination of the classification of chronic pain:

- Nociceptive.
  - Superficial (e.g., from the skin and tissues proximal to the surface).
  - Deep pain.
    - Visceral (i.e., from the internal organs).
    - Deep somatic (i.e., from the musculoskeletal system).
- Neuropathic.
  - Peripheral (e.g., neuropathies).
  - Central (i.e., arising from the brain or spinal cord).
- Somatosensory disorder (SSD), formerly termed somatization syndrome.

Treatment strategies match the classification of pain as described below.

<table>
<thead>
<tr>
<th>Classification of pain</th>
<th>Evidence-based strategies employed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nociceptive:</strong></td>
<td></td>
</tr>
<tr>
<td>- Superficial (e.g., from the skin and tissues proximal to the surface).</td>
<td>• Non-opioid pharmacologic management.</td>
</tr>
<tr>
<td>- Deep pain.</td>
<td>• Surgical management.</td>
</tr>
<tr>
<td>- Visceral (i.e., from the internal organs).</td>
<td>• Physical therapy and exercises.</td>
</tr>
<tr>
<td>- Deep somatic (i.e., from the musculoskeletal system).</td>
<td></td>
</tr>
<tr>
<td><strong>Neuropathic:</strong></td>
<td></td>
</tr>
<tr>
<td>- Peripheral (e.g., neuropathies).</td>
<td>• Non-opioid pharmacologic management.</td>
</tr>
<tr>
<td>- Central (i.e., arising from the brain or spinal cord).</td>
<td>• Antiepileptic medications.</td>
</tr>
<tr>
<td></td>
<td>• Surgical management (after failure of conservative therapy unless concern over rapid worsening).</td>
</tr>
<tr>
<td><strong>Somatosensory disorder (SSD), formerly termed somatization syndrome.</strong></td>
<td>• Behavioral health therapy.</td>
</tr>
<tr>
<td></td>
<td>• Multidisciplinary approach.</td>
</tr>
</tbody>
</table>

**Limitations:**

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

Prestige Health Choice benefits may exclude services as not medically necessary if there is insufficient evidence.

**Background**

Pain, mostly chronic as opposed to acute, is a very common condition in the U.S. population. Over 100 million Americans suffer from chronic pain, more than diabetes, coronary heart disease, stroke, and cancer put together. About 63 percent of pain sufferers have consulted a physician about their pain (AAPM, 2017). Among the most common types of pain are back (27 percent), headache and migraine headache (15), neck
(15), and facial (4), according to the National Centers for Health Statistics (NCHS, 2006).

An Institute of Medicine (IOM) report called “Relieving Pain in America” noted acute and chronic pain is a public health problem impacting 116 million American adults (IOM, 2011). The annual cost to society was $560 – 635 billion and $99 billion annually to government in 2008. Chronic pain accounts for almost 20 percent of outpatient utilization. There is a clear reduction in quality of life for affected individuals. Chronic pain can lead to physical disability, impeding the ability to work regardless of its cause. It is associated with depression, anxiety, and substance use. Individuals suffering from chronic pain are at increased risk for emotional disorders, maladaptive cognitions, functional deficits, and physical deconditioning.

Between 5 percent and 33 percent of all patients presenting in primary care settings have complaints of chronic pain. Because of this high prevalence, there is a vast array of strategies for reduction of pain. Most individuals have acute pain syndromes for which medication, therapies, and surgical procedures are available. However, chronic pain is a complex condition arising from injury, nerve damage, disease states, or mismanaged acute pain, or it can be idiopathic. Chronic pain requires an evidence-based approach that can reduce the pain. According to the IOM (2011), pain care must be tailored to each person’s experience. Financing, referrals, and records management should support this flexibility. The majority of care and management should take place through self-management and primary care, with specialty services focused on recalcitrant or more complex cases.

**Searches**

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality Guideline Clearinghouse and evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on March 6, 2018. Search terms were: "Pain Management/organization and administration" [Mesh] and "Pain Management/standards" [Mesh] along with free text terms “chronic pain” and “pain management.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies —which also rank near the top of evidence hierarchies.

**Findings**
A large number of papers submitted to medical journals on pain management are often from small studies. Because of technical difficulties, they are generally not blinded trials and are considered lower levels of evidence as described in Prestige Health Choice Clinical Policy 18.04.01: Hierarchy of Strength of Evidence. As a result, guidelines and practice standards for pain management often vary, resulting in disparities in care practice and quality.

Moreover, a review of the medical literature on PubMed on March 29, 2017, found 519 meta-analyses for “pain management” and another 404 for “chronic pain.” Systematic reviews for these two terms were far more numerous (2,783 and 1,763). References are typically focused on particular conditions marked by pain, or on efficacy of specific treatments for pain. Thus, clinical policies that review these particular areas would be more helpful than one for an extremely broad subject like pain management.

The potential benefits of practice guidelines are only as good as the quality of the guidelines. To identify the best available evidence for this policy, we applied the Appraisal of Guidelines for Research and Evaluation Global Rating Scale Instrument (AGREE II-GRS) to assess the process of practice guideline development and the quality of reporting (AGREE, 2015; Appendix A). The AGREE II-GRS is a valid and reliable short-item tool based on the AGREE II and includes the following items for assessment:

- Overall quality of guideline development methods.
- Overall quality of guideline presentation.
- Completeness of reporting.
- Overall quality of guideline recommendations.
- Overall quality of the guideline.

We identified several evidence-based guidelines for pain management that incorporate the best available evidence from research and clinical experience. Each guideline is summarized in Appendices B through H. They are:

- Failed back surgery syndrome — an algorithm of care (Ganty, 2012; Appendix B).
- Joint clinical practice guideline for low back pain (Chou, 2007; Appendix C).
- Management of chronic pain (Scottish Intercollegiate Guidelines Network [SIGN], 2013; Appendix D).
- An algorithmic approach for clinical management of chronic spinal pain (Manchikanti, 2009; Appendix E).
- Managing chronic pain in adults with, or in recovery from, substance use disorders (Substance Abuse and Mental Health Services Administration [SAMHSA], 2012; Appendix F).
- Biopsychosocial approach to chronic pain (Gatchel, 2007; Appendix G).

Policy updates:

In 2017, a total of four guidelines/other were added to this policy.
In 2018, two guidelines/other were added to the policy.

References

Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**

10.3 Inpatient Hospital Pain Rehabilitation Programs. Effective date not posted.  
[https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=23&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=pain&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAACAAAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=23&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=pain&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAACAAAAAA%3d%3d&). Accessed March 6, 2018.

10.4 Outpatient Hospital Pain Rehabilitation Programs. Effective date not posted.  

**Local Coverage Determinations (LCDs):**

[https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33595&ver=4&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=pain+management&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAACAAAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33595&ver=4&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=pain+management&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAACAAAAAA%3d%3d&). Accessed March 6, 2018.


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>64550</td>
<td>Application of surface transcutaneous neurostimulator</td>
<td></td>
</tr>
<tr>
<td>64553</td>
<td>Percutaneous implantation of neurostimulator electrode array; cranial nerve</td>
<td></td>
</tr>
<tr>
<td>CPT Code</td>
<td>Description</td>
<td>Comments</td>
</tr>
<tr>
<td>----------</td>
<td>------------------------------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>64555</td>
<td>Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)</td>
<td></td>
</tr>
<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array, sacral nerve (transforaminal placement) including image guidance if performed</td>
<td></td>
</tr>
<tr>
<td>64565</td>
<td>Percutaneous implantation of neurostimulator electrode array, neuromuscular</td>
<td></td>
</tr>
<tr>
<td>64566</td>
<td>Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming</td>
<td></td>
</tr>
<tr>
<td>64568</td>
<td>Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</td>
<td></td>
</tr>
<tr>
<td>64569</td>
<td>Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connecting to existing pulse generator</td>
<td></td>
</tr>
<tr>
<td>64570</td>
<td>Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</td>
<td></td>
</tr>
<tr>
<td>64575</td>
<td>Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)</td>
<td></td>
</tr>
<tr>
<td>64580</td>
<td>Incision of implantation of neurostimulator for electrode array, neuromuscular</td>
<td></td>
</tr>
<tr>
<td>64581</td>
<td>Incision for implantation of neurostimulator for electrode array, sacral nerve (transforaminal placement)</td>
<td></td>
</tr>
<tr>
<td>64585</td>
<td>Revision or removal of peripheral neuromuscular electrode array</td>
<td></td>
</tr>
<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
<td></td>
</tr>
<tr>
<td>64595</td>
<td>Revision or removal of peripheral or gastric neurostimulator or pulse generator</td>
<td></td>
</tr>
<tr>
<td>+90785</td>
<td>Interactive complexity</td>
<td></td>
</tr>
<tr>
<td>90791</td>
<td>Psychiatric diagnostic evaluation</td>
<td></td>
</tr>
<tr>
<td>90792</td>
<td>Psychiatric diagnostic evaluation with medical services</td>
<td></td>
</tr>
<tr>
<td>90832</td>
<td>Psychotherapy, 30 minutes with the patient and/or family member</td>
<td></td>
</tr>
<tr>
<td>+90833</td>
<td>Psychotherapy, 30 minutes with the patient and/or family member when performed with an evaluation and management service.</td>
<td></td>
</tr>
<tr>
<td>90834</td>
<td>Psychotherapy, 45 minutes with the patient and/or family member</td>
<td></td>
</tr>
<tr>
<td>+90836</td>
<td>Psychotherapy, 45 minutes with the patient and/or family member when performed with an evaluation and management service</td>
<td></td>
</tr>
<tr>
<td>90837</td>
<td>Psychotherapy, 60 minutes with the patient and/or family member</td>
<td></td>
</tr>
<tr>
<td>+90838</td>
<td>Psychotherapy, 60 minutes with the patient and/or family member when performed with an evaluation and management service</td>
<td></td>
</tr>
<tr>
<td>90839</td>
<td>Psychotherapy for crisis, first 60 minutes</td>
<td></td>
</tr>
<tr>
<td>+90840</td>
<td>Each additional 30 minutes</td>
<td></td>
</tr>
<tr>
<td>96150</td>
<td>Health and behavior assessment (eg, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with patient; initial assessment</td>
<td></td>
</tr>
<tr>
<td>97010</td>
<td>Application of a modality to 1 or more areas; hot or cold packs</td>
<td></td>
</tr>
<tr>
<td>97012</td>
<td>Application of a modality to 1 or more areas; traction, mechanical</td>
<td></td>
</tr>
<tr>
<td>97014</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (unattended)</td>
<td></td>
</tr>
<tr>
<td>97016</td>
<td>Application of a modality to one or more areas; vasopneumatic devices</td>
<td></td>
</tr>
<tr>
<td>97018</td>
<td>Application of a modality to 1 or more areas; paraffin bath</td>
<td></td>
</tr>
<tr>
<td>97022</td>
<td>Application of modality to 1 or more areas; whirlpool</td>
<td></td>
</tr>
<tr>
<td>97024</td>
<td>Application of modality to 1 or more areas; diathermy (eg, microwave)</td>
<td></td>
</tr>
<tr>
<td>97026</td>
<td>Application of a modality to 1 or more areas; infrared</td>
<td></td>
</tr>
<tr>
<td>97028</td>
<td>Application of a modality to 1 or more areas; ultraviolet</td>
<td></td>
</tr>
<tr>
<td>CPT Code</td>
<td>Description</td>
<td>Comments</td>
</tr>
<tr>
<td>----------</td>
<td>------------------------------------------------------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>97032</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes</td>
<td></td>
</tr>
<tr>
<td>97033</td>
<td>Application of modality to 1 or more areas; iontophoresis, each 15 minutes</td>
<td></td>
</tr>
<tr>
<td>97034</td>
<td>Application of modality to 1 or more areas; contrast baths, each 15 minutes</td>
<td></td>
</tr>
<tr>
<td>97035</td>
<td>Application of modality to 1 or more areas; ultrasound, each 15 minutes</td>
<td></td>
</tr>
<tr>
<td>97036</td>
<td>Application of modality to 1 or more areas; Hubbard tank, each 15 minutes</td>
<td></td>
</tr>
<tr>
<td>97039</td>
<td>Unlisted modality</td>
<td></td>
</tr>
<tr>
<td>97110</td>
<td>Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility</td>
<td></td>
</tr>
<tr>
<td>97112</td>
<td>Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture and/or proprioception for sitting and/or standing activities</td>
<td></td>
</tr>
<tr>
<td>97113</td>
<td>Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises</td>
<td></td>
</tr>
<tr>
<td>97116</td>
<td>Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)</td>
<td></td>
</tr>
<tr>
<td>97124</td>
<td>Therapeutic procedure, 1 or more areas, each 15 minutes; massage including effleurage, petrissage and/or tapotement (stroking, compression, percussion)</td>
<td></td>
</tr>
<tr>
<td>97139</td>
<td>Unlisted therapeutic procedure</td>
<td></td>
</tr>
<tr>
<td>97140</td>
<td>Manual therapy techniques (eg, mobilization/manipulation, manual lymphatic drainage, manual traction) one or more areas; each 15 minutes</td>
<td></td>
</tr>
<tr>
<td>97150</td>
<td>Therapeutic procedure(s), group (2 or more individuals)</td>
<td></td>
</tr>
<tr>
<td>97530</td>
<td>Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes</td>
<td></td>
</tr>
<tr>
<td>97542</td>
<td>Wheelchair management (eg, assessment, fitting, training), each 15 minute</td>
<td></td>
</tr>
<tr>
<td>97545</td>
<td>Work hardening/conditioning; initial 2 hours</td>
<td></td>
</tr>
<tr>
<td>+97546</td>
<td>Each additional hour</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>G89.2</td>
<td>Chronic Pain</td>
<td></td>
</tr>
<tr>
<td>G89.4</td>
<td>Chronic Pain syndrome</td>
<td></td>
</tr>
<tr>
<td>G90.50-G90.59</td>
<td>Complex regional pain syndrome of lower limb</td>
<td></td>
</tr>
<tr>
<td>G43.-G43.D1</td>
<td>Migraine</td>
<td></td>
</tr>
<tr>
<td>G56.40-G56.42</td>
<td>Complex regional pain syndrome of upper limb</td>
<td></td>
</tr>
<tr>
<td>Multiple diagnosis codes</td>
<td>Injury and poisoning</td>
<td></td>
</tr>
<tr>
<td>Multiple diagnosis codes</td>
<td>Late effects of injuries</td>
<td></td>
</tr>
<tr>
<td>Multiple diagnosis codes</td>
<td>Personal history of injury</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
</table>

Appendix A. AGREE II-GRS Instrument (AGREE, 2016)

Instructions: For each item, please choose the response on the 7-point scale which best characterizes the clinical practice guideline.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Lowest Quality (1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
<th>(5)</th>
<th>(6)</th>
<th>Highest Quality (7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Rate the overall quality of the guideline development methods.</td>
<td>Consider: <em>Were the appropriate stakeholders involved in the development of the guideline?</em> <em>Was the evidence base developed systematically? Were recommendations consistent with the literature?</em></td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Rate the overall quality of the guideline presentation.</td>
<td>Consider: <em>Was the guideline well organized? Were the recommendations easy to find?</em></td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Rate the completeness of reporting.</td>
<td>Consider: <em>Was the guideline development process transparent and reproducible? How complete was the information to inform decision making?</em></td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. Rate the overall quality of the guideline recommendations.</td>
<td>Consider: <em>Are the recommendations clinically sound? Are the recommendations appropriate for the intended patients?</em></td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. Rate the overall quality of the guideline.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

General Questions: Overall Guideline Assessment

Instructions: For each item, please choose the response on the 7 point scale which best characterizes the clinical practice guideline.

<table>
<thead>
<tr>
<th>Item</th>
<th>Strongly Disagree (1)</th>
<th>Disagree (2)</th>
<th>Disagree Slightly (3)</th>
<th>Neither Agree nor Disagree (4)</th>
<th>Agree Slightly (5)</th>
<th>Agree (6)</th>
<th>Strongly Agree (7)</th>
</tr>
</thead>
</table>
1. I would recommend this guideline for use in practice.

2. I would make use of a guideline of this quality in my professional decisions.
Appendix B. Failed back surgery syndrome — an algorithm of care (Ganty, 2012)

SCS: Spinal cord stimulation; PMP: Pain Management Programme
ITDDS: Intrathecal Drug Delivery System
Appendix C. Joint clinical practice guideline for low back pain (used with permission of the American College of Physicians) (Chou, 2007)

Initial evaluation of low back pain (LBP). Do not use this algorithm for back pain associated with major trauma, nonspinal back pain, or back pain due to systemic illness.
Management of low back pain (LBP). MRI = magnetic resonance imaging; NSAIDs = nonsteroidal anti-inflammatory drugs; TCA = tricyclic antidepressants.
Appendix D. Management of chronic pain (SIGN, 2013)

Major recommendations with grade of evidence:

1.) Supported self-management
   - C — Self management resources should be considered to complement other therapies in the treatment of patients with chronic pain.

2.) Pharmacological therapies

   Non-opioid analgesics (simple and topical)
   - Non-steroidal anti-inflammatory drugs (NSAIDs)
     - B — NSAIDs should be considered in the treatment of patients with chronic non-specific low back pain.
     - B — Cardiovascular and gastrointestinal risk needs to be taken into account when prescribing any NSAID.
   - Acetaminophen
     - C — Acetaminophen (1,000 – 4,000 mg/day) should be considered alone or in combination with NSAIDs in the management of pain in patients with hip or knee osteoarthritis, in addition to non-pharmacological treatments.
   - Topical NSAIDs
     - A — Topical NSAIDs should be considered in the treatment of patients with chronic pain from musculoskeletal conditions, particularly in patients who cannot tolerate oral NSAIDs.
   - Topical capsaicin
     - A — Topical capsaicin patches (8 percent) should be considered in the treatment of patients with peripheral neuropathic pain when first line pharmacological therapies have been ineffective or not tolerated.
   - Topical lidocaine
     - B — Topical lidocaine should be considered for the treatment of patients with postherpetic neuralgia if first-line pharmacological therapies have been ineffective.
   - Topical rubefacients
     - B — Topical rubefacients should be considered for the treatment of pain in patients with musculoskeletal conditions if other pharmacological therapies have been ineffective.

Opioids
   - B — Strong opioids should be considered as an option for pain relief for patients with chronic low back pain or osteoarthritis, and only continued if there is ongoing pain relief. Regular review is required.
   - B — Patients prescribed opioids should be advised of the likelihood of common side effects such as nausea and constipation.
   - B — It may be necessary to trial more than one opioid sequentially, as both effectiveness and side effects vary between opioids.
   - C — Signs of abuse and addiction should be sought at re-assessment of patients using strong opioids. Routine urine drug testing, pill counts or prescription monitoring should not be used to detect problem use.
   - B — Currently available screening tools should not be relied upon to obtain an accurate prediction of patients at risk of developing problem opioid use before commencing treatment.
   - D — Specialist referral or advice should be considered if there are concerns about rapid-dose
escalation with continued unacceptable pain relief or if >180 mg/day morphine equivalent dose is required.

**Anti-epilepsy drugs**
- Gabapentin
  - A — Gabapentin (titrated up to at least 1,200 mg daily) should be considered for the treatment of patients with neuropathic pain.
- Pregabalin
  - A — Pregabalin (titrated up to at least 300 mg daily) is recommended for the treatment of patients with neuropathic pain if other first- and second-line pharmacological treatments have failed.
  - A — Pregabalin (titrated up to at least 300 mg daily) is recommended for the treatment of patients with fibromyalgia.
  - B — Flexible dosing may improve tolerability. Failure to respond after an appropriate dose for several weeks should result in trial of a different compound.
- Carbamazepine
  - B — Carbamazepine should be considered for the treatment of patients with neuropathic pain. Potential risks of adverse events should be discussed.

**Antidepressants**
- Tricyclic antidepressants
  - A — Tricyclic antidepressants should not be used for the management of pain in patients with chronic low back pain.
  - A — Amitriptyline (25-125 mg/day) should be considered for the treatment of patients with fibromyalgia and neuropathic pain (excluding human immunodeficiency virus [HIV]-related neuropathic pain).
- Serotonin norepinephrine reuptake inhibitor
  - A — Duloxetine (60 mg/day) should be considered for the treatment of patients with diabetic neuropathic pain if other first- or second-line pharmacological therapies have failed.
  - A — Duloxetine (60 mg/day) should be considered for the treatment of patients with fibromyalgia or osteoarthritis.
- Selective serotonin reuptake inhibitor
  - B — Fluoxetine (20 – 80 mg/day) should be considered for the treatment of patients with fibromyalgia.

**Chronic pain with concomitant depression**
- B — Optimized antidepressant therapy should be considered for the treatment of patients with chronic pain with moderate depression.

**Combination therapies**
- A — Combination therapies should be considered for patients with neuropathic pain (a pathway for patients with neuropathic pain can be found in Annex 3 in the original guideline document).
- A — For patients with neuropathic pain who do not respond to gabapentinoid (gabapentin/pregabalin) alone and are unable to tolerate other combinations, consideration should be given to the addition of an opioid such as morphine or oxycodone. The risks and benefits of opioid use need to be considered.

### 3.) Psychologically based interventions

**Multidisciplinary pain management programs**
- C — Referral to a pain management program should be considered for patients with chronic pain.

**Unidisciplinary education**
• Brief education
  o C — Brief education should be given to patients with chronic pain to help patients continue to work.

Behavioral therapies
• Respondent behavioral therapies
  o C — Progressive relaxation or electromyographic (EMG) biofeedback should be considered for the treatment of patients with chronic pain.
• Cognitive behavioral therapy
  o C — Cognitive behavioral therapy should be considered for the treatment of patients with chronic pain.

4.) Physical therapies

  Manual therapy
  • Low back pain
    o B — Manual therapy should be considered for short-term relief of pain for patients with chronic low back pain.
  • Neck pain
    o B — Manual therapy, in combination with exercise, should be considered for the treatment of patients with chronic neck pain.

Exercise
  • B — Exercise and exercise therapies, regardless of their form, are recommended in the management of patients with chronic pain.
  • A — Advice to stay active should be given in addition to exercise therapy for patients with chronic low back pain to improve disability in the long term. Advice alone is insufficient.
  • The following approaches should be used to improve adherence to exercise:
    o B — Supervised exercise sessions.
    o B — Individualized exercises in group settings.
    o C — Addition of supplementary material.
    o B — Provision of a combined group and home exercise program.

Electrotherapy
  • B — Transcutaneous electrical nerve stimulation (TENS) should be considered for the relief of chronic pain. Either low or high-frequency TENS can be used.
  • B — Low-level laser therapy should be considered as a treatment option for patients with chronic low back pain.

5.) Complementary therapies

  Acupuncture
  • A — Acupuncture should be considered for short-term relief of pain in patients with chronic low back pain or osteoarthritis.

Definitions

Levels of evidence:

1++: High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs) or RCTs with a very low risk of bias.
1+: Well-conducted meta-analyses, systematic reviews or RCTs with a low risk of bias.
1: Meta-analyses, systematic reviews or RCTs with a high risk of bias.
2++: High-quality systematic reviews of case control or cohort studies. High-quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal.
2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal.
2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal.
3: Non-analytic studies (e.g., case reports or case series).
4: Expert opinion.

Grades of recommendation:

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review or RCT rated as 1++ and directly applicable to the target population; or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results.
B: A body of evidence including studies rated as 2++, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+.
C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++.
D: Evidence level 3 or 4; or extrapolated evidence from studies rated as 2+.

Potential benefits

Appropriate management of adults with chronic pain.

Potential harms

Adverse drug reactions:

- Opioids: somnolence, gastrointestinal effects (constipation, nausea, dyspepsia), headache, fatigue, lethargy and urinary complications (retention hesitancy, disturbance). Serious side effects can include sedation and respiratory depression. Refer to "Side Effects" and "Opioid Misuse" in Section 5.3 in the original Scottish guideline document for further information. (See references)
- Gabapentin: dizziness, somnolence, peripheral edema and gait disturbance.
- NSAIDs: abdominal pain, diarrhea, edema, dry mouth, rash, dizziness, headache and tiredness.
- Pregabalin: dizziness, somnolence.
- Carbamazepine: rashes.
- Amitriptyline: excessive drowsiness.
- Topical lidocaine plasters: skin reddening and irritation.
Qualifying statements

- This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should it be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgment must be made by the appropriate health care professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgment should only be made following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is, however, advised that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.
- Recommendations within this guideline are based on the best clinical evidence. Some recommendations may be for medicines prescribed out with the marketing authorization (MA), also known as product license. This is known as 'off-label' use.
- Medicines may be prescribed off-label in the following circumstances:
  - For an indication not specified within the marketing authorization.
  - For administration via a different route.
  - For administration of a different dose.
  - For a different patient population.

Date released: December 2013

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the full-text guideline document.

Appendix E. An algorithmic approach for clinical management of chronic spinal pain (Manchikanti, 2009).

Medical necessity management: The following criteria should be considered carefully in performing interventional techniques:

- Complete initial evaluation, including history and physical examination.
- Psychosocial and functional assessment, as necessary and feasible.
- Determination of indications and medical necessity:
  - Suspected organic problem.
  - Nonresponsiveness to less invasive modalities of treatments except in acute situations, such as acute disc herniation, herpes zoster, complex regional pain syndrome (CRPS) and intractable cancer-related pain.
  - Pain and disability of moderate-to-severe degree.
  - No evidence of contraindications, such as severe spinal stenosis resulting in intraspinal obstruction, infection, impaired coagulation or predominantly psychogenic pain.
  - Responsiveness to prior interventions with improvement in physical and functional status to justify repeat blocks or other interventions.
  - Repeating interventions only upon return of pain and deterioration in functional status; decreased pain and increased function after the initial intervention must be documented.
Appendix F. Managing chronic pain in adults with, or in recovery from, substance use disorders (SAMHSA, 2012)

Scope

Disease/Condition(s): Chronic noncancer pain (CNCP) associated with a history of substance use disorders (SUDs).
Guideline objective(s): To equip clinicians with practical guidance and tools for treating CNCP in adults with histories of SUDs.
Note: This guideline does not describe how to treat SUDs or other behavioral health disorders in patients with CNCP. It provides readers with information about SUD assessments and referrals for further evaluation.
Target population: Adults in the United States with histories of SUDs who are suffering from CNCP, including patients with sickle cell disease (SCD) and human immunodeficiency virus (HIV).

Interventions and practices considered

Diagnosis/Evaluation:
- Comprehensive initial assessment (history and physical evaluation, including individual and family history of SUDs, mental status, and diagnosis of source of pain, if possible).
- Screening for SUD.
- Assessment of pain level and functioning.
- Assessment of psychiatric comorbid conditions.
- Ongoing reassessment.

Management/Treatment:
- Development of a pain treatment plan.
- Integration of pain and comorbidity treatment.
- Initial treatment with non-opioid and no pharmacological methods, including complementary and alternative medicines (CAMs).
- Treatment with opioids following careful risk/benefit analysis.
- Addition of an addiction treatment specialist to the care team.
- Tapering and discontinuation of opioid or other failing treatment.
- Monitoring for and management of aberrant drug-related behavior (ADRB).
- Establishing relationships with drug testing laboratory staff and addiction specialists.

Counseling:
- Use of an empathetic demeanor.
- Obtaining informed consent.
- Encouraging active patient role in pain management.
- Provision of information over time and in a variety of ways.
- Use of treatment agreement documents between patients and physicians.

Major outcomes considered:
- Sensitivity, specificity and validity of assessment and screening tools.
- Prevalence of problems associated with chronic opioid therapy (e.g., addiction, dependence, abuse, ADRB and misuse).
- Pain relief.
- Pain relapse.
- Rate of referral to inpatient programs.
• Rate of medication adherence.
• Development of medication tolerance.
• Adverse effects of medications.

The treatment improvement protocol (TIP) was not developed to advise clinicians on how to treat the many individual types of CNCP, such as low back pain, neck pain, fibromyalgia or migraines. Instead, evidence was sought that would be relevant to a clinician who may treat any type of chronic pain in patients with a history of SUDs. The literature search was complex because, in most databases used, much of the information was not indexed in a way that facilitated the search.

Recommendations

Major recommendations:

Patient assessment
• Patients should receive a comprehensive initial assessment.
• It is important to discover the cause of a patient’s chronic pain; however, clinicians should not assume a patient is disingenuous if the cause is not discovered.
• The patient’s personal and family substance use histories and current substance use patterns should be assessed.
• It is crucial to obtain collateral information on the patient’s pain level and functioning, as well as SUD status.
• Comorbid psychological disorders should be assessed and treated.
• Assessment of the patient with co-occurring chronic pain and SUD or other behavioral health disorders should be ongoing.

Chronic pain management
• Pain treatment goals should include improved functioning and pain reduction.
• Treatment for pain and comorbidities should be integrated.
• Non-opioid pharmacological and non-pharmacological therapies, including CAM, should be considered routine before opioid treatment is initiated.
• Opioids may be necessary and should not be ruled out based on an individual's having an SUD history.
• The decision to treat pain with opioids should be based on a careful consideration of benefits and risks.
• Addiction specialists should be part of the treatment team and should be consulted in the development of the pain treatment plan, when possible.
• A substantial percentage of patients with and without SUDs will fail to benefit from prolonged opioid therapy, in which case it should be discontinued, as with any other failed treatment.

Managing addiction risk in patients treated with opioids
• Patients on chronic opioid therapy should be monitored closely for signs of benefit, harm, and ADRBs.
• All ADRBs should be documented, investigated, and acted upon.
• Difficult conversations should be managed with compassion and empathy.
• Clinicians should establish and respectfully maintain strict limits with patients who insist on opioids.
• Clinicians should establish relationships with drug-testing laboratory staff and addiction specialists.
• When it is necessary to discontinue chronic opioid therapy, a conscientious tapering plan should be provided.

Patient education and treatment agreements
• Patient education is necessary for informed consent and equips patients to take an active role in their pain management.
Education must be tailored to the individual patient. More research is needed on tailoring education to patients who have CNCP.

Clinicians should take time to educate their patients and make sure patients understand how to help themselves.

People learn in different ways; clinicians should have a variety of learning materials at their disposal.

Treatment agreements document the treatment plan and the responsibilities of the patient and the clinician.

Clinical algorithm(s) provided in the original guideline document:
- Managing chronic pain in patients with SUD.
- Exit strategy.

Evidence supporting the recommendations is not specifically stated. The literature review (see the "Availability of Companion Documents" field) presents the evidence on which the TIP's recommendations are based. Where sufficient evidence does not exist, the TIP is based on the clinical experience and judgment of the TIP's consensus panel of experts.

Potential harms

Adverse effects of non-opioid medications:
- NSAIDs may cause gastrointestinal bleeding and renal insufficiency.
- Tricyclic antidepressants may be associated with anticholinergic side effects and orthostatic hypotension (fall risk in older people).
- Antipsychotics can cause extrapyramidal reactions and metabolic syndrome.

Adverse effects of opioids:
- Opioids have limitations, such as diminished efficacy over time. Opioids also have adverse effects that many patients cannot tolerate (e.g., nausea, sedation, constipation). Other drawbacks include risk of addiction or addiction relapse, opioid-induced hyperalgesia (OIH), and many potential drug interactions.
- Serotonin syndrome can cause agitation, confusion, fever and seizures, and it can be lethal if undetected or untreated. Patients who take selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), St. John’s Wort, monoamine oxidase inhibitors, lithium or HIV medications are at increased risk of serotonin syndrome. In addition, patients who take opioids chronically are at increased risk of serotonin syndrome if medications such as fentanyl, meperidine or pentazocine are needed in emergency or surgical care settings.

Adverse effects of drugs used in medication-assisted recovery:
- Buprenorphine can induce acute opioid withdrawal.
- Methadone is especially toxic because of issues of accumulation, drug interaction and QT prolongation. For these reasons, it should be prescribed only by providers who are thoroughly familiar with it. Patients starting methadone should receive a thorough education in the dangers of inadvertent overdose with this medication. It is critical for the clinician to advise patients to stop methadone treatment if they become sedated.
- Patients taking naltrexone should not be prescribed outpatient opioids for any reason. Because naltrexone displaces opioid agonists from their binding sites, opioid analogs will not be effective in patients on naltrexone. Increasing the dose of opioids to overcome the blockade puts the patient at risk of respiratory arrest. If patients on naltrexone require emergency opioids for acute pain, higher doses are required, which, if continued, can become toxic as naltrexone levels wane. In this situation, inpatient or prolonged emergency department monitoring is required.

Urine drug testing (UDT) is subject to false-positive and false-negative results.
Contraindications

- Patients taking naltrexone should not be prescribed outpatient opioids for any reason.
- Patients dependent on opioids or sedatives (including benzodiazepines) should not be withdrawn from these medications while undergoing acute medical interventions.
- If the patient declines to give consent, prolonged treatment with controlled substances may be contraindicated.

Qualifying statements

- The views, opinions and content of this publication are those of the authors and do not necessarily reflect the views, opinions or policies of SAMHSA or U.S. Department of Health and Human Services (HHS).
- Although each consensus-based TIP strives to include an evidence base for the practices it recommends, SAMHSA recognizes that behavioral health is continually evolving, and research frequently lags behind the innovations pioneered in the field. A major goal of each TIP is to convey "front-line" information quickly but responsibly. If research supports a particular approach, citations are provided.
- The TIP was not developed to advise clinicians on how to treat the many individual types of CNCP, such as low back pain, neck pain, fibromyalgia or migraines. Instead, evidence was sought that would be relevant to a clinician who may treat any type of chronic pain in patients with a history of SUDs.

Appendix G. The biopsychosocial approach to chronic pain: scientific advances and future directions (Gatchel, 2007).

Key points:

- Most widely accepted chronic pain perspective.
- Biopsychosocial model connects disease (biological event) with illness (subjective experience).
- Developed by Engel in response to the previously widely accepted dualistic viewpoint of pain.
- Connects physical illness with the interaction between physiologic, psychological and social.
- Understanding chronic pain through biopsychosocial framework allowed for development of multidisciplinary pain management.