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: May 18, 2016
Next Review Date: May 2017

Policy contains:
- Chronic pain management.
- Drug pain management.
- Behavioral health management.
- Surgical algorithm.

Related policies:

CP# 18.04.01  Hierarchy of strength of evidence
CP# 14.02.08  Prolotherapy

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’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 Keystone First 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. Keystone First’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. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First 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:

- 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>• Non-opioid pharmacologic management.</td>
</tr>
<tr>
<td>• Superficial (e.g., from the skin and tissues proximal to the surface).</td>
<td>• Surgical management.</td>
</tr>
<tr>
<td>• Deep pain.</td>
<td>• Physical therapy and exercises.</td>
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<tr>
<td>- Visceral (i.e., from the internal organs).</td>
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<tr>
<td>- Deep somatic (i.e., from the musculoskeletal system).</td>
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<tr>
<td><strong>Neuropathic:</strong></td>
<td>• Non-opioid pharmacologic management.</td>
</tr>
<tr>
<td>• Peripheral (e.g., neuropathies).</td>
<td>• Antiepileptic medications.</td>
</tr>
<tr>
<td>• Central (i.e., arising from the brain or spinal cord).</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>
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<tr>
<td></td>
<td>• Multidisciplinary approach.</td>
</tr>
</tbody>
</table>

**Limitations:**

Keystone First benefits may exclude services as not medically necessary if there is insufficient evidence.

Note: The following CPT/HCPCS codes are not listed in the Pennsylvania Medicaid fee schedule:

- 64550 - Application of surface transcutaneous neurostimulator
- 64553 - Percutaneous implantation of neurostimulator electrode array; cranial nerve
- 64565 - Percutaneous implantation of neurostimulator electrode array, neuromuscular
- 64566 - Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
- 64580 - Incision of implantation of neurostimulator for electrode array, neuromuscular
- +90785 - Interactive complexity
- +90833 - Psychotherapy, 30 minutes with the patient and/or family member when performed with an evaluation and management service.
- +90836 - Psychotherapy, 45 minutes with the patient and/or family member when performed with an evaluation and management service
- +90838 - Psychotherapy, 60 minutes with the patient and/or family member when performed with an evaluation and management service
Background

An Institute of Medicine (IOM) report called “Pain in America” noted acute and chronic pain is a public health problem impacting at least 100 million American adults (IOM, 2015). The costs to society and government are approximately $600 billion and $100 billion annually, respectively. 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 abuse. 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 (2015), pain care must be tailored to each person’s experience. Financing, referrals, 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

Keystone First 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 22, 2016. Search terms were: "Pain Management/organization and administration"[Mesh], "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 Keystone First 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.

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], 2011; Appendix F).
- Assessment and management of chronic pain guidelines (Hooten, 2013; Appendix G).
- Biopsychosocial approach to chronic pain (Gatchel, 2007; Appendix H).

**Glossary**

**Chronic pain** — Pain that persists for at least six months, is greater or beyond the expected healing time, or is not associated with ongoing tissue damage. Chronic pain may also be marked by frequent recurrence.

**Neuropathic pain** — Chronic pain that is initiated by nervous system lesions or dysfunction, and can be maintained by a number of different mechanisms (From Nicholson, 2006).

**Nociceptive pain** — Nociceptive pain results from activity in neural pathways secondary to actual tissue damage or potentially tissue-damaging stimuli (From Nicholson, 2006).

**Somatosensory disorder** — A disorder in which the individual feels real pain sensation with no evidence of pathology. The individual is not malingering, but the pain distribution may not meet anatomic expectations. Also termed Somatization Syndrome.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**Clinical trials:**

Searched clinicaltrials.gov on April 22, 2016 using terms open studies | chronic pain | United States. 228 studies found.

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


**Local Coverage Determinations (LCDs):**


**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>Comment</th>
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</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>
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<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>
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<tr>
<td>64569</td>
<td>Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connecting to existing pulse generator</td>
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<tr>
<td>64570</td>
<td>Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</td>
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<tr>
<td>64575</td>
<td>Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)</td>
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<tr>
<td>64580</td>
<td>Incision of implantation of neurostimulator electrode array; peripheral nerve</td>
<td></td>
</tr>
<tr>
<td>64581</td>
<td>Incision for implantation of neurostimulator for electrode array, sacral nerve (transforaminal placement)</td>
<td></td>
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<tr>
<td>64585</td>
<td>Revision or removal of peripheral neuromuscular electrode array</td>
<td></td>
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<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>
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<tr>
<td>90832</td>
<td>Psychotherapy, 30 minutes with the patient and/or family member</td>
<td></td>
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<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>
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<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>
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<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>
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<tr>
<td>CPT Code</td>
<td>Description</td>
<td>Comment</td>
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<td>-----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
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<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,</td>
<td>behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with patient; initial assessment</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</td>
<td>(unattended)</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>97032</td>
<td>Application of a modality to 1 or more areas; electrical stimulation</td>
<td>(manual), each 15 minutes</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</td>
<td>exercises to develop strength and endurance, range of motion and flexibility</td>
</tr>
<tr>
<td>97112</td>
<td>Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular</td>
<td>reeducation of movement, balance, coordination, kinesthetic sense, posture and/or proprioception for sitting and/or standing activities</td>
</tr>
<tr>
<td>97113</td>
<td>Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy</td>
<td>with therapeutic exercises</td>
</tr>
<tr>
<td>97116</td>
<td>Therapeutic procedure, 1 or more areas, each 15 minutes; gait training</td>
<td>(includes stair climbing)</td>
</tr>
<tr>
<td>97124</td>
<td>Therapeutic procedure, 1 or more areas, each 15 minutes; massage including</td>
<td>effleurage, petrissage and/or tapotement (stroking, compression, percussion)</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</td>
<td>drainage, manual traction) one or more areas; each 15 minutes</td>
</tr>
<tr>
<td>97150</td>
<td>Therapeutic procedure(s), group (2 or more individuals)</td>
<td></td>
</tr>
<tr>
<td>CPT Code</td>
<td>Description</td>
<td>Comment</td>
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<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>
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<tr>
<td>97545</td>
<td>Work hardening/conditioning; initial 2 hours</td>
<td></td>
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<tr>
<td>+97546</td>
<td>Each additional hour</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
<td>G89.2</td>
<td>Chronic Pain</td>
<td></td>
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<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>G43.43-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>I11.0</td>
<td>Hypertensive disease with heart failure</td>
<td></td>
</tr>
<tr>
<td>I11.9</td>
<td>Hypertensive disease without heart failure</td>
<td></td>
</tr>
<tr>
<td>I50.1-I50.9</td>
<td>Congestive Heart Failure</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>
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<tr>
<td>Multiple diagnosis codes</td>
<td>Personal history of injury</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
<td>N/A</td>
<td></td>
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</tbody>
</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: Were the appropriate stakeholders involved in the development of the guideline? Was the</td>
<td>□</td>
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<td>□</td>
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<tr>
<td>Item</td>
<td>Strongly Disagree (1)</td>
<td>Disagree (2)</td>
<td>Disagree Slightly (3)</td>
<td>Neither Agree nor Disagree (4)</td>
<td>Agree Slightly (5)</td>
<td>Agree (6)</td>
<td>Strongly Agree (7)</td>
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<tr>
<td>2. Rate the overall quality of the guideline presentation.</td>
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<tr>
<td>Consider: <em>Was the guideline well organized? Were the recommendations easy to find?</em></td>
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<td>3. Rate the completeness of reporting.</td>
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<tr>
<td>Consider: <em>Was the guideline development process transparent and reproducible? How complete was the information to inform decision making?</em></td>
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<td>4. Rate the overall quality of the guideline recommendations.</td>
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<tr>
<td>Consider: <em>Are the recommendations clinically sound? Are the recommendations appropriate for the intended patients?</em></td>
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<td>5. Rate the overall quality of the guideline.</td>
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</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.
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)

Conduct assessment to include pain and its effects on function and quality of life. Rule out need for further surgery (spinal surgery review).

Consider role of pharmacological adjustments / Spinal interventions (e.g., RF Denervation / Transforaminal epidural steroid injection) / Encourage and support self-management.

Significant psychological and behavioural issues: Consider assessment for PMP and/or Psychology counseling sessions to prepare for PMP / Neuromodulation.

Minimal improvement & severe pain, disability and distress. MDT Assessment for PMP / Neuromodulation.

Suitable for PMP and satisfactory outcome following PMP.

Good outcome following PMP/No need for PMP. But, patient still in severe pain and warrants further treatment.

Predominant neuropathic back/leg pain.

Predominant neuropathic back pain.

Trial of conventional SCS.

Unsuccessful SCS trial.

Successful trial.

Permanent implantation.

Consider Intrathecal trial, rigorous assessment following trial and implantation of ITDDS if suitable.

Long-term follow-up, Re-program as needed. Outcome data collection.

May need battery replacement or other hardware related trouble shooting or regular pump refills.

On-going support from GP / Pain clinic / Neuromodulation clinic.

Appendix C. Joint clinical practice guideline for low back pain (used with permission of the American College of Physicians) (Chou, 2007)

From: Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society
doi:10.7326/0003-4819-147-7-200710020-00006
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. CRP = C-reactive protein; EMG = electromyography; ESR = erythrocyte sedimentation rate; MRI = magnetic resonance imaging; NCV = nerve conduction velocity.
From: Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society
doi:10.7326/0003-4819-147-7-200710020-00006
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
  o A — Gabapentin (titrated up to at least 1,200 mg daily) should be considered for the treatment of patients with neuropathic pain.

• Pregabalin
  o 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.
  o A — Pregabalin (titrated up to at least 300 mg daily) is recommended for the treatment of patients with fibromyalgia.
  o 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
  o B — Carbamazepine should be considered for the treatment of patients with neuropathic pain. Potential risks of adverse events should be discussed.

**Antidepressants**

• Tricyclic antidepressants
  o A — Tricyclic antidepressants should not be used for the management of pain in patients with chronic low back pain.
  o 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
  o 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.
  o A — Duloxetine (60 mg/day) should be considered for the treatment of patients with fibromyalgia or osteoarthritis.

• Selective serotonin reuptake inhibitor
  o 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 gabapentinoind (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
  - C — Brief education should be given to patients with chronic pain to help patients continue to work.

*Behavioral therapies*

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

4.) **Physical therapies**

*Manual therapy*

- Low back pain
  - B — Manual therapy should be considered for short-term relief of pain for patients with chronic low back pain.
- Neck pain
  - 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:
  - B — Supervised exercise sessions.
  - B — Individualized exercises in group settings.
  - C — Addition of supplementary material.
  - 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.
Appendix F. Managing chronic pain in adults with, or in recovery from, substance use disorders (SAMHSA, 2011)

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 analgesics 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. Assessment and management of chronic pain (Hooten, 2013)

Assessment of pain

- Initial diagnosis should seek to identify biological mechanism of pain; ICSI identifies neuropathic, muscle, inflammatory and mechanical/compressive pain.
- Categories of pain are non-exclusive.
- Include specialty care if required.

Management of pain

- Employ function goals.
- Pharmacologic management:
  - Employ NSAIDs for inflammatory/non-neuropathic pain.
  - Identify goals and treat specific pain sources.
  - Recognize that medication is not the only focus of pain management and is a tool working in conjunction with other tools.
  - Frequent pharmacologic treatment includes NSAIDS, non-opioid analgesics, opioids, other antidepressants (including tricyclic), anticonvulsant drugs, topical agents, muscle relaxants/antispasmodics, anxiolytics and insomnia drugs.
- Intervention management seeks to identify neural or musculoskeletal causes of pain.
Complementary management includes the use of alternative treatments including acupuncture and herbal products.

Appendix H. 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.