

RULE 17, EXHIBIT 7

**Complex Regional Pain Syndrome/
Reflex Sympathetic Dystrophy
Medical Treatment Guidelines**

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DIVISION OF WORKERS' COMPENSATION**



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DEPARTMENT OF LABOR AND EMPLOYMENT

Division of Workers' Compensation

CCR 1101-3

RULE 17, EXHIBIT 7

COMPLEX REGIONAL PAIN SYNDROME/REFLEX SYMPATHETIC DYSTROPHY MEDICAL TREATMENT GUIDELINES

A. INTRODUCTION

This document has been prepared by the Colorado Department of Labor and Employment, Division of Workers' Compensation (Division) and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Colorado's Workers' Compensation Act as injured workers with Complex Regional Pain Syndrome (CRPS), formerly known as Reflex Sympathetic Dystrophy (RSD).

Although the primary purpose of this document is advisory and educational, these guidelines are enforceable under the Workers' Compensation Rules of Procedure, 7 CCR 1101-3. The Division recognizes that acceptable medical practice may include deviations from these guidelines, as individual cases dictate. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care.

To properly utilize this document, the reader should not skip nor overlook any sections.

B. GENERAL GUIDELINE PRINCIPLES

The principles summarized in this section are key to the intended implementation of all Division of Workers' Compensation guidelines and critical to the reader's application of the guidelines in this document.

1. **APPLICATION OF GUIDELINES** The Division provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer and patient through the Workers' Compensation Rules of Procedure. In lieu of more costly litigation, parties may wish to seek administrative dispute resolution services through the Division or the office of administrative courts.
2. **EDUCATION** of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of chronic pain injuries and disability. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring information to the patient. More in-depth education currently exists within a treatment regime employing functional restorative and innovative programs of prevention and rehabilitation. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.
3. **TREATMENT PARAMETER DURATION** Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document.
4. **ACTIVE INTERVENTIONS** emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.
5. **ACTIVE THERAPEUTIC EXERCISE PROGRAM** goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.
6. **POSITIVE PATIENT RESPONSE** Positive results are defined primarily as functional gains that can be objectively measured. Objective functional gains include, but are not limited to: positional tolerances, range-of-motion, strength, endurance, activities of daily living, ability to function at work, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.
7. **RE-EVALUATION OF TREATMENT EVERY 3 TO 4 WEEKS** If a given treatment or modality is not producing positive results within 3 to 4 weeks, the treatment should be either modified or discontinued. Reconsideration of

diagnosis should also occur in the event of poor response to a seemingly rational intervention.

8. **SURGICAL INTERVENTIONS** Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of “cure” with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.
9. **SIX-MONTH TIME FRAME** The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than six months. The emphasis within these guidelines is to move patients along a continuum of care and return-to-work within a six-month time frame, whenever possible. It is important to note that time frames may be less pertinent for injuries that do not involve work-time loss or are not occupationally related.
10. **RETURN-TO-WORK** is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific written physical limitations and the patient should never be released to “sedentary” or “light duty.” The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, overhead work, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated.

The practitioner should consider all of the physical demands of the patient’s job position before returning the patient to full duty and should request clarification of the patient’s job duties. Clarification should be obtained from the employer or if necessary, including, but not limited to: a healthcare professional with experience in ergonomics, an occupational health nurse, occupational therapist, vocational rehabilitation specialist, or an industrial hygienist.

11. **DELAYED RECOVERY** By definition, patients with complex regional pain syndrome will fit into the category of delayed recovery. All of these patients should have a psychological or psychiatric evaluation, if not previously provided as well as interdisciplinary rehabilitation or vocational goal setting. It is essential to address all barriers to recovery which might include issues related to psychosocial, personality, employment, litigation, and compensation. The Division recognizes that 3 to 10% of all industrially injured patients will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatments beyond the limits discussed within this document, but such treatment will require clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.
12. **GUIDELINE RECOMMENDATIONS AND INCLUSION OF MEDICAL EVIDENCE** Guidelines are recommendations based on available evidence and/or consensus recommendations. When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. When interpreting medical evidence statements in the guideline, the following apply:

Consensus means the opinion of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as “generally well accepted,” “generally accepted,” “acceptable,” or “well-established.”

“Some” means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective.

“Good” means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective.

“Strong” means the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment.

All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, regardless of the level of evidence attached to it. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as “not recommended.”

13. **TREATMENT OF PRE-EXISTING CONDITIONS** that preexisted the work injury/disease will need to be managed under two circumstances: (a) A preexisting condition exacerbated by a work injury/disease should be treated until the patient has returned to their objectively verified prior level of functioning or MMI; and (b) A preexisting condition not directly caused by a work injury/disease but which may prevent recovery from that injury should be treated until its objectively verified negative impact has been controlled. The focus of treatment should remain on the work injury/disease.

The remainder of this document should be interpreted within the parameters of these guideline principles that may lead to more optimal medical and functional outcomes for injured workers.

C. INTRODUCTION TO COMPLEX REGIONAL PAIN SYNDROME

Complex Regional Pain Syndrome (CRPS Types I and II) describes painful syndromes, which were formerly referred to as Reflex Sympathetic Dystrophy (RSD) and causalgia. CRPS conditions usually follow injury that appears regionally and have a distal predominance of abnormal findings, exceeding the expected clinical course of the inciting event in both magnitude and duration and often resulting in significant impairment of limb function.

CRPS-I (RSD) is a syndrome that usually develops after an initiating noxious event, is not limited to the distribution of a single peripheral nerve, and appears to be disproportionate to the inciting event. It is associated at some point with evidence of edema, changes in skin, blood flow, abnormal sudomotor activity in the region of the pain, allodynia or hyperalgesia. The site is usually in the distal aspect of an affected extremity or with a distal to proximal gradient. The peripheral nervous system and possibly the central nervous system are involved.

CRPS-II (Causalgia) is the presence of burning pain, allodynia, and hyperpathia usually in the hand or foot after partial injury to a nerve or one of its major branches. Pain is within the distribution of the damaged nerve but not generally confined to a single nerve.

Historically, three stages Stage 1- Acute (Hyperemic); Stage 2- Dystrophic (Ischemic); and Stage 3 (Atrophic) were thought to occur, However, the Stages in CRPS-I are not absolute and in fact, may not all be observed in any single patient. Signs and symptoms fluctuate over time and are reflective of ongoing dynamic changes in both the peripheral and central nervous systems.

More recent descriptors of CRPS have used the terms 'warm' denoting cases with initial increased temperature and edema and 'cool' denoting cases with the affected limb having a cooler temperature and less often demonstrating edema.

D. DEFINITIONS

1. **AFTER SENSATION** – Refers to the abnormal persistence of a sensory perception, provoked by a stimulus even though the stimulus has ceased.
2. **ALLODYNIA** – Pain due to a non-noxious stimulus that does not normally provoke pain.

Mechanical Allodynia – Refers to the abnormal perception of pain from usually non-painful mechanical stimulation.

Static Mechanical Allodynia – Refers to pain obtained by applying a single stimulus such as light pressure to a defined area.

Dynamic Mechanical Allodynia – Obtained by moving the stimulus such as a brush or cotton tip across the abnormal hypersensitive area.

Thermal Allodynia – Refers to the abnormal sensation of pain from usually non-painful thermal stimulation such as cold or warmth.
3. **CENTRAL PAIN** – Pain initiated or caused by a primary lesion or dysfunction in the central nervous system (CNS).
4. **CENTRAL SENSITIZATION** The experience of pain evoked by the excitation of non-nociceptive neurons or of nerve fibers that normally relay non-painful sensations to the spinal cord. This results when non-nociceptive afferent neurons act on a sensitized central nervous system (CNS). Experimental data suggest that pathways normally carrying pain signals themselves become overstimulated and/or fail to respond to inhibitory influences causing increased pain. An example is 'wind-up' which occurs when cells in the dorsal horn of the spinal cord increase their rate of action potential discharge in response to repeated stimulation by nociceptors.
5. **DYSTONIA** – State of abnormal (hypo or hyper) tonicity in any of the tissues.
6. **HYPERALGESIA** – Refers to an exaggerated pain response from a usually painful stimulation.
7. **HYPEREMIA** – Presence of increased blood in a part or organ.
8. **HYPERESTHESIA** (Positive Sensory Phenomenon) – Includes allodynia, hyperalgesia, and hyperpathia. Elicited by light touch, pin-prick, cold, warm vibration, joint position sensation or two-point discrimination, which is perceived as increased or more.
9. **HYPERPATHIA**: a condition of altered perception such that stimuli which would normally be innocuous, if repeated or prolonged, result in severe explosive persistent pain.
10. **HYPOESTHESIA** – (also hypesthesia), diminished sensitivity to stimulation.
11. **PAIN BEHAVIOR** – The nonverbal actions (such as grimacing, groaning, limping, using visible pain relieving or support devices and requisition of pain medications, among others) that are outward manifestations of pain, and through which a person may communicate that pain is being experienced.

12. **SUDOMOTOR CHANGES** – Alteration in function of sweat glands; sweat output may increase or decrease due to changes in autonomic input to the gland.
13. **SYMPATHETICALLY MAINTAINED PAIN (SMP)** – A pain that is maintained by sympathetic efferent innervations or by circulating catecholamines and which may be a separate condition from CRPS.
14. **TROPHIC CHANGES** – Tissue alterations due to interruption of nerve or blood supply; may include changes in hair growth and texture of skin.
15. **VASOMOTOR CHANGES** – Alteration in regulation of dilation or constriction of blood vessels.

E. INITIAL EVALUATION

The Division recommends the following diagnostic procedures be considered, at least initially, the responsibility of the workers' compensation carrier to ensure that an accurate diagnosis and treatment plan can be established. Standard procedures that should be utilized when initially diagnosing a work-related chronic pain complaint are listed below. Because CRPS-I is commonly associated with other injuries, it is essential that all related diagnoses are defined and treated. These disturbances are typically restricted to one extremity, usually distally, but are variable in their expression.

1. **HISTORY TAKING AND PHYSICAL EXAMINATION (Hx & PE)** are generally accepted, well-established and widely used procedures that establish the foundation/basis for and dictates subsequent stages of diagnostic and therapeutic procedures. When findings of clinical evaluations and those of other diagnostic procedures are not complementing each other, the objective clinical findings should have preference. Before the diagnosis of CRPS-I or CRPS-II is established, an experienced practitioner must perform a detailed neurological and musculoskeletal exam to exclude other potentially treatable pain generators or neurological lesions. The medical records should reasonably document the following:

- a. **Medical History:** As in other fields of medicine, a thorough patient history is an important part of the evaluation of pain. In taking such a history, factors influencing a patients' current status can be made clear and taken into account when planning diagnostic evaluation and treatment. One efficient manner in which to obtain historical information is by using a questionnaire. The questionnaire may be sent to the patient prior to the initial visit or administered at the time of the office visit. History should ascertain the following elements:
 - i. General Information – General items requested are name, sex, age, birth date, etc.
 - ii. Level of Education – The level of patients' education may influence response to treatment.
 - iii. Work History/Occupation – To include both impact of injury on job duties and impact on ability to perform job duties, work history, job description, mechanical requirements of the job, duration of employment, and job satisfaction.
 - iv. Current employment status.
 - v. Marital status.
 - vi. Family Environment – Is the patient living in a nuclear family or with friends? Is there or were there, any family members with chronic illness or pain problems? Responses to such questions reveal the nature of the support system or the possibility of conditioning toward chronicity.
 - vii. Ethnic Origin – Ethnicity of the patient, including any existing language barriers, may influence the patient's perception of and

response to pain. Literature indicates that providers may under-treat patients of certain ethnic backgrounds due to underestimation of their pain.

- viii. Belief System – Patients should be asked about their value systems, including spiritual and cultural beliefs, in order to determine how these may influence the patient's and family's response to illness and treatment recommendations.
- ix. Activities of Daily Living – Pain has a multidimensional effect on the patient that is reflected in changes in usual daily vocational, social, recreational, and sexual activities.
- x. Past and present psychological problems.
- xi. History of abuse – Physical, emotional, sexual.
- xii. History of disability in the family.
- xiii. Sleep disturbances.
- xiv. Causality: How did this injury occur? Was the problem initiated by a work-related injury or exposure?
- xv. Presenting symptoms related to CRPS:
 - A) Severe, generally unremitting burning and/or aching pain and/or allodynia.
 - B) Swelling of the involved area.
 - C) Changes in skin color.
 - D) Asymmetry in nail and/or hair growth.
 - E) Abnormal sweat patterns of the involved extremity.
 - F) Motor dysfunction- limited active range-of-motion, atrophy, tremors, dystonia, weakness.
 - G) Subjective temperature changes of the affected area.

b. Pain History: Characterization of the patient's pain and of the patient's response to pain is one of the key elements in treatment.

- i. Site of Pain – localization and distribution of the pain help determine the type of pain the patient has (i.e., central versus peripheral).
- ii. Pain Diagram drawing to document the distribution of pain.
- iii. Visual Analog Scale (VAS) including a discussion of the range of pain during the day and how activities, use of modalities, and other actions affect the intensity of pain.

- iv. Duration.
- v. Circumstances during which the pain began (e.g. an accident, an illness, a stressful incident or spontaneous onset).
- vi. Pain characteristics – such as burning, shooting, stabbing, aching). Time of pain occurrence as well as intensity, quality and radiation give clues to the diagnosis and potential treatment. quality of pain can be helpful in identifying neuropathic pain which is normally present most of the day, at night and is described as burning.
- vii. Response of pain to activity. List of activities which aggravate or exacerbate, ameliorate, or have no effect on the level of pain.
- viii. Associated Symptoms – Does the patient have numbness or paresthesia, dysesthesia, weakness, bowel or bladder dysfunction, decreased temperature, increased sweating, cyanosis or edema? Is there local tenderness, allodynia, hyperesthesia or hyperalgesia?

c. Medical Management History:

- i. History of diagnostic tests and results including but not limited to any response to sympathetic nerve blocks, results of general laboratory studies, EMG and nerve conduction studies, radiological examinations, including triple phase bone scan or thermography with autonomic stress testing, and tests of sudomotor functioning such as QSART.
- ii. Prior Treatment - Chronological review of medical records including previous medical evaluations and response to treatment interventions. In other words, what has been tried and what has been helpful?
- iii. Prior Surgery – If the patient has had prior surgery specifically for the pain, he/she may be less likely to have a positive outcome.
- iv. History of and current use of medications, including over-the-counter and herbal/dietary supplements to determine drug usage (or abuse) interactions and efficacy of treatment. Drug allergies and other side effects experienced with previous or current medication therapy and adherence to currently prescribed medications should be documented. Ideally, this includes dosing schedules as reported by the patient or patient representative. Information should be checked against the Colorado Prescription Drug Monitoring Program, offered by the Colorado Pharmacy Board.
- v. Review of Systems Check List – Determine if there is any interaction between the pain complaint and other medical conditions.
- vi. Psychosocial Functioning – Determine if any of the following are present: current symptoms of depression or anxiety; evidence of

stressors in the workplace or at home; and past history of psychological problems or other confounding psychosocial issues may be present, such as the presence of psychiatric disease. Due to the high incidence of co-morbid problems in populations that develop chronic pain, it is recommended that patients diagnosed with CRPS be referred for a full psychosocial evaluation. All patients with CRPS have chronic pain and are likely to suffer psychosocial consequences.

vii. Pre-existing Conditions – Treatment of these conditions is appropriate when the preexisting condition affects recovery from chronic pain.

viii. Family history pertaining to similar disorders

d. Substance Use/Abuse:

i. Alcohol use.

ii. Smoking history and use of nicotine replacements.

iii. History of current and prior prescription and/or illicit drug use and abuse.

iv. The use of caffeine or caffeine-containing beverages.

v. Substance abuse information may be only fully obtainable from multiple sources over time. Patient self reports may be unreliable. Patient self reports should always be checked against medical records.

e. Other Factors Affecting Treatment Outcome:

i. Compensation/Disability/Litigation.

ii. Treatment Expectations – What does the patient expect from treatment: complete relief of pain or reduction to a more tolerable level?

f. Physical Examination: should include examination techniques applicable to those portions of the body in which the patient is experiencing subjective symptomatology and should include:

i. Inspection – Changes in appearance of the involved area, to include trophic changes, changes in hair and nail growth, muscular atrophy, changes in skin turgor, swelling and color changes.

ii. Temperature Evaluation – Palpable temperature changes may not be detectable in early disease stages, and the examiner will generally only be able to appreciate significant temperature variations. Objective testing is preferred to demonstrate temperature asymmetries. Temperature differences of 1°C may be significant; however, these differences also occur commonly with other pain conditions.

- iii. Edema - is an important finding in CRPS. Its presence should be described in detail by the physician and when possible verified with objective testing such as volumetric testing or bilateral circumference measurements, usually performed by therapists.
- iv. Motor Evaluation – Involuntary movements, dystonia, muscle weakness, atrophy, or limited range of active motion in the involved limb(s).
- v. Sensory Evaluation – A detailed sensory examination is crucial in evaluating a patient with chronic pain complaints, including the presence of allodynia and the anatomic pattern of any associated sensory abnormalities to light touch, deep touch, pain and thermal stimulation. Quantitative sensory testing may be useful.
- vi. Musculoskeletal Evaluation – Presence of associated myofascial problems, such as contractures, ROM or trigger points.
- vii. Evaluation of Nonphysiologic Findings – Determine the presence of the following: variabilities on formal exam including variable sensory exam; inconsistent tenderness, and/or swelling secondary to extrinsic sources. Inconsistencies between formal exam and observed abilities of range of motion, motor strength, gait and cognitive/emotional state; and/or observation of inconsistencies between pain behaviors, affect and verbal pain rating, and physical re-examination can provide useful information.

F. DIAGNOSTIC CRITERIA AND PROCEDURES

1. **DIAGNOSIS OF CRPS** Diagnosis of complex regional pain syndrome continues to be controversial. The clinical criteria used by the International Association for the Study of Pain is thought to be overly sensitive and unable to differentiate well between those patients with other pain complaints and those with actual complex regional pain syndrome (CRPS). In a recent study in which different diagnostic sets were reviewed using patient report and physician confirmed signs, the highest specificities were found for the signs of hyperesthesia, allodynia, temperature asymmetry, skin color asymmetry and edema. This pattern is predominant in the other studies reporting on similar assessed physical findings. Sudomotor/sweating limb differences and atrophic changes, including nail, hair and skin changes, occur in less than half of the clinical CRPS patients; in contrast, verified temperature asymmetry, edema, and decreased motor function are frequently cited as predictive.

Clinical criteria alone are not dependable nor necessarily reliable and require objective testing. One study of interrater reliability for diagnosing CRPS Type 1 showed poor reliability for assessment of temperature difference and color difference between the affected limbs. Two other studies compared physician's assessment with actual measured signs of CRPS Type 1. The first study advocated bedside use of infrared thermometer and volume measurements. The study found a volume difference between the hands of 30.4 cc and a dorsal hand temperature difference of at least 0.78 degrees C could be used to help establish the diagnosis. The study also noted frequent decreased mobility in the little finger. This study only included patients known to have CRPS, thus agreement between the objective measurements and the physicians' observations was good. The second study compared physicians' clinical assessments with measured objective results and found that the clinical establishment of temperature and volume asymmetry was inadequate. It also noted poor to moderate correspondence between patient reported severity of symptoms and the physicians' clinical judgment and actual measurements.

A separate study used skin surface temperature to differentiate between CRPS in patients after a fracture and control patients with other complaints following a fracture. This study also incorporated a control group of healthy patients without complaints. Notably there was significantly more asymmetry between the temperature findings in the CRPS group than in both the control groups, with and without complaints. However, the control group with complaints had greater temperature differences than the otherwise healthy group. The study concluded that the ability of skin surface temperatures under resting conditions to discriminate between CRPS patients and other patients is limited. Historically some authors have used 2°C as a limit for temperature differences and others have used lower cutoffs. This study also applied various temperature asymmetry cut offs and could identify no specific combination resulting in sufficient predictive power. However, negative predictive power was present at 84% for resting temperature asymmetry less than 0.7 degrees C. This would seem to suggest that it is unlikely a patient has CRPS if they do not have resting temperature asymmetry; however, resting temperature asymmetry differences may be due to a variety of reasons other than CRPS.

Several studies have assessed skin temperature changes in variable settings. In one study skin temperature measurements were recorded over 5-8 hours and the

instruments were able to compare the difference between the limbs with every day activities. Twenty-two patients with CRPS, 18 with limb pain of other origin and 22 of healthy controls were compared. Examining the asymmetry throughout the time period, a difference of 2° centigrade could differentiate CRPS from patients with other painful disease with specificity of 67%, and 79% versus healthy controls. It was noted many patients in all groups had a 2° difference between the limbs at one time or another, however the persistence of the difference and the asymmetry was important in the diagnosis. The difference between the limbs could occur in either direction, warmer or cooler than the unaffected side.

Thermographic imaging has been done in two studies using whole body warming and cooling. The initial study established the fact that in CRPS patients the temperature difference between hands increases significantly when the sympathetic system is provoked with whole body temperature changes. A separate more detailed study induced whole body warming and cooling and compared temperature and blood flow in three sets of patients, one with CRPS, one with patients of extremity pain of other origins and a third group of healthy volunteers. None of the participants were on medications affecting vascular functions. Three patterns of temperature change were noted for CRPS patients. In some patients with “warm” CRPS the temperature continually exceeded the temperature of the unaffected limb during the cooling and warming period. In others, where the affected limb was cooler than the unaffected limb, the affected limb may have remained cooler throughout the cooling and warming period. Finally, in a few patients there was an unusual crossover where initially the patient had a warm or cooler limb compared to the unaffected side and later the affected limb showed temperature differences in the opposite direction. All of these patterns demonstrate an autonomic asymmetry that was not found in healthy volunteers whose limbs temperatures adjust in a symmetrical manner. Thus, the asymmetry of limb temperature under stress appears to be the most important factor. In this study the temperature differences needed to exceed 2.2 degrees C to distinguish between the groups.

Another study reviewed skin temperature from thermography, thermoregulatory sweat tests (TST) and quantitative sudomotor axon reflex test (QSART), early and late in patients with clinically diagnosed CRPS. In this study the differences identified with TST persisted during later testing while QSART differences did not. Skin temperature was asymmetrical between the limbs early and late, although generally in opposite directions. This study describes the dynamic nature of CRPS.

These studies appear to confirm the fact that causing an objectively measured, sympathetically evoked response is likely to be more predictive of CRPS than merely resting temperature differences or resting sudomotor/sweating differences. Temperature testing at any one point in time is probably not sensitive and able to distinguish between patients with pain complaints and those with CRPS. Other review articles have made similar observations regarding the need for dynamic testing.

There is good evidence that CRPS is characterized by inhibition of sympathetic cutaneous responses on the affected side and by blunted sympathetic response to physiologic stimuli. Based on the relatively common finding of temperature discrepancy in non-CRPS patients with chronic pain, a stress test thermogram should be used. Unfortunately only two studies have been published in this area and neither used a blinded control for comparison. However, the physiology behind the stress thermography testing is convincing given the prior studies. In a

similar manner the QSART provides an autonomic stress that is measurable. Perhaps the main issue with the sudomotor test in isolation is that it appears some CRPS patients do not have an abnormal sweat test. To verify the diagnosis, all of these test results need to be compared to other test results, physical exam findings and symptoms.

Thermal quantitative sensory testing has been used to study neuropathic conditions and CRPS. Components of the test include identification of light touch, warmth, cold, and pain with pressure, cold or heat. The testing relies on patient response to various recordable levels of testing in these areas. Generally CRPS patients appear to demonstrate hypoalgesia in both the affected and unaffected limbs when compared to normals; hyperalgesia to thermal pain generators and hyperalgesia to blunt pressure. Findings on the specific TST test components differ according to the CRPS classification of warm or cold. There is also some overlap of findings with other neuropathic conditions. In addition patient response testing can be problematic in a medical legal setting, thus more objective tests are used for confirmation of CRPS. Routine clinical exam techniques should be used to evaluate the patient for hyper and hypoalgesia and allodynia.

Significant harm can be done to individuals by over-diagnosing CRPS and subjecting patients to the side effects and potential morbidity of multiple sympathetic blocks, invasive procedures or chronic medications, as well as psychological effects from the diagnosis. In order to safe guard against such harmful outcomes, patients should have objective testing to verify their diagnosis before such procedures are considered and/or are continued after the initial diagnosis. Several reviews on the subject have identified the need for more objective measurements. Therefore, individuals must have a confirmed diagnosis of CRPS to receive these procedures.

2. **DIAGNOSTIC COMPONENTS OF CLINICAL CRPS** Patients who meet the following criteria for clinical CRPS, consistent with the Budapest criteria may begin initial treatment with oral steroids and/or tricyclics, physical therapy, a diagnostic sympathetic block, and other treatments found in the chronic pain guidelines. Further invasive or complex treatment will require a confirmed diagnosis.

Patient must meet the criteria below.

- (1) Continuing pain, which is disproportionate to any inciting event
- (2) At least one symptom in *three of the four* following categories:
 - *Sensory*: reports of hyperesthesia and/or allodynia.
 - *Vasomotor*: reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry.
 - *Sudomotor/edema*: reports of edema and/or sweating changes and/or sweating asymmetry.
 - *Motor/trophic*: reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes

(hair, nail, skin).

(3) At least one sign at time of evaluation in *two or more* of the following categories:

- *Sensory*: evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch and/or deep somatic pressure and/or joint movement).
- *Vasomotor*: evidence of temperature asymmetry and/or skin color changes and/or asymmetry. Temperature asymmetry should ideally be established by infrared thermometer measurements showing at least a 1 degree Celsius difference between the affected and unaffected extremities.
- *Sudomotor/edema*: evidence of edema and/or sweating changes and/or sweating asymmetry. Upper extremity volumetrics may be performed by therapists that have been trained in the technique to assess edema.
- *Motor/trophic*: evidence of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin).

(4) No other diagnosis that better explains the signs and symptoms

3. **DIAGNOSTIC COMPONENTS OF CONFIRMED CRPS** - patients should have a confirmed diagnosis of CRPS to proceed to other treatment measures in this guideline.

Both CRPS I and II confirmed diagnoses require the same elements. CRPS II is distinguished from CRPS I by the history of a specific peripheral nerve injury as the inciting event.

Patient must meet the below criteria:

- a) A clinical diagnosis meeting the above criteria in 2, and
- b) At least 2 positive tests from the following categories of diagnostic tests:
 - i. Trophic tests
 - A) Comparative X-rays of both extremities including the distal phalanges.
 - B) Triple Phase Bone Scan.
 - iii. Vasomotor/Temperature test - Infrared Stress Thermography.
 - iv. Sudomotor test - Autonomic Test Battery with an emphasis on QSART.

v. Sensory/ Sympathetic nerve test - Sympathetic Blocks.

4. **SYMPATHETICALLY MAINTAINED PAIN (SMP)** Patients who do not qualify as confirmed CRPS may have SMP. Patients with SMP may use sympathetic blocks and active and passive therapy from this guideline. For all other treatment, refer to the Division's Chronic Pain Medical Treatment Guidelines. Characteristics of SMP are

- i. Patient complains of pain.
- ii. Usually does not have clinically detectable vasomotor or sudomotor signs, and
- iii. Has significant pain relief with sympathetic blocks.

5. **NOT CRPS OR SMP:** Criteria listed below. Refer to the Division Chronic Pain Medical Treatment Guidelines for treatment.

- i. Patient complains of pain.
- ii. May or may not have vasomotor or sudomotor signs.
- iii. No relief with sympathetic blocks, and
- iv. No more than one other diagnostic test procedure is positive.

6. **DIAGNOSTIC IMAGING** is a generally accepted diagnostic procedure for CRPS. Results must be interpreted within the context of a full medical evaluation.

a. **Plain Film Radiography:**

Description - A radiological finding in CRPS may be unilateral osteoporosis; however, osteoporosis may be absent in many cases. In CRPS-I, the osteoporosis may be rapid in progression. The disorder typically affects the distal part of an extremity such as a phalanges, hand or foot; however intermediate joints such as the knee or elbow may be involved. Contralateral x rays should be taken for comparison and should include the distal phalanges.

Results - The radiological appearance of osteoporosis has been characterized as spotty or patchy. Although CRPS-I may exist in the absence of osteoporosis, the diagnosis of CRPS-I cannot be made solely on the basis of radiographic appearance or the osteoporosis alone.

b. **Triple Phase Bone Scan:**

Description - Radionucleotide imaging scintigraphy employing radio-pharmaceutical technetium coupled to a phosphate complex has been used to help facilitate the diagnosis of CRPS-1. It was hoped that a three-phase radionucleotide study would be selective in the face of demineralization of the bone as seen in CRPS-I. However, there are many different types of conditions that can produce osteoporosis and a triple-phase bone scan does not distinguish between the causes of bone demineralization.

Results - Clinical information can be derived from each of the three phases of the bone scan following injection. In the early course of CRPS-I, there is an increased uptake seen during Phase 1. However, in the late course of the disease process, there can actually be a decreased uptake seen. In Phase 2, which reflects the soft tissue vascularity, an increased diffuse uptake may be appreciated during the early course of CRPS-I. During Phase 3, one will see a diffuse uptake of multiple bone involvement of the involved limb, reflecting the bone turnover secondary to osteoporosis. Negative bone scans may be found in up to 40 percent of patients clinically diagnosed with CRPS-I; however, when positive it may help to confirm the diagnosis of CRPS-I.

7. INJECTIONS – DIAGNOSTIC SYMPATHETIC

Description — Diagnostic sympathetic injections are generally accepted procedures to aid in the diagnosis of CRPS I & II and SMP. Sympathetic blocks lack specificity for CRPS I & II. Each diagnostic injection has inherent risk and risk versus benefit should always be evaluated when considering injection therapy. Since these procedures are invasive, less invasive or non-invasive procedures should be considered first. Selection of patients, choice of procedure, and localization of the level for injection should be determined by clinical information.

Special Considerations – Injections with local anesthetics of differing duration are required to confirm a diagnosis. In some cases, injections at multiple levels may be required to accurately diagnose pain. Refer to Section G. 5., Therapeutic Procedures, Non-Operative, Injections – Therapeutic, for information on specific injections.

Since fluoroscopic and/or CT guidance during procedures is recommended to document technique and needle placement, an experienced physician should perform the procedure. The physician should have experience in ongoing injection training workshops provided by organizations such as the International Spinal Intervention Society (ISIS). In addition, physicians should obtain fluoroscopy training and must also have the appropriate training in radiation safety, usually overseen by a radiation safety officer.

Complications – Complications may include transient neurapraxia, nerve injury, inadvertent spinal injection, infection, venous or arterial vertebral puncture, laryngeal paralysis, respiratory arrest, vasovagal effects, as well as permanent neurological damage.

Contraindications – Absolute contraindications of diagnostic injections include: (a) bacterial infection – systemic or localized to region of injection, (b) bleeding diatheses, (c) hematological conditions, and (d) possible pregnancy.

Relative Contraindications:

Relative Contraindications: Relative contraindications of these injections may include: (a) allergy to contrast or shellfish, (b) poorly controlled diabetes mellitus and/or hypertension.

Drugs affecting coagulation, such as aspirin, NSAIDs and other anti-platelets or anti-coagulants require restriction from use. Decisions

regarding the number of restricted days should be made in consultation with the prescribing physician and other knowledgeable experts.

Test Results – To confirm the accuracy of the block there should be a documented temperature difference between the affected and unaffected extremities of at least 1 degree Celsius. The interpretation of the test result is primarily based upon pain relief of 50 percent or greater and evidence of functional improvement, for at least the duration of the local anesthetic used. A pain diary should be obtained for any diagnostic block. The patient must have minimal sedation from opioids or other medication in order to be conscious and responsive during the procedure. The diagnostic significance of the test result should be evaluated in conjunction with clinical information and further information should be obtained from functional and physical reassessment performed by physical and/or occupational therapy the same day of the block.

Local anesthetics of different durations of action should be considered and could take the place of doing a "placebo" block (i.e. - procaine, lidocaine, bupivacaine). Pain relief should be at least 50 percent or greater for the duration of the local anesthetic accompanied by functional improvement. It should be noted that with CRPS-I it is not unusual for the relief to last longer than the duration of the local anesthetic. If a placebo block is done, the needle should not be placed down to the sympathetic chain nor should an injection of saline be done around the sympathetic chain. A "sham block" would be preferable to see if the patient is a placebo responder. Contact with the sympathetic nerves by a needle or pressure on the chain by saline can cause a temporary sympathetic block and give a false positive placebo test. Additionally, patients with definite CRPS-I can also be placebo responders. The fact that the patient responds positively to a placebo does not mean that he/she does not have CRPS-1. It merely means that the patient is a placebo responder. This increases the value of doing another confirmatory test.

- a. **Stellate Ganglion Block:** For diagnosis and treatment of sympathetic pain involving the face, head, neck, and upper extremities secondary to CRPS-I and II. This block is commonly used for differential diagnosis and is one of the treatments for CRPS-I pain involving the upper extremity. For diagnostic testing, use two blocks over a 3-14 day period. For a positive response, pain relief should be 50% or greater for the duration of the local anesthetic and pain relief should be associated with demonstrated functional improvement.
- b. **Lumbar Sympathetic Block:** Useful for diagnosis and treatment of pain of the pelvis and lower extremity secondary to CRPS-I and II. This block is commonly used for differential diagnosis and is the preferred treatment of sympathetic pain involving the lower extremity. For diagnostic testing, use two blocks over a 3-14 day period. For a positive response, pain relief should be 50% or greater for the duration of the local anesthetic and pain relief should be associated with demonstrated functional improvement.
- c. **Phentolamine Infusion Test:** are not recommended for diagnosis or treatment due to lack of effect on sudomotor testing, pain, regional blood flow or hyperalgesia.

8. **THERMOGRAPHY (INFRARED STRESS THERMOGRAPHY)**

Description –There is good evidence that CRPS is characterized by inhibition of sympathetic cutaneous responses on the affected side and by blunted sympathetic response to physiologic stimuli. Based on the relatively common finding of temperature discrepancy in non-CRPS patients with chronic pain, a stress test thermogram should be used. Infrared thermography may be useful for patients with suspected CRPS-I and II, and SMP. Thermography can distinguish abnormal thermal asymmetry of 1.0 degree Celsius which is not distinguishable upon physical examination. It may also be useful in cases of suspected small caliber fiber neuropathy and to evaluate patient response to sympatholytic interventions.

Special Considerations – The practitioner who supervises and interprets the thermographic evaluation shall follow recognized protocols and be board certified by one of the examining boards of the American Academy of Medical Infrared Imaging, American Academy of Thermology, or American Chiropractic College of Thermology, or have equivalent documented training.

Medications with anticholinergic activity (tricyclics, cyclobenzaprine, antiemetics, antipsychotics) may interfere with autonomic testing. The pre-testing protocol which includes cessation of specific medication therapy must be followed for accurate test results. Results of autonomic testing may be affected by peripheral polyneuropathy, radiculopathy or peripheral nerve injury, peripheral vascular disease, generalized autonomic failure, or by Shy-Drager syndrome.

Thermographic Tests – Functional autonomic stress testing may include the following methods:

- a. **Cold Water Stress Test (Cold Pressor Test):** Paroxysmal response in the affected upper extremity is strongly suggestive of vasomotor instability.
- b. **Warm Water Stress Test:** Paroxysmal response in the affected upper extremity is strongly suggestive of vasomotor instability.
- c. **Whole Body Thermal Stress:** Analysis of persistent non-dermal temperature anomalies in response to whole body thermal stress.

9. **AUTONOMIC TEST BATTERY**

Description – Resting skin temperature (RST), resting sweat output (RSO), and quantitative sudomotor axon reflex test (QSART) are a generally accepted test battery. There is good evidence that CRPS is characterized by inhibition of sympathetic cutaneous responses on the affected side and by blunted sympathetic response to physiologic stimuli. The tests can provide additional information regarding malfunction of the sympathetic system and the diagnosis of CRPS. Prior authorization is required. As with all diagnostic testing, the results must be interpreted in relationship to the patient's signs and symptoms.

Special Considerations - Medications with anticholinergic activity (tricyclics, cyclobenzaprine, antiemetics, anti-psychotics) may interfere with autonomic testing. Results of autonomic testing may be affected by peripheral polyneuropathy, radiculopathy or peripheral nerve injury, peripheral vascular disease, generalized autonomic failure, or by Shy-Drager syndrome.

Test Battery –These tests measure asymmetries in physiologic manifestations of autonomic activity between an affected limb and an unaffected contralateral limb. Skin temperature reflects vasomotor activity and sweat output measures sudomotor activity. The results of the three test components must be combined and scored. The battery of tests must include a measurement of each component (RST, RSO, and QSART).

- a. **Infrared Resting Skin Temperature (RST)**: Provides thermographic measurements between the affected and unaffected limb. Generally, a 1° Celsius difference is significant. Given the previous discussion regarding differences in resting temperature between the affected and unaffected limbs in non-CRPS patients, the temperature findings may need to be interpreted cautiously as they do not reflect a stress on the sympathetic system.
- b. **Resting Sweat Output (RSO)**: Measures an increase or reduction of 50 percent between the affected and unaffected limb.
- c. **Quantitative Sudomotor Axon Reflex Test (QSART)**: Measures the sweat output elicited by iontophoretic application of acetylcholine. An increase or reduction of 50 percent between the affected and unaffected limb is significant.

The results of these tests should be recorded separately as abnormal or within the normal range.

A further assessment can then be done by the clinician when this information is collaborated with clinical findings. However clinical analysis is separate from the strict interpretation of each of the above three tests.

10. **OTHER DIAGNOSTIC TESTS NOT SPECIFIC FOR CRPS**: The following tests and procedures are not used to establish the diagnosis of CRPS but may provide additional information. The following are listed in alphabetical order.

- a. **Electrodiagnostic Procedures**: Electromyography (EMG) and Nerve Conduction Studies (NCS) are generally accepted, well-established and widely used for localizing the source of the neurological symptoms and establishing the diagnosis of focal nerve entrapments, such as carpal tunnel syndrome or radiculopathy, which may contribute to or coexist with CRPS II (causalgia). Traditional electrodiagnosis includes nerve conduction studies, late responses, (F-Wave, H-reflex) and electromyographic assessment of muscles with needle electrode examination. As CRPS II occurs after partial injury to a nerve, the diagnosis of the initial nerve injury can be made by electrodiagnostic studies. The later development of sympathetically mediated symptomatology however, has no pathognomonic pattern of abnormality on EMG/NCS. When issues of diagnosis are in doubt, a referral or consultation with a physiatrist or neurologist trained in electrodiagnosis is appropriate.
- b. **Laboratory Tests**: The Division recommends the following diagnostic procedures be considered the responsibility of the workers' compensation carrier to ensure that an accurate diagnosis and treatment plan can be established.

Laboratory tests are generally accepted, well-established, and widely used procedures and can provide useful diagnostic and monitoring information. They may be used when there is suspicion of systemic illness, infection, neoplasia, or underlying rheumatologic disorder, connective tissue disorder, or based on history and/or physical examination. Tests include, but are not limited to:

- i. Complete Blood Count (CBC) with differential can detect infection, blood dyscrasias, and medication side effects.
 - ii. Erythrocyte sedimentation rate, rheumatoid factor, anti-nuclear antigen (ANA), human leukocyte antigen (HLA), and C-reactive protein can be used to detect evidence of a rheumatologic, infection, or connective tissue disorder, serum protein electrophoresis.
 - iii. Thyroid, glucose and other tests to detect endocrine disorders, (e.g. catecholamines, free and total testosterone levels, both of which may be deficient in chronic pain patients secondary to prolonged stress and/or chronic use of opioid analgesics).
 - iv. Serum calcium, phosphorous, uric acid, alkaline phosphatase, and acid phosphatase can detect metabolic bone disease.
 - v. Urinalysis for calcium, phosphorus, hydroxyproline, or hematuria.
 - vi. Liver and kidney function may be performed for baseline testing and monitoring of medications, and
 - vii. Toxicology screen. Serum and/or urine as appropriate and/or blood alcohol level if alcohol abuse is suspected.
- c. **Peripheral Blood Flow (Laser Doppler or Xenon Clearance Techniques)**: This is currently being evaluated as a diagnostic procedure in CRPS-I and is not recommended by the Division at this time.

11. **PERSONALITY/ PSYCHOLOGICAL/PSYCHOSOCIAL EVALUATION FOR PAIN MANAGEMENT**

Are generally accepted, well-established, and widely used diagnostic procedures not only with selected use in acute pain problems, but also with more widespread use in subacute, chronic pain and CRPS populations. Diagnostic evaluations should distinguish between conditions that are pre-existing, aggravated by the current injury or work related.

Psychosocial evaluations should determine if further psychosocial or behavioral interventions are indicated for patients diagnosed with CRPS. The interpretations of the evaluation should provide clinicians with a better understanding of the patient in his or her social environment, thus allowing for more effective rehabilitation. Psychosocial assessment requires consideration of variations in pain experience and expression resulting from affective, cognitive, motivational and coping processes, and other influences such as gender, age, race, ethnicity, national origin, religion, sexual orientation, disability, language, or socioeconomic status.

While there is some agreement about which psychological factors need to be assessed in patients with CRPS, a comprehensive psychological evaluation should attempt to identify both primary psychiatric risk factors or “red flags” (e.g. psychosis, active suicidality), as well as secondary risk factors or “yellow flags” (e.g. moderate depression, job dissatisfaction). Significant personality disorders must be taken into account when considering a patient for spinal cord stimulation and other major procedures.

Psychometric testing is a valuable component of a consultation to assist the physician in making a more effective treatment plan. There is good evidence that can have significant ability to predict medical treatment outcome. For example, one study found that psychometric testing exceeded the ability of discography to predict disability in patients with low back pain. Pre-procedure psychiatric/psychological evaluation must be done prior to diagnostic confirmatory testing for the procedure. Examples include discography for fusion, spinal cord stimulation, or intrathecal drug delivery systems and should not be done by a psychologist employed by the physician planning to perform the procedure.

In many instances, psychological testing has validity comparable to that of commonly used medical tests; for example, the correlation between high trait anger and blood pressure is equal to the correlation between reduced blood flow and the failure of a synthetic hemodialysis graft. Thus, psychometric testing may be of comparable validity to medical tests and may provide unique and useful information.

All patients who are diagnosed as having CRPS should be referred for a psychosocial evaluation, as well as concomitant interdisciplinary rehabilitation treatment. This referral should be performed in a way so as to not imply that the patient’s claims are invalid, or that the patient is malingering or mentally ill. Even in cases where no diagnosable mental condition is present, these evaluations can identify social, cultural, coping and other variables that may be influencing the patient’s recovery process and may be amenable to various treatments including behavioral therapy. As pain is understood to be a biopsychosocial phenomenon, these evaluations should be regarded as an integral part of the assessment of CRPS.

i. Qualifications:

- a) A psychologist with a PhD, PsyD, EdD credentials, or a physician with Psychiatric MD/DO credentials may perform the initial comprehensive evaluations. It is preferable that these professionals have experience in diagnosing and treating CRPS in injured workers.
- b) Psychometric tests should be administered by psychologists with a PhD, PsyD, or EdD, or health professionals working under the supervision of a doctorate level psychologist. Physicians with appropriate training may also administer such testing but interpretation of the tests should be done by properly credentialed mental health professionals.

ii. Clinical Evaluation:

Special note to health care providers: most providers are required to adhere to the federal regulations under the health insurance portability

and accountability act (HIPAA). Unlike general health insurers, workers compensation insurers are not required to adhere to HIPAA standards. Thus, providers should assume that sensitive information included in a report sent to the insurer could be forwarded to the employer. The Colorado statute provides a limited waiver of medical information regarding the work-related injury or disease to the extent necessary to resolve the claim. It is recommended that the health care provider either 1) obtain a full release from the patient regarding information that may go to the employer or 2) not include sensitive health information not directly related to the work related conditions in reports sent to the insurer.

All CRPS patients should have a clinical evaluation that addresses the following areas:

A) History of Injury – The history of the injury should be reported in the patient's words or using similar terminology. Caution must be exercised when using translators.

- Nature of injury.
- Psychosocial circumstances of the injury.
- Current symptomatic complaints.
- Extent of medical corroboration.
- Treatment received and results.
- Compliance with treatment.
- Coping strategies used, including perceived locus of control, catastrophizing, and risk aversion.
- Perception of medical system and employer.
- History of response to prescription medications.

B) Health History.

- Nature of injury.
- Medical history.
- Psychiatric history.
- History of alcohol or substance abuse.
- Activities of daily living.
- Previous injuries, including disability, impairment, and compensation.

C) Psychosocial History.

- Childhood history, including abuse/neglect.
- Educational history.
- Family history, including disability.
- Marital history and other significant adulthood activities and events.
- Legal history, including criminal and civil litigation.
- Employment history.
- Military duty- because post-traumatic stress disorder (PTSD) might be an unacceptable condition for many military personnel to acknowledge, it may be prudent to screen initially for signs of depression or anxiety – both of which may be present in PTSD.
- Signs of pre-injury psychological dysfunction.
- Current and past interpersonal relations, support, living situation.
- Financial history.

- D) Mental status exam including cognition, affect, mood, orientation, thinking, and perception. May include mini mental status exam or frontal assessment battery if appropriate.
- E) Assessment of any danger posed to self or others.
- F) Psychological test results, if performed.
- G) Current psychiatric diagnosis consistent with the standards of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders.
- H) Pre-existing psychiatric conditions. Treatment of these conditions is appropriate when the pre-existing condition affects recovery from CRPS.
- I) Causality (to address medically probable cause and effect, distinguishing pre-existing psychological symptoms, traits and vulnerabilities from current symptoms).
- J) Treatment recommendations with respect to specific goals, frequency, timeframes, and expected outcomes.

iii. **Tests of Psychological Functioning:** Psychometric testing is a valuable component of a consultation to assist the physician in making a more effective treatment plan. Psychometric testing is useful in the assessment of mental conditions, pain conditions, cognitive functioning,

treatment planning, vocational planning, and evaluation of treatment effectiveness. While there is no general agreement as to which psychometric tests should be specifically recommended for psychological evaluations of CRPS conditions, standardized tests are preferred over those which are not for assessing diagnosis.

In contrast, non-standardized tests can be useful for “ipsative” outcome assessment, where a test is administered more than once, and a patient’s current reports are compared with his or her own reports in the past.

It is appropriate for the mental health provider to use their discretion and administer selective psychometric tests within their expertise and within standards of care in the community. Use of screening psychometrics by non-mental health providers is encouraged but mental health provider consultation should always be utilized for CRPS patients in which invasive palliative pain procedures or chronic opiate treatment is being contemplated. Some of these tests are available in Spanish and other languages, and many are written at a 6th grade reading level. Examples of frequently used psychometric tests performed include, but not limited to the following:

i. Comprehensive Inventories for Medical Patients:

a) Battery for Health Improvement, 2nd Edition (BHI-2TM).

What it measures – Depression, anxiety and hostility; violent and suicidal ideation; borderline, dependency, chronic maladjustment, substance abuse, conflicts with work, family and physician, pain preoccupation, somatization, perception of functioning and others.

Benefits – When used as a part of a comprehensive evaluation, can contribute substantially to the understanding of psychosocial factors underlying pain reports, perceived disability and somatic preoccupation; as well as to design interventions. Serial administrations can track changes in a broad range of variables during the course of treatment, and assess outcome.

Characteristics – Standardized test normalized patients with chronic pain or injury and on community members, with reference groups for six other subcategories of injured patients.

b) MillonTM Behavioral Medical Diagnostic (MBMDTM):

What it measures – Updated version of the Millon Behavioral Health Inventory (MBHI). Provides information on coping styles (introverted, inhibited, dejected, cooperative, sociable, etc.), health habits (smoking, drinking, eating, etc.), psychiatric indications (anxiety, depression, etc.), stress moderators (illness apprehension vs. illness tolerance, etc.), treatment prognostics (interventional fragility vs. interventional

resilience, medication abuse vs. medication competence, etc.) and other factors.

Benefits – When used as a part of a comprehensive evaluation, can contribute substantially to the understanding of psychosocial factors affecting medical patients. Understanding risk factors and patient personality type can help to optimize treatment protocols for a particular patient.

Characteristics – Standardized test normalized on medical patients with various diseases, on obesity, and on chronic pain groups.

ii. Comprehensive Psychological Inventories:

These tests are designed for detecting various psychiatric syndromes, but in general are more prone to false positive findings when administered to medical patients.

- a) Millon™ Clinical Multiaxial Inventory™, 3rd Edition (MCMI-III™).

What it measures – Has scales based on DSM diagnostic criteria for affective, personality and psychotic disorders and somatization.

Benefits – When used as a part of a comprehensive evaluation, can screen for a broad range of DSM diagnoses.

Characteristics – Standardized test normalized on psychiatric patients.

- b) Minnesota Multiphasic Personality Inventory®, 2nd Edition (MMPI-2®).

What it measures – Original scale constructs, such as hysteria and psychesthesia are archaic but continue to be useful. Newer content scales include depression, anxiety, health concerns, bizarre mentation, social discomfort, low self-esteem, and almost 100 others.

Benefits – When used as a part of a comprehensive evaluation, measure a number of factors that have been associated with poor treatment outcome.

Characteristics – Standardized test normalized on community members.

- c) Minnesota Multiphasic Personality Inventory®, 2nd Edition Revised Form (MMPI-2®).

What it measures – 50 scales assess a wide range of psychiatric disorders and personality traits, plus 8 validity scales, critical items.

Benefits – new version of MMPI-2 has undergone extensive revision to correct perceived MMPI-2 deficiencies. Has advantages over the original MMPI-2 in psychiatric assessment, but may be less capable when assessing patients with chronic pain.

Characteristics – Standardized test normalized on community members, with multiple other reference groups.

d) Personality Assessment Inventory™ (PAI)

What it measures – A measure of general psychopathology that assesses depression, anxiety, somatic complaints, stress, alcohol and drug use reports, mania, paranoia, schizophrenia, borderline, antisocial, and suicidal ideation and more than 30 others.

Benefits – When used as a part of a comprehensive evaluation, can contribute substantially to the identification of a wide variety of risk factors that could potentially affect the medical patient.

Characteristics – Standardized test normalized on community members.

iii. Brief Multidimensional Screens for Medical Patients:

Treating providers, to assess a variety of psychological and medical conditions, including depression, pain, disability and others, may use brief instruments. These instruments may also be employed as repeated measures to track progress in treatment, or as one test in a more comprehensive evaluation. Brief instruments are valuable in that the test may be administered in the office setting and hand scored by the physician. Results of these tests should help providers distinguish which patients should be referred for a specific type of comprehensive evaluation.

a) Brief Battery for Health Improvement, 2nd Edition (BBHI-2™).

What it measures – Depression, anxiety, somatization, pain, function, and defensiveness.

Benefits – Can identify patients needing treatment for depression and anxiety, and identify patients prone to somatization, pain magnification and self-perception of disability. Can compare the level of factors above to other pain patients and community members. Serial

administrations can track changes in measured variables during the course of treatment, and assess outcome.

Characteristics – Standardized test normalized on patients with chronic pain or injury and on community members, with reference groups for six subcategories of injured patients.

b) Pain Patient Profile (P3®).

What it measures – Assesses depression, anxiety, and somatization.

Benefits – Can identify patients needing treatment for depression and anxiety, as well as identify patients prone to somatization. Can compare the level of depression, anxiety and somatization to other pain patients and community members. Serial administrations can track changes in measured variables during the course of treatment, and assess outcome.

Characteristics – Standardized test normalized on patients with chronic pain, and on community members.

c) Multidimensional Pain Inventory (MPI):

What it measures – Interference, support, pain severity, life-control, affective distress, response of significant other to pain, and self-perception of disability at home and work, and in social and other activities of daily living.

Benefits – Can identify patients with high levels of disability perceptions, affective distress, or those prone to pain magnification. Serial administrations can track changes in measured variables during the course of treatment, and assess outcome.

Characteristics – Partially standardized test, initially developed primarily with male military personnel, and later normalized on patients with chronic pain in the United States and Sweden.

d) SF-36®:

What it measures – A survey of general health, well-being and functional states.

Benefits – Assesses a broad spectrum of patient disability reports. Serial administrations could be used to track patient perceived functional changes during the course of treatment, and assess outcome.

Characteristics – Non-standardized test without norms.

e) Sickness Impact Profile© (SIP).

What it measures – Perceived disability in the areas of sleep, eating, home management, recreation, mobility, body care, social interaction, emotional behavior, and communication.

Benefits – Assesses a broad spectrum of patient disability reports. Serial administrations could be used to track patient perceived functional changes during the course of treatment, and assess outcome.

Characteristics – Non-standardized test without norms.

f) McGill Pain Questionnaire (MPQ):

What it measures – Cognitive, emotional and sensory aspects of pain.

Benefits – Can identify patients prone to pain magnification. Repeated administrations can track progress in treatment for pain.

Characteristics – Non-standardized test without norms.

g) McGill Pain Questionnaire – Short Form (MPQ-SF):

What it measures – Emotional and sensory aspects of pain.

Benefits – Can identify patients prone to pain magnification. Repeated administrations can track progress in treatment for pain.

Characteristics – Non-standardized test without norms.

h) Oswestry Disability Questionnaire (ODQ):

What it measures – Disability secondary to low back pain.

Benefits – Can measure patients' self-perceptions of disability. Serial administrations could be used to track changes in self-perceptions of functional ability during the course of treatment, and assess outcome.

Characteristics – Non-standardized test without norms.

i) Visual Analog Scales (VAS):

What it measures – Graphical measure of patient's pain report, where the patient makes a mark on a line to represent pain level.

Benefits – Quantifies the patients' pain report, most-commonly using a 10 centimeter horizontal line. Serial administrations could be used to track changes in pain

reports during the course of treatment and assess outcome.

Characteristics – Non-standardized test without norms. Some patients may have difficulty with this conceptual test format, depending on perceptual, visuomotor, cultural orientation or other factors.

j) Numerical Rating Scales (NRS):

What it measures – Numerical report of patients' pain.

Benefits – Quantifies the patients' pain report, typically on a 0-10 scale. Serial administrations could be used to track changes in pain reports during the course of treatment and assess outcome.

Characteristics – Recommended by JCAHO. Non-standardized test without norms. May be more easily understood than the VAS.

iv. Brief Multidimensional Screens for Psychiatric Patients:

These tests are designed for detecting various psychiatric syndromes, but in general are more prone to false positive findings when administered to medical patients.

a) Brief Symptom Inventory (BSI®).

What it measures - Somatization, obsessive-compulsive, depression, anxiety, phobic anxiety, hostility, paranoia, psychoticism, and interpersonal sensitivity.

Benefits - Can identify patients needing treatment for depression and anxiety, as well as identify patients prone to somatization. Can compare the level of depression, anxiety, and somatization to community members. Serial administrations could be used to track changes in measured variables during the course of treatment, and assess outcome.

Characteristics – standardized test normalized on community members

b) Brief Symptom Inventory – 18 (BSI-18):

What it Measures - Depression, anxiety, somatization.

Benefits - Can identify patients needing treatment for depression and anxiety, as well as identify patients prone to somatization. Can compare the level of depression, anxiety, and somatization to community members. Serial administrations could be used to track patient perceived functional changes during the course of treatment, and assess outcome.

Characteristics – standardized test normalized on patients with chronic pain associated with cancer

c) Symptom Check List 90 (SCL 90):

What it measures - Somatization, obsessive-compulsive, depression, anxiety, phobic anxiety, hostility, paranoia, psychoticism, and interpersonal sensitivity.

Benefits - Can identify patients needing treatment for depression and anxiety, as well as identify patients prone to somatization. Can compare the level of depression, anxiety and somatization to community members. Serial administrations could be used to track changes in measured variables during the course of treatment, and assess outcome.

Characteristics – standardized test normalized on community members

v. Brief Specialized Psychiatric Screening Measures:

a) Beck Depression Inventory® (BDI).

What it measures - Depression.

Benefits - Can identify patients needing referral for further assessment and treatment for depression and anxiety, as well as identify patients prone to somatization. Repeated administrations can track progress in treatment for depression, anxiety, and somatic preoccupation. Requires a professional evaluation to verify diagnosis.

Characteristics – standardized test without norms, uses cutoff scores.

b) Post Traumatic Stress Diagnostic Scale (PDS®).

What it Measures - Post Traumatic Stress Disorder (PTSD).

Benefits - Helps confirm suspected PTSD diagnosis. Repeated administrations can track treatment progress of PTSD patients.

Characteristics – standardized test normalized on community members.

c) Center of Epidemiologic Studies – Depression Questionnaire:

What it measures - Depression.

Benefits - Brief self-administered screening test.
Requires a professional evaluation to verify diagnosis.

Characteristics – non-standardized test without norms

- d) Brief Patient Health Questionnaire™ from PRIME - MD®

What it measures - Depression, panic disorder.

Benefits - Brief self-administered screening test.
Requires a professional evaluation to verify diagnosis.

Characteristics – non-standardized test without norms,
keyed to diagnostic criteria, uses cutoff scores.

- e) Zung Questionnaire:

What it measures - Depression.

Benefits - Brief self-administered screening test.
Requires a professional evaluation to verify diagnosis.

Characteristics – Non-standardized test without norms.

12. **SPECIAL TESTS** are generally well-accepted tests and are performed as part of a skilled assessment of the patients' capacity to return to work, his/her strength capacities, and/or physical work demand classifications and tolerance. The procedures in this subsection are listed in alphabetical order.

- a. **Computer-Enhanced Evaluations:** may include isotonic, isometric, isokinetic and/or isoinertial measurement of movement, range-of-motion, endurance or strength. Values obtained can include degrees of motion, torque forces, pressures, or resistance. Indications include determining validity of effort, effectiveness of treatment and demonstrated motivation. These evaluations should not be used alone to determine return to work restrictions.

❖ Frequency: One time for evaluation. Can monitor improvements in strength every 3 to 4 weeks up to a total of 6 evaluations.

- b. **Functional Capacity Evaluations (FCE):** is a comprehensive or modified evaluation of the various aspects of function as they relate to the worker's ability to return-to-work. Areas such as endurance, lifting (dynamic and static), postural tolerance, specific range-of-motion, coordination and strength, worker habits, employability and financial status, as well as psychosocial aspects of competitive employment may be evaluated. Components of this evaluation may include: (a) musculoskeletal screen; (b) cardiovascular profile/aerobic capacity; (c) coordination; (d) lift/carrying analysis; (e) job-specific activity tolerance; (f) maximum voluntary effort; (g) pain assessment/psychological screening; (h) non-material and material handling activities. Standardized national guidelines (such as

National Institute for Occupational Safety and Health (NIOSH) should be used as the basis for FCE recommendations.

When a FCE is being used to determine return to a specific jobsite, the provider is responsible for fully understanding the job duties. A jobsite evaluation is frequently necessary. FCEs cannot be used in isolation to determine work restrictions. The authorized treating physician must interpret the FCE in light of the individual patient's presentation and medical and personal perceptions. FCEs should not be used as the sole criteria to diagnose malingering.

Full FCEs are rarely necessary. In many cases, a work tolerance screening will identify the ability to perform the necessary job tasks.

- ❖ Frequency: Can be used: 1) initially to determine baseline status; and 2) for case closure when patient is unable to return to the pre-injury position and further information is desired to determine permanent work restrictions. Prior authorization is required for FCEs performed during treatment.

- c. **Jobsite Evaluation and Alterations:** is a comprehensive analysis of the physical, mental, and sensory components of a specific job. The goal of the jobsite evaluation is to identify any job modification needed to ensure the safety of the employee upon return to work. These components may include, but are not limited to: (a) postural tolerance (static and dynamic); (b) aerobic requirements; (c) range-of-motion; (d) torque/force; (e) lifting/carrying; (f) cognitive demands; (g) social interactions; (h) visual perceptual; (i) environmental requirements of a job; (j) repetitiveness; and (k) essential functions of a job; and (l) ergonomic set up. Job descriptions provided by the employer are helpful but should not be used as a substitute for direct observation.

Jobsite evaluation and alteration should include input from a health care professional with experience in ergonomics or a certified ergonomist; the employee, and the employer. The employee must be observed performing all job functions in order for the jobsite evaluation to be a valid representation of a typical workday.

A jobsite evaluation may include observation and instruction of how work is done, what material changes (desk, chair) should be made, and determination of readiness to return to work.

Requests for a jobsite evaluation should describe the expected goals for the evaluation. Goals may include, but are not limited to the following:

- i. To determine if there are potential contributing factors to the person's condition and/or for the physician to assess causality;
- ii. To make recommendations for, and to assess the potential for ergonomic changes;
- iii. To provide a detailed description of the physical and cognitive job requirements;

- iv. To assist the patient in their return to work by educating them on how they may be able to do their job more safely in a bio-mechanically appropriate manner;
- v. To give detailed work/activity restrictions.
 - ❖ Frequency: One time with additional visits as needed for follow-up per jobsite.
- d. **Vocational Assessment:** Once an authorized practitioner has reasonably determined and objectively documented that a patient will not be able to return to his/her former employment and can reasonably prognosticate final restrictions, implementation of a timely vocational assessment can be performed. The vocational assessment should provide valuable guidance in the determination of future rehabilitation program goals. It should clarify rehabilitation goals, which optimize both patient motivation and utilization of rehabilitation resources. If prognosis for return to former occupation is determined to be poor, except in the most extenuating circumstances, vocational assessment should be implemented within 3 to 12 months post-injury. Declaration of Maximum Medical Improvement (MMI) should not be delayed solely due to lack of attainment of a vocational assessment.
 - ❖ Frequency: One time with additional visits as needed for follow-up.
- e. **Work Tolerance Screening (Fitness for Duty):** is a determination of an individual's tolerance for performing a specific job based on a job activity or task. It may include a test or procedure to specifically identify and quantify work-relevant cardiovascular, physical fitness and postural tolerance. It may also address ergonomic issues affecting the patient's return-to-work potential. May be used when a full FCE is not indicated.
 - ❖ Frequency: One time for initial screen. May monitor improvements in strength every 3 to 4 weeks up to a total of 6 visits.

G. THERAPEUTIC PROCEDURES – NON-OPERATIVE

Non-operative therapeutic rehabilitation is applied to patients with Complex Regional Pain Syndrome (CRPS) or Sympathetically Mediated Pain (SMP) who experience chronic and complex problems of de-conditioning and functional disability. Treatment modalities may be utilized sequentially or concomitantly depending on chronicity and complexity of the problem, and treatment plans should always be based on a diagnosis utilizing appropriate diagnostic procedures.

Before initiation of any therapeutic procedure, the authorized treating physician, employer and insurer must consider these important issues in the care of the injured worker:

- a. Patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to Section G.12 Therapeutic Procedures, Non-operative, Return-to-Work for detailed information.
- b. Reassessment of the patient's status in terms of functional improvement should be documented after each treatment. If patients are not responding within the recommended time periods, alternative treatment interventions, further diagnostic studies or consultations should be pursued. Continued treatment should be monitored using objective measures such as:
 - Return to work or maintaining work status.
 - Fewer restrictions at work or performing activities of daily living (ADL).
 - Decrease in usage of medications related to the work injury, and
 - Measurable functional gains, such as increased range-of-motion or documented increase in strength.
- c. Clinicians should provide and document education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms.
- d. Psychological or psychosocial screening should be performed on all chronic pain patients.

The following procedures are listed in alphabetical order.

1. **ACUPUNCTURE** When acupuncture has been studied in randomized clinical trials, it is often compared with sham acupuncture and/or with no acupuncture (usual care). The differences between true acupuncture and usual care have been moderate, but clinically important. These differences can be partitioned into two components: nonspecific effects and specific effects. Nonspecific effects, such as patient beliefs and expectations, attention from the acupuncturist, administration of acupuncture in a relaxing setting, and other components of

what is often called the placebo effect. Specific effects refer to any additional effects which occur in the same setting of expectations and attention, but are attributable to the penetration of the skin in the specific, classic acupuncture points on the surface of the body by the needles themselves.

In most controlled studies the differences between the sham and the classic acupuncture, specific effects of classic acupuncture, have been small in relation to the nonspecific effects. However, the sham controlled studies have shown consistent advantages of both true and sham acupuncture over no acupuncture, when the studies have included a third comparison group which was randomized to usual medical care. Having this third comparison group has been advantageous in the interpretation of the nonspecific effects of acupuncture, since the third comparison group controls for some influences on study outcome including more frequent contact with providers, the natural history of the condition, regression to the mean, the effect of being observed in a clinical trial, and, if the follow-up observations are done consistently in all three treatment groups, for biased reporting of outcomes. Controlling for these factors enables researchers to more closely estimate the contextual and personal interactive effects of acupuncture as it is generally practiced.

Because the sham acupuncture interventions in the clinical trials are generally done by trained acupuncturists, and not by totally untrained personnel, the sham acupuncture interventions may include some of the effects of true acupuncture, much as a partial agonist of a drug may produce some of the effects of the actual drug. For example, a sham procedure involving toothpicks rather than acupuncture needles may stimulate cutaneous afferents in spite of not penetrating the skin, much as a neurological sensory examination may test nociceptor function without skin penetration. To the extent that afferent stimulation is part of the mechanism of action of acupuncture, interpreting the sham results as purely a control group would lead to an underestimation of the analgesic effects of acupuncture. Thus we consider in our analysis that “sham” or non-classic acupuncture may have a positive clinical effect when compared to usual care.

Clinical trials of acupuncture typically enroll participants who are interested in acupuncture, and may respond to some of the nonspecific aspects of the intervention more than would be expected of patients who have no interest in or desire for acupuncture. The nonspecific effects of acupuncture may not be produced in patients who have no wish to be referred for it.

There is good evidence that both acupuncture and sham acupuncture are superior to usual care without acupuncture for moderate short-term and mild long-term alleviation of low back pain, neck pain, and the pain of joint osteoarthritis. In these studies 5-15 treatments were provided. Comparisons of acupuncture and sham acupuncture have been inconsistent, and the advantage of true over sham acupuncture has been small in relation to the advantage of sham over no acupuncture.

Acupuncture is recommended for chronic pain patients who are trying to increase function and/or decrease medication usage and have an expressed interest in this modality. Acupuncture is not the same procedure as dry needling for coding purposes; however, some acupuncturists may use acupuncture treatment for myofascial trigger points. Dry needling is performed specifically for myofascial trigger points. Refer to Section F. 5. e. Therapeutic Procedures, Non-Operative, Trigger Point Injections and Dry Needling Treatment.

Credentialed practitioners, with experience in evaluation and treatment of chronic pain patients must perform acupuncture evaluations. The exact mode of action is only partially understood. Western medicine studies suggest that acupuncture stimulates the nervous system at the level of the brain, promotes deep relaxation, and affects the release of neurotransmitters. Acupuncture is commonly used as an alternative or in addition to traditional Western pharmaceuticals. It may be used when pain medication is reduced or not tolerated; as an adjunct to physical rehabilitation, surgical intervention; and/or as part of multidisciplinary treatment to hasten the return of functional activity. Acupuncture must be performed by practitioners with the appropriate credentials in accordance with state and other applicable regulations. Therefore, if not otherwise within their professional scope of practice and licensure, those performing acupuncture must have the appropriate credentials, such as L.A.c., R.A.c, or Dipl. Ac.

- a. **Acupuncture:** is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated, and retained for a period of time. Acupuncture has a variety of possible physiologic actions, but their relevance to the clinical response is speculative, for example, one crossover trial measured increased nitric oxide synthase activity in arms which had had acupuncture, increasing palmar blood flow, but this observation may have no bearing on actual analgesic effects.

Indications include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain.

- b. **Acupuncture with Electrical Stimulation:** is the use of electrical current (micro- amperage or milli-amperage) on the needles at the acupuncture site. It is used to increase effectiveness of the needles by continuous stimulation of the acupoint. Physiological effects (depending on location and settings) can include endorphin release for pain relief, reduction of inflammation, increased blood circulation, analgesia through interruption of pain stimulus, and muscle relaxation.

It is indicated to treat chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites.

- c. **Other Acupuncture Modalities:** Acupuncture treatment is based on individual patient needs and therefore treatment may include a combination of procedures to enhance treatment effect. Other procedures may include the use of heat, soft tissue manipulation/massage, and exercise. Refer to Sections F.13 and 14, Active Therapy (Therapeutic Exercise) and Passive Therapy sections (Massage and Superficial Heat and Cold Therapy) for a description of these adjunctive acupuncture modalities and time frames.

- d. **Total Time Frames For Acupuncture and Acupuncture with Electrical Stimulation:** Time frames are not meant to be applied to each of the above sections separately. The time frames are to be applied to all acupuncture treatments regardless of the type or combination of therapies being provided.

❖ Time to Produce Effect: 3 to 6 treatments.

- ❖ Frequency: 1 to 3 times per week.
- ❖ Optimum Duration: 1 to 2 months.
- ❖ Maximum Duration: 15 treatments.

Any of the above acupuncture treatments may extend longer if objective functional gains can be documented or when symptomatic benefits facilitate progression in the patient's treatment program. Treatment beyond 15 treatments must be documented with respect to need and ability to facilitate positive symptomatic and functional gains. Such care should be re-evaluated and documented with each series of treatments.

2. **BIOFEEDBACK** is a form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology, such as muscle activity, brain waves, and measures of autonomic nervous system activity. There is good evidence that biofeedback and cognitive behavioral therapy are equally effective in managing chronic pain. Stress-related psycho-physiological reactions may arise as a reaction to organic pain and in some cases may cause pain. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorily, or tactilely with coaching by a biofeedback specialist.

Indications for biofeedback include individuals who are suffering from musculoskeletal injury where muscle dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of pain, anxiety, panic, anger or emotional distress, opioid withdrawal, insomnia/sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often utilized for relaxation training. Mental health professionals may also utilize it as a component of psychotherapy, where biofeedback and other behavioral techniques are integrated with psychotherapeutic interventions. Biofeedback is often used in conjunction with physical therapy or medical treatment.

Recognized types of biofeedback include the following:

- a. **EMG/Electromyogram (EMG)**: Used for self-management of pain and stress reactions involving muscle tension.
- b. **Skin Temperature**: Used for self-management of pain and stress reactions, especially vascular headaches.
- c. **Respiration Feedback (RFB)**: Used for self-management of pain and stress reactions via breathing control.
- d. **Respiratory Sinus Arrhythmia (RSA)**: Used for self-management of pain and stress reactions via synchronous control of heart rate and respiration. Respiratory sinus arrhythmia is a benign phenomenon which consists of a small rise in heart rate during inhalation, and a corresponding decrease during exhalation. This phenomenon has been observed in meditators and athletes, and is thought to be a psycho-physiological indicator of health.
- e. **Heart Rate Variability (HRV)**: Used for self-management of stress via managing cardiac reactivity.

- f. **Electrodermal Response (EDR):** Used for self-management of stress involving palmar sweating or galvanic skin response.
- g. **Electroencephalograph (EEG, QEEG):** Used for self-management of various psychological states by controlling brainwaves.

The goal in biofeedback treatment is normalizing the physiology to the pre-injury status to the extent possible and involves transfer of learned skills to the workplace and daily life. Candidates for biofeedback therapy or training should be motivated to learn and practice biofeedback and self-regulation techniques. In the course of biofeedback treatment, patient stressors are discussed and self-management strategies are devised. If the patient has not been previously evaluated, a psychological evaluation should be performed prior to beginning biofeedback treatment for chronic pain. The psychological evaluation may reveal cognitive difficulties, belief system conflicts, somatic delusions, secondary gain issues, hypochondriasis, and possible biases in patient self-reports, which can affect biofeedback. Home practice of skills is often helpful for mastery and may be facilitated by the use of home training tapes.

Psychologists or psychiatrists, who provide psycho-physiological therapy which integrates biofeedback with psychotherapy, should be either Biofeedback Certification International Alliance (BCIA) certified or practicing within the scope of their training. All non-licensed health care providers of biofeedback for chronic pain patients must be BCIA certified and shall have their biofeedback treatment plan approved by the authorized treating psychologist or psychiatrist. Biofeedback treatment must be done in conjunction with the patient's psychosocial intervention. Biofeedback may also be provided by health care providers, who follow a set treatment and educational protocol. Such treatment may utilize standardized material or relaxation tapes.

- ❖ Time to Produce Effect: 3 to 4 sessions.
- ❖ Frequency: 1 to 2 times per week.
- ❖ Optimum Duration: 6 to 8 sessions.
- ❖ Maximum Duration: 10 to 12 sessions. Treatment beyond 12 sessions must be documented with respect to need, expectation, and ability to facilitate positive symptomatic and functional gains.

- 3. **COMPLEMENTARY ALTERNATIVE MEDICINE (CAM)** is a term used to describe a broad range of treatment modalities, a number of which are generally accepted and supported by some scientific literature, and others which still remain outside the generally accepted practice of conventional Western Medicine. In many of these approaches, there is attention given to the relationship between physical, emotional, and spiritual well-being. While CAM may be performed by a myriad of both licensed and non-licensed health practitioners with training in one or more forms of therapy, credentialed practitioners should be used when available or applicable.

Although CAM practices are diverse and too numerous to list, they can be generally classified into five domains:

- a. **Alternative Medical Systems:** These are defined as medical practices that have developed their own systems of theory, diagnosis and

treatment and have evolved independent of and usually prior to conventional Western Medicine. Some examples are Traditional Chinese Medicine, Ayurvedic Medicine, Homeopathy, and Naturopathy.

- b. **Mind-body Interventions:** These include practices such as hypnosis, meditation, bioenergetics, and prayer. Reflexology does not appear to relieve low back pain.
- c. **Biological-based Practices:** These include herbal and dietary therapy as well as the use of nutritional supplements. To avoid potential drug interactions, supplements should be used in consultation with the authorized treating physician.
- d. **Body-based Therapy:** Included in this category are the practices of Yoga and Rolfing bodywork.
- e. **Energy-based Practices:** Energy-based practices include a wide range of modalities that support physical as well as spiritual and/or emotional healing. Some of the more well-known energy practices include Qi Gong, Tai Chi, Healing Touch and Reiki. Practices such as Qi Gong and Tai Chi are taught to the patient and are based on exercises the patient can practice independently at home. Other energy-based practices such as Healing Touch and Reiki involve a practitioner/patient relationship and may provide some pain relief. Tai Chi may improve range of motion in those with rheumatoid arthritis.

Methods used to evaluate chronic pain patients for participation in CAM will differ with various approaches and with the training and experience of individual practitioners. A patient may be referred for CAM therapy when the patient's cultural background, religious beliefs, or personal concepts of health suggest that an unconventional medical approach might assist in the patient's recovery or when the physician's experience and clinical judgment support a CAM approach. The patient must demonstrate a high degree of motivation to return to work and improve their functional activity level while participating in therapy. Other more traditional conservative treatments should generally be attempted before referral to CAM. Treatment with CAM requires prior authorization.

- ❖ Time to Produce Effect: Functional treatment goals and number of treatments for time to produce effect should be set with the practitioner and the patient before the beginning of treatment.
- ❖ Frequency: Per CAM therapy selected.
- ❖ Optimum Duration: Should be based upon the physician's clinical judgment and demonstration by the patient of positive symptomatic and functional gains. Practitioner provided CAM therapy is not recommended on a maintenance basis.

- 4. **DISTURBANCES OF SLEEP** are common in chronic pain. Although primary insomnia may accompany pain as an independent co-morbid condition, it more commonly occurs secondary to the pain condition itself. Exacerbations of pain often are accompanied by exacerbations of insomnia; the reverse can also occur. Sleep laboratory studies have shown disturbances of sleep architecture in pain patients. Loss of deep slow-wave sleep and increase in light sleep occur and sleep efficiency, the proportion of time in bed spent asleep, is decreased. These

changes are associated with patient reports of non-restorative sleep. Sleep apnea may also occur as a primary diagnosis or be caused or exacerbated opioid and hypnotic use. This should be investigated diagnostically (refer to Section F. 7. g., Medications and Medical Management, Opioids).

Many chronic pain patients develop behavioral habits that exacerbate and maintain sleep disturbances. Excessive time in bed, irregular sleep routine, napping, low activity, and worrying in bed are all maladaptive responses that can arise in the absence of any psychopathology. Relaxation training such as progressive relaxation, biofeedback, mindfulness meditation, or imagery training and other forms of cognitive therapy can reduce dysfunctional beliefs and attitudes about sleep.

There is some evidence that behavioral modification, such as patient education and group or individual counseling with cognitive behavioral therapy can be effective in reversing the effects of insomnia. Cognitive and behavioral interventions should be undertaken before prescribing medication solely for insomnia. Behavioral modifications are easily implemented and can include:

- a. Maintaining a regular sleep schedule, retiring and rising at approximately the same time on weekdays and weekends.
- b. Limiting naps to 30 minutes twice per day or less.
- c. Avoiding caffeinated beverages after lunchtime.
- d. Making the bedroom quiet and comfortable, eliminating disruptive lights, sounds, television sets, pets, and keeping a bedroom temperature of about 65 degrees Fahrenheit.
- e. Avoiding alcohol or nicotine within two hours of bedtime.
- f. Avoiding large meals within two hours of bedtime.
- g. Exercising vigorously during the day, but not within two hours of bedtime, since this may raise core temperature and activate the nervous system.
- h. Associating the bed with sleep and sexual activity only, using other parts of the home for television, reading and talking on the telephone.
- i. Leaving the bedroom when unable to sleep for more than 20 minutes, returning to the bedroom when ready to sleep again.
- j. Reducing time in bed to estimated typical sleeping time.
- k. Arising at a regular time each day, regardless of the number of hours slept.
- l. Engaging in relaxing activities until drowsy.

Behavioral modifications should be trialed before the use of hypnotics. Reinforcing these behaviors may also decrease hypnotic use and overall medication costs. There is some evidence that group cognitive behavioral therapy reduces the severity and daytime consequences of insomnia for at least six months. Melatonin or ramelteon a longer acting melatonin agonist may be preferred by some patients and is a reasonable

alternative to sedative hypnotics. There is some evidence that ramelteon, while producing a small amount of reduction in sleep latency, does not appreciably increase total sleep time or daytime function.

5. **INJECTIONS — THERAPEUTIC** When considering the use of injections in CRPS management, the treating physician must carefully consider the inherent risks and benefits. First, it is understood that these injections are seldom meant to be “curative” and when used for therapeutic purposes they are employed in conjunction with other treatment modalities for maximum benefit.

Second, education of the patient should include the proposed goals of the injections, expected gains, risks or complications, and alternative treatment.

Lastly, reassessment of the patient’s status in terms of functional improvement should be documented after each injection and/or series of injections. Any continued use of injections should be monitored using objective measures such as:

- a. Return to work or maintaining work status.
- b. Fewer restrictions at work or when performing activities of daily living (ADL).
- c. Decrease in usage of medications related to the work injury.
- d. Measurable functional gains, such as increased range-of-motion or documented increase in strength.

Visual analog scales (VAS) provide important subjective data but cannot be used to measure function.

The physician must be aware of the possible placebo effect as well as the long-term effects of injections related to the patient’s physical and mental status. Strict adherence to contraindications, both absolute and relative, may prevent potential complications. Subjecting the patient to potential risks, (i.e., needle trauma, infection, nerve injury, or systemic effects of local anesthetics and corticosteroids), must be considered before the patient consents to such procedures.

a. **Sympathetic Injections:**

Description – Sympathetic injections are generally accepted, well-established procedures. They include stellate ganglion blocks and lumbar sympathetic blocks. Unfortunately, there are no high quality randomized controlled trials in this area. It is recommended that all patients receiving therapeutic blocks participate in an appropriate exercise program that may include a functionally directed rehabilitation program.

Indications – Greater than 50% pain relief and demonstrated functional improvement from previous diagnostic or therapeutic blocks. Range of motion or increased strength are examples of objective gains that can be documented for most CRPS patients.

Special Considerations – Except for Bier blocks, fluoroscopic and/or CT guidance during procedures is recommended to document technique and needle placement; an experienced physician should perform the procedure. The physician should participate in ongoing injection training workshops provided by organizations such as the International Spine Intervention Society (ISIS). Physicians should obtain fluoroscopy training and must also have the appropriate training in radiation safety, usually overseen by a radiation safety officer.

Complications – Complications may include transient neurapraxia, nerve injury, inadvertent spinal injection, infection, venous or arterial vertebral puncture, laryngeal paralysis, respiratory arrest, vasovagal effects, as well as permanent neurologic damage.

Contraindications – Absolute contraindications of therapeutic injections include: (a) bacterial infection – systemic or localized to region of injection, (b) bleeding diatheses, (c) hematological conditions, and (d) possible pregnancy.

Relative Contraindications: Relative contraindications of these injections may include: (a) allergy to contrast or shellfish, (b) poorly controlled diabetes mellitus and/or hypertension.

Drugs affecting coagulation, such as aspirin, NSAIDs and other anti-platelets or anti-coagulants require restriction from use. Decisions regarding the number of restricted days should be made in consultation with the prescribing physician and other knowledgeable experts.

Treatment Parameters – To be effective as a treatment modality, the patient should be making measurable progress in their rehabilitation program and should be achieving an increasing or sustained duration of relief between blocks. If appropriate outcomes are not achieved, changes in treatment should be undertaken.

- ❖ Time to Produce Effect: 1 to 2 blocks. Demonstrated greater than 50% pain relief and objective/functional gains as noted under treatment parameters.
- ❖ Frequency: Variable, depending upon duration of pain relief and functional gains. During the first two weeks of treatment, blocks may be provided every 3 to 5 days, based on patient response meeting above criteria. The blocks must be combined with active therapy. After the first two weeks, blocks may be given weekly with tapering for a maximum of 7 -10.
- ❖ Optimum Duration: 10 over a period of 6 months with documentation of progressive functional gain verified by therapist or increased work capability after each injection.
- ❖ Maximum: If sympathetic and functional benefits are documented with the blocks refer to Section I. 12, Maintenance Management, for information on further blocks.

- b. **Trigger Point Injections:** May be appropriate when myofascial trigger points are present on examination. They are generally not

recommended for CRPS as it is a neuropathic syndrome. Refer to the Division's Chronic Pain Medical Treatment Guidelines for treatment parameters.

- c. **Peripheral Nerve Blocks:** May be appropriate when peripheral nerve pathology is identified as in CRPS II or for some patients with extremity CRPS I. Refer to the Divisions' Chronic Pain Medical Treatment Guidelines, Initial Evaluation and Diagnostic Procedures (Section E. 5. b) for treatment parameters.
 - d. **Other Intravenous Medications and Regional Blocks:** One inadequately powered study found that IV guanethidine blocks are ineffective and a review of lower level literature reveals no advantage for other regional blocks. In addition regional blocks given by the Bier block method have the potential of aggravating CRPS due to the constriction of the extremity required for the procedure. Another inadequately powered study found no advantage from Bier blocks of lidocaine and methylprednisolone. It is unlikely that either type of block provides a significant clinical advantage to the patient, therefore they are not recommended. Intravenous blocks with reserpine, droperidol and atropine are also not recommended due to lack of effect in small studies. A small, inadequately powered study seemed to show a 3 month benefit for bretyllium Bier block. IV phentolamine has not been adequately studied. The above treatments are not generally recommended, however in cases where repeat sympathetic blocks are contraindicated or ineffective, Bier blocks (usually alpha sympathetic blocking agent with lidocaine) may be useful when the patient has peripheral findings (CRPS II), and demonstrates functional gains. The number of blocks should not exceed those done for sympathetic blocks and active therapy must be done at the same time.
 - e. **Continuous Brachial Plexus Infusions:** are not recommended due to possible complications of bleeding, infection, pneumothoracic, phrenic nerve paralysis, lack of literature documenting effectiveness and cost.
 - f. **Epidural Infusions:** These are not recommended. Literature on long-term infusions with clonidine is not adequate to support their long term benefit. There is some evidence of a high rate of infection [33%], which can include meningitis.
 - g. **Ketamine** is referenced in this guideline in Section G., Therapeutic Procedures, Non-Operative, CRPS-Specific Medications.
6. **INTERDISCIPLINARY REHABILITATION PROGRAMS** are the gold standard of treatment for individuals with chronic pain who have not responded to less intensive modes of treatment. In addition, there are current studies to support the use of pain programs. There is good evidence that interdisciplinary programs which include screening for psychological issues, identification of fear-avoidance beliefs and treatment barriers, and establishment of individual functional and work goals, will improve function and decrease disability. These programs should assess the impact of pain and suffering on the patient's medical, physical, psychological, social, and/or vocational functioning. In general, interdisciplinary programs evaluate and treat multiple and sometimes irreversible conditions, including but not limited to painful musculoskeletal, neurological, and other chronic painful disorders and psychological issues, drug dependence, abuse or addiction, high levels of stress and anxiety, failed surgery; and pre-existing or latent psychopathology. The number of professions involved in the team in a chronic pain

program may vary due to the complexity of the needs of the person served. The Division recommends consideration of referral to an interdisciplinary program within 6 months post-injury in patients with delayed recovery unless successful surgical interventions or other medical and/or psychological treatments complications intervene.

Chronic pain patients need to be treated as outpatients within a continuum of treatment intensity. Outpatient chronic pain programs are available with services provided by a coordinated interdisciplinary team within the same facility (formal) or as coordinated among practices by the authorized treating physician (informal). Formal programs are able to provide coordinated, high intensity level of services and are recommended for most chronic pain patients who have received multiple therapies during acute management.

Patients with addiction problems or high dose opioid or other drugs of abuse use may require inpatient and/or outpatient chemical dependency treatment programs before or in conjunction with other interdisciplinary rehabilitation. Guidelines from the American Society of Addiction Medicine are available and may be consulted relating to the intensity of services required for different classes of patients in order to achieve successful treatment.

Informal interdisciplinary pain programs may be considered for patients who are currently employed, those who cannot attend all day programs, those with language barriers, or those living in areas not offering formal programs. Before treatment has been initiated, the patient, physician, and insurer should agree on treatment approach, methods, and goals. Generally the type of outpatient program needed will depend on the degree of impact the pain has had on the patient's medical, physical, psychological, social and/or vocational functioning.

When referring a patient for formal outpatient interdisciplinary pain rehabilitation, an occupational rehabilitation or an opioid treatment program, the Division recommends the program meets the criteria of the Commission on Accreditation of Rehabilitation Facilities (CARF).

Inpatient pain rehabilitation programs are rarely needed but may be necessary for patients with any of the following conditions: (a) High risk for medical instability; (b) Moderate-to-severe impairment of physical/functional status; (c) Moderate-to-severe pain behaviors; (d) Moderate impairment of cognitive and/or emotional status; (e) Dependence on medications from which he or she needs to be withdrawn; and (f) the need for 24-hour supervised nursing.

Whether formal or informal programs, they should be comprised of the following dimensions:

- a. Communication: To ensure positive functional outcomes, communication between the patient, insurer and all professionals involved must be coordinated and consistent. Any exchange of information must be provided to all professionals, including the patient. Care decisions should be communicated to all and should include the family or other support system.
- b. Documentation: Through documentation by all professionals involved and/or discussions with the patient, it should be clear that functional goals are being actively pursued and measured on a regular basis to determine their achievement or need for modification.

- c. **Treatment Modalities:** Use of modalities may be necessary early in the process to facilitate compliance with and tolerance to therapeutic exercise, physical conditioning, and increasing functional activities. Active treatments should be emphasized over passive treatments. Active treatments should encourage self-coping skills and management of pain, which can be continued independently at home or at work. Treatments that can foster a sense of dependency by the patient on the caregiver should be avoided. Treatment length should be decided based upon observed functional improvement. For a complete list of active and passive therapies, refer to Sections F. 13 and 14, Therapeutic Procedures, Non-Operative. All treatment timeframes may be extended based upon the patient's positive functional improvement.
- d. **Therapeutic Exercise Programs:** A therapeutic exercise program should be initiated at the start of any treatment rehabilitation. Such programs should emphasize education, independence, and the importance of an on-going exercise regime. There is good evidence that exercise alone or part of a multi-disciplinary program results in decreased disability for workers with non-acute low back pain. There is no sufficient evidence to support the recommendation of any particular exercise regimen over any other exercise regimen.
- e. **Return-to-Work:** The authorized treating physician should continually evaluate the patient for their potential to return to work. When return-to-work is an option, it may be appropriate to implement a Work Hardening Program (as described in Section F. 12, Therapeutic Procedures, Non-Operative). For patients currently employed, efforts should be aimed at keeping them employed. Formal rehabilitation programs should provide assistance in creating work profiles. For more specific information regarding return-to-work, refer to the Return-to-work section in this guideline.
- f. **Patient Education:** Patients with pain need to re-establish a healthy balance in lifestyle. All providers should educate patients on how to overcome barriers to resuming daily activity, including pain management, decreased energy levels, financial constraints, decreased physical ability, and change in family dynamics.
- g. **Psychosocial Evaluation and Treatment:** Psychosocial evaluation should be initiated, if not previously done. Providers of care should have a thorough understanding of the patient's personality profile; especially if dependency issues are involved. Psychosocial treatment may enhance the patient's ability to participate in pain treatment rehabilitation, manage stress, and increase their problem-solving and self-management skills.
- h. **Vocational Assistance:** Vocational assistance can define future employment opportunities or assist patients in obtaining future employment. Refer to Return-to-work section for detailed information.

Interdisciplinary programs are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of the treatment program. These programs are for patients with greater levels of perceived disability, dysfunction, de-conditioning and psychological involvement. Programs should have sufficient personnel to work with the individual in the following areas: behavior, functional,

medical, cognitive, pain management, psychological, social and vocational.

The following programs are listed in alphabetical order.

a. Formal Interdisciplinary Rehabilitation Programs:

Interdisciplinary Pain Rehabilitation: An Interdisciplinary Pain Rehabilitation Program provides outcomes-focused, coordinated, goal-oriented interdisciplinary team services to measure and improve the functioning of persons with pain and encourage their appropriate use of health care system and services. The program can benefit persons who have limitations that interfere with their physical, psychological, social, and/or vocational functioning. The program shares information about the scope of the services and the outcomes achieved with patients, authorized providers, and insurers.

The interdisciplinary team maintains consistent integration and communication to ensure that all interdisciplinary team members are aware of the plan of care for the patient, are exchanging information, and implement the plan of care. The team members make interdisciplinary team decisions with the patient and then ensure that decisions are communicated to the entire care team.

The Medical Director of the pain program should ideally be board certified in pain management, or be board certified in his or her specialty area and have completed a one year fellowship in interdisciplinary pain medicine or palliative care recognized by a national board, or have two years experience in an interdisciplinary pain rehabilitation program. Individuals who assist in the accomplishment of functional, physical, psychological, social and vocational goal must include: a medical director, pain team physician(s), and pain team psychologist. Other disciplines on the team may include, but are not limited to: Biofeedback Therapist, Occupational Therapist, Physical Therapist, Registered Nurse, case manager, exercise physiologist, psychologist, psychiatrist, and/or nutritionist.

- ❖ Time to Produce Effect: 3 to 4 weeks.
- ❖ Frequency: Full-time programs - no less than 5 hours/day; part-time programs - 5 days/week and for part-time programs- 4 hours/day for 2-3 days per week.
- ❖ Optimum Duration: 3 to 12 weeks at least 2-3 times a week. With follow up visits weekly or every other week during the first one to two months after the initial program is completed.
- ❖ Maximum duration: 4 months for full time programs and up to 6 months for part-time programs. Periodic review and monitoring thereafter for one year, additional follow up based upon the documented maintenance of functional gains.

- ii. Occupational Rehabilitation is an interdisciplinary program addressing a patient's employability and return-to-work. It includes a progressive increase in the number of hours per day that a patient completes work simulation tasks until the patient can tolerate a full workday. A full workday is case specific and is defined by the previous employment of the patient. Safe work place practices and education of the employer and social support system regarding the person's status should be included. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return-to-work.

There is some evidence that an integrated care program, consisting of workplace interventions and graded activity teaching that pain need not limit activity, is effective in returning patients with chronic low back pain to work, even with minimal reported reduction of pain.

The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation, team physicians having experience in occupational rehabilitation, occupational therapy and physical therapy.

As appropriate, the team may also include: chiropractor, RN, case manager, psychologist and vocational specialist or certified biofeedback therapist.

- ❖ Time to Produce Effect: 2 weeks.
- ❖ Frequency: 2 to 5 visits per week, up to 8 hours/day.
- ❖ Optimum Duration: 2 to 4 weeks.
- ❖ Maximum Duration: 6 weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic and functional gains.

- b. **Informal Interdisciplinary Rehabilitation Program:** A coordinated interdisciplinary pain rehabilitation program is one in which the authorized treating physician coordinates all aspects of care. This type of program is similar to the formal programs in that it is goal oriented and provides interdisciplinary rehabilitation services to manage the needs of the patient in the following areas: (a) functional, (b) medical, (c) physical, (d) psychological, (e) social, and (f) vocational.

This program is different from a formal program in that it involves lower frequency and intensity of services/treatment. Informal rehabilitation is geared toward those patients who do not need the intensity of service offered in a formal program or who cannot attend an all-day program due to employment, daycare, language or other barriers.

Patients should be referred to professionals experienced in outpatient treatment of chronic pain. The Division recommends the authorized treating physician consult with physicians experienced in the treatment of chronic pain to develop the plan of care. Communication among care providers regarding clear objective goals and progress toward the goals is essential. Employers should be involved in return to work and work restrictions and the family/social support system

should be included in the treatment plan. Other disciplines likely to be involved include biofeedback therapist, occupational therapist, physical therapist, registered nurse, psychologist, case manager, exercise physiologist, psychiatrist, and/or nutritionist.

- ❖ Time to Produce Effect: 3 to 4 weeks.
- ❖ Frequency: Full-time programs - no less than 5 hours/day; part-time programs - 5 days/week and for part-time programs- 4 hours/day for 2-3 days per week.
- ❖ Optimum Duration: 3 to 12 weeks at least 2-3 times a week. With follow up visits weekly or every other week during the first one to two months after the initial program is completed.
- ❖ Maximum duration: 4 months for full time programs and up to 6 months for part-time programs. Periodic review and monitoring thereafter for one year, additional follow up based upon the documented maintenance of functional gains.

c. Opioid/Chemical Treatment Programs:

Chemical dependency, which for worker compensation issues will usually be related to opioids, anxiolytics, or hypnotics as prescribed for the original workers compensation injury, should be treated with specific programs providing medical and psychological assessment, treatment planning and individual as well group counseling and education.

They may be inpatient or outpatient programs, depending upon the level of intensity of services required. Formal treatment programs are appropriate for patients who have more intense (e.g. use extraordinarily excessive doses of prescription drugs to which they have developed tolerance) or multiple drug abuse issues (e.g. benzodiazepines and/or alcohol) and those with complex medical conditions or psychiatric issues drug misuse. A medical physician with appropriate training preferably board certified in addiction medicine, should provide the initial evaluation and oversee the program. Full primary assessment should include behavioral health assessment; medical history; physical examination, mental status; current level of functioning; employment history; legal history; history of abuse, violence, and risk taking behavior; education level; use of alcohol, tobacco and other drugs; and social support system.

Addiction counselors, and other trained health care providers as needed, are involved in the program. Peer and group support is an integral part of the program and families are encouraged to attend. There should be good communication between the program and other external services, external health care providers, Alanon, AA and pain medicine providers. Drug screening is performed as appropriate for the individual, minimally initially and at least weekly during the initial detoxification and intensive initial treatment.

Clear withdrawal procedures are delineated for voluntary, against medical advice, and involuntary withdrawal. Withdrawal programs must have a clear treatment plan and include description of symptoms of medical and emotional distress, significant signs of opioid withdrawal, and actions taken. All programs should have clear direction on how to deal with violence in order to assure safety for all participants. Transition and discharge should be carefully planned with full

communication to outside resources. Duration of inpatient programs are usually 4 weeks while outpatient programs may take 12 weeks.

Drug detoxification may be performed on an outpatient or inpatient basis. Detoxification is unlikely to succeed in isolation when not followed by prolonged chemical dependency treatment. Isolated detoxification is usually doomed to failure with very high recidivism rates.

Neither ultra-rapid nor rapid-detoxification are recommended due to possible respiratory depression and death and the lack of evidence for long range treatment success.

Abstinence models are preferred by most chemical dependency treatment programs but are problematic for those chronic pain patients who may require the continued use of opioid analgesics. Methadone, buprenorphine, or buprenorphine/naloxone are usually the first line agents for treating such patients; however, continued use in an outpatient setting of methadone for opioid dependency requires dispensing by a licensed methadone clinic and buprenorphine, for the same purpose, by a physician possessing a special DEA license. As of the time of this guideline writing, some formulations of buprenorphine/naloxone have been FDA approved for the treatment of opioid dependence. It is strongly recommended that the use of either drug for the purpose of treating chronic pain be limited to physicians with additional training. In the case of methadone, there are increasing numbers of inadvertent deaths due to misuse, including prescribing errors. In the case of buprenorphine, its use as an analgesic is not currently FDA approved and conversion to this drug from other opioids is difficult. It should never be a first-line analgesic for chronic pain due to high cost and the presence of other opioids that may be more effective for moderate-to-severe chronic pain.

Tapering opioids on an outpatient basis requires a highly motivated patient and diligent treatment team and may be accomplished by decreasing the current dose 10% per day or per week. Tapering should be accompanied by addiction counseling. Failing a trial of tapering a patient should be sent to a formal addiction program. When the dose has reached 1/3 of the original dose, the taper should proceed at half or less of the initial rate. Doses should be held or possibly increased if severe withdrawal symptoms, pain, or reduced treatment failure otherwise occurs. This method is tedious, time consuming and more likely to fail than more rapid and formalized treatment programs.

- ❖ Time to Produce Effect: 3 to 4 weeks.
- ❖ Frequency: No less than 5 hours/day; 5 days/week for full time programs and 4 hours/day for 2-3 days per week for part time programs.
- ❖ Optimum Duration: 3 to 12 weeks at least 2-3 times a week. With follow up visits weekly or every other week during the first one to two months after the initial program is completed.
- ❖ Maximum duration: 4 months for full time programs and up to 6 months for part-time programs. Periodic review and monitoring thereafter for one year, additional follow up based upon the documented maintenance of functional gains.

7. **MEDICATIONS AND MEDICAL MANAGEMENT** There is no single formula for pharmacological treatment of patients with chronic nonmalignant pain. A thorough medication history, including use of alternative and over the counter medications, should be performed at the time of the initial visit and updated periodically. The medication history may consist of evaluating patient refill records through pharmacies to determine if the patient is appropriately taking their prescribed regimen. Appropriate application of pharmacological agents depends on the patient's age, past history (including history of substance abuse), drug allergies and the nature of all medical problems. It is incumbent upon the healthcare provider to thoroughly understand pharmacological principles when dealing with the different drug families, their respective side effects, Drug interactions, bioavailability profiles, and primary reason for each medication's usage. Patients should be aware that medications alone are unlikely to provide complete pain relief. In addition to pain relief, a primary goal of drug treatment is to improve the patient's function as measured behaviorally. In addition to taking medications, continuing participation in exercise programs and using self-management techniques, such as biofeedback, cognitive behavioral therapy, and other individualized physical, and psychological practices are essential elements for successful chronic pain management.

Control of chronic non-malignant pain is expected to involve the use of medication. Strategies for pharmacological control of pain cannot be precisely specified in advance. Rather, drug treatment requires close monitoring of the patient's response to therapy, flexibility on the part of the prescriber and a willingness to change treatment when circumstances change. Many of the drugs discussed in the medication section were licensed for indications other than analgesia, but are effective in the control of some types of chronic pain.

It is generally wise to begin management with lower cost medications whose efficacy equals higher cost medications and with a greater safety profile. Decisions to progress to more expensive, non-generic, and/or riskier products are made based on the drug profile, patient feedback, and improvement in function. The provider must carefully balance the untoward side effects of the different drugs with therapeutic benefits, as well as monitoring for any drug interactions.

Consensus regarding the use of opioids has generally been reached in the field of cancer pain, where nociceptive mechanisms are usually identifiable, expected survival may be short, and symptomatic relief is emphasized more than functional outcomes. In injured workers, by contrast, central and neuropathic mechanisms frequently overshadow nociceptive processes, expected survival is relatively long, and return to a high level of function is a major goal of treatment. Approaches to pain, which were developed in the context of malignant pain, therefore may not be transferable to chronic non-malignant pain.

All medications should be given an appropriate trial in order to test for therapeutic effect. The length of an appropriate trial varies widely depending on the individual drug. Certain medications may take several months to determine the efficacy, while others require only a few doses. It is recommended that patients with CRPS be maintained on drugs that have the least serious side effects. For example, patients need to be tried or continued on acetaminophen and/or low-dose generic antidepressant medications whenever feasible as part of their overall treatment for chronic pain. Patients with renal or hepatic disease may need increased dosing intervals with chronic acetaminophen use. Chronic use of NSAIDs is generally not recommended due to increased risk of cardiovascular

events and GI bleeding. There is good evidence that naproxen has the least risk for cardiovascular events when compared to other NSAIDs.

Opioid analgesics and other drugs of potential abuse such as sedative hypnotics or benzodiazepines may be used in properly selected cases for CRPS patients, with total elimination desirable whenever clinically feasible. It is strongly recommended that such pharmacological management be monitored or managed by an experienced pain medicine physician. Multimodal therapy is the preferred mode of treatment for chronic pain patients whether or not these drugs were used acutely or sub-acutely.

For CRPS management a burst of oral steroids is usually prescribed initially followed by tricyclics. Bisphosphonates are used when osteotrophic changes are present. Neuropathic pain can be treated with a variety of medications; however, all have specific side effects and other interactions that clinicians must be mindful of. It is suggested that patients with significant peripheral neuropathic pain be trialed with a tricyclic medication initially, as low dose medication in this category frequently is tolerated and performs sufficiently to decrease pain 30 to 50%. When these fail, side effects are not tolerated, or a patient has medical issues precluding the use of this class of drugs, other appropriate medications can be tried. Second line drugs include the anti-convulsants gabapentin and pregabalin. Comparison studies of amitriptyline and gabapentin or carbamazepine have shown no appreciable difference between the drugs; thus, there is good evidence that there is little clinical outcome difference between the medications, although gabapentin may be better tolerated. Third line drugs are the SNRI's, which have demonstrated some effectiveness for treating neuropathic pain, and topical lidocaine. The SNRI duloxetine has not been shown to be superior to the tricyclic amitriptyline and there is no reason to prefer duloxetine in patients who have not been treated with a tricyclic. Fourth line drugs are opioids and tramadol. Other medications have few clinical trials to support them but may be helpful in some patients.

For the clinician to interpret the following material, it should be noted that: (1) drug profiles listed are not complete; (2) dosing of drugs will depend upon the specific drug, especially for off-label use; and (3) not all drugs within each class are listed, and other drugs within the class may be appropriate. Clinicians should refer to informational texts or consult a pharmacist before prescribing unfamiliar medications or when there is a concern regarding drug interactions.

The following drug classes are listed in alphabetical order, not in order of suggested use which has been outlined above for neuropathic pain.

a. CRPS-Specific Medications:

A) Oral Steroids-

Inflammation is thought to be one of the first physiological changes in CRPS; therefore, strong anti-inflammatories should provide some relief especially if provided early. There is some evidence to support oral steroid use early in the course of CRPS. The strongest study was performed on patients with CRPS of the shoulder and hand following a stroke. Forty milligrams of prednisone were given for 14 days and then tapered by 10 mg per week while physical therapy was provided. An observational study and a lower quality blinded study support this conclusion. This early treatment may be trialed on patients who meet the

clinical diagnostic criteria for CRPS and do not have contraindications to steroid use. Side effects in some patients include mood changes, fluid retention, hyperglycemia, gastric irritation and ulcers, aseptic necrosis, and others.

- B) Bisphosphonates: are potent inhibitors of bone resorption. There is good evidence that their use effectively decreases pain and some evidence it increases joint motion in patients with CRPS. One study used alendronate 40 mg orally for 8 weeks and another used IV clodronate 300 mg daily for 10 days. Several other studies that did not meet evidence criteria used different medications and dosages. As of the time of this guideline writing, the FDA has not approved use for this indication. It should not be used in those with severe renal dysfunction. Osteonecrosis of the jaw has been reported and there may be an association with atypical subtrochanter femoral fractures especially with long term use. The recommended dose and time period for treatment are not clear. There are no studies addressing use for patients without evidence of resorption and therefore it is not recommended for these patients.
- C) Vitamin C - there is some evidence that Vitamin C 500mg taken for 50 days after a wrist fracture may help to prevent CRPS. It may be useful to prescribe Vitamin C to patients who historically have had or currently have CRPS if they suffer a fracture in order to prevent exacerbation of CRPS.
- D) Ketamine Hydrochloride
- 1) Description – An N-methyl-D-aspartate (NMDA) receptor antagonist. Proponents of using NMDA receptor antagonists in CRPS suspect that prolonged and high intensity pain induces the NMDA receptors which trigger inflammation and central sensitization of pain leading to abnormal pain manifestations such as allodynia and hyperalgesia.
 - 2) Indications – As of the time of this guideline writing, formulations of ketamine hydrochloride have been FDA approved for injection as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation. There is some evidence that in CRPS 1 patients, low dose daily infusions of ketamine can provide pain relief compared to placebo. The relief, however, faded within a few weeks. Studies have not shown any functional improvements in patients with CRPS treated with ketamine infusions. Because their potential harm, as described below, outweighs evidence of limited short-term benefit in patients with CRPS, NMDA receptor antagonists are not recommended. Less harmful therapies with longer term effects are available.
 - 3) Contraindications – Can cause significant elevations in blood pressure.

- 4) Side Effects – Known to cause emergence reactions in anesthetic doses in 12% of patients. These reactions range from pleasant dream-like states to delirium accompanied by irrational behavior. Repeated prolonged injections have resulted in drug-induced liver damage that resolved when treatment was stopped. Respiratory depression, apnea, and laryngospasm have occurred in anesthetic doses. Patients treated for CRPS with ketamine infusions up to 18% have had hallucinations.
 - 5) Drug interactions – When given with barbiturates or opioids, patients may have a prolonged recovery time.
 - 6) Due to the potential harm and limited short-term benefit in patients with CRPS, NMDA receptor antagonists are not recommended since less harmful therapies are available.
- E) Calcitonin: has been described in two low quality studies and was not shown to benefit CRPS patients. It was thought to provide analgesic properties through release of b-endorphin and the inhibition of bone resorption. It is not approved by the FDA for use with CRPS. Some patients have GI side effects and hyperglycemia has been reported. Rare cases of neurological side effects have been reported. It is not recommended.

b. **Alpha-Acting Agents**: Noradrenergic pain-modulating systems are present in the central nervous system and the alpha-2 adrenergic receptor may be involved in the functioning of these pathways. Alpha-2 agonists may act by stimulating receptors in the substantia gelatinosa of the dorsal horn of the spinal cord, inhibiting the transmission of nociceptive signals. Spasticity may be reduced by pre-synaptic inhibition of motor neurons. Given limited experience with their use, they cannot be considered first-line or second line analgesics for neurogenic or CRPS pain, but a trial of their use may be warranted in some cases of refractory pain.

I. Clonidine

- A) Description – central alpha 2 agonist.
- B) Indications – sympathetically mediated pain, treatment of withdrawal from opioids. IV clonidine and lidocaine should be used for upper extremity surgery with IV regional anesthesia in patients with a history of CRPS as there is some evidence that it decreases the risk of recurrence.

As of the time of this guideline writing, formulations of clonidine have been FDA approved for hypertension.

- C) Major contraindications – severe coronary insufficiency, renal impairment.
- D) Dosing and time to therapeutic effect – increase dosage weekly to therapeutic effect.
- E) Major side effects – sedation, hypotension, sexual dysfunction, thrombocytopenia, weight gain, agitation, rebound hypertension with cessation.
- F) Drug interactions – beta adrenergics, tricyclic antidepressants.
- G) Laboratory Monitoring – Renal function, blood pressure.

c. **Anticonvulsants:** Although the mechanism of action of anticonvulsant drugs in neuropathic pain states remains to be fully defined, some appear to act as nonselective sodium channel blocking agents. A large variety of sodium channels are present in nervous tissue, and some of these are important mediators of nociception, as they are found primarily in unmyelinated fibers and their density increases following nerve injury. While the pharmacodynamic effects of the various anticonvulsant drugs are similar, the pharmacokinetic effects differ significantly. Gabapentin and pre-gabapentin, by contrast, are relatively non-significant enzyme inducers, creating fewer drug interactions. Because anticonvulsant drugs may have more problematic side-effect profiles, their use should usually be deferred until tricyclic-related medications have failed to relieve pain. All patients on these medications should be monitored for suicidal ideation.

Carbamazepine has important effects as an inducer of hepatic enzymes and may influence the metabolism of other drugs enough to present problems in patients taking interacting drugs. There is some evidence that oxcarbazepine may be effective for neuropathic pain but dose escalation must be done carefully, since there is good evidence that rapid dose titration produces side-effects greater than the analgesic benefits. Carbamazepine is generally not recommended.

There is an association between older anticonvulsants including gabapentin and non-traumatic fractures for patients older than 50; this should be taken into account when prescribing these medications.

i. Gabapentin

- A) Description – Structurally related to gamma-aminobutyric acid (GABA) but does not interact with GABA receptors.
- B) Indications –As of the time of this guideline writing formulations of gabapentin has been FDA approved for post-herpetic neuralgia and partial seizures.

There is some evidence that gabapentin may benefit some patients with post-traumatic neuropathic pain. There is good evidence that gabapentin is not superior to amitriptyline. There is some evidence that nortriptyline

and gabapentin are equally effective for pain relief of post herpetic neuralgia. There is some evidence that gabapentin given with morphine may result in lower side effects from morphine and produces greater analgesia at lower doses than those usually required for either medication alone. There is strong evidence that gabapentin is more effective than placebo for neuropathic pain, even though it provides complete pain relief to a minority of patients. There is some evidence that a combination of gabapentin and nortriptyline provides more effective pain relief than monotherapy with either drug. Given the cost of gabapentin it is recommended that patients who are medically appropriate receive a trial of tricyclics before use of gabapentin.

- C) Relative Contraindications – Renal insufficiency. Dosage may be adjusted to accommodate renal dysfunction.
- D) Dosing and Time to Therapeutic Effect – Dosage should be initiated at a low dose in order to avoid somnolence and may require 4 to 8 weeks for titration. Dosage should be adjusted individually.
- E) Major Side Effects – sedation, confusion, dizziness, peripheral edema. Patients should also be monitored for suicidal ideation and drug abuse.
- F) Drug Interactions – antacids.
- G) Laboratory Monitoring – Renal function.

ii. Pregabalin

- A) Description – Structurally related to gamma-aminobutyric acid (GABA) but does not interact with GABA receptors.
- B) Indications –As of the time of this guideline writing formulations of pregabalin have been FDA approved for neuropathic pain associated with diabetic peripheral neuropathy, post-herpetic neuralgia, and fibromyalgia. It may also be an adjunctive therapy for partial-onset seizures.

There is strong evidence that pregabalin has a substantive benefit for a minority, about 25%, of neuropathic pain patients, most of whom report between 30 and 50% relief of symptoms. Given the cost of pregabalin and its response for a minority of patients it is recommended that patients who are medically appropriate to receive a trial of amitriptyline or another first-line agent -before use of pregabalin.

- C) Contraindications – allergy to medication, prior history of angioedema, renal insufficiency is a relative contraindication, requiring a modified dose.
- D) Dosing and Time to Therapeutic Effect – Dosage may be increased over several days and doses above 150 mg are usually required. The full benefit may not be achieved for 6 to 8 weeks.
- E) Major Side Effects – Dizziness, confusion, sedation, dry mouth, weight gain, and visual changes have been reported. Patients should also be monitored for suicidal ideation and drug abuse. Congestive heart failure may be exacerbated in some patients. Decreased platelets have been reported.
- F) Drug Interactions – Opioids, benzodiazepines, alcohol.
- G) Laboratory Monitoring – Renal function, Platelets, and creatinine kinase as appropriate for individual cases.

iii. Topiramate

- A) Description – Sulfamate substitute monosacchride.
- B) Indications – As of the time of this guideline writing, formulations of this drug have been FDA approved for partial seizures or prophylaxis for migraines. There is good evidence that topiramate demonstrates minimal effect on chronic lumbar radiculopathy or other neuropathic pain. Therefore it is generally not recommended for chronic pain with the exception of chronic, functionally impairing headache. If it is utilized, this would be done as a third or fourth line medication in appropriate patients.

iv. Lamotrigine

- A) This anti-convulsant drug is not FDA for use with neuropathic pain. Due to reported deaths from toxic epidermal necrolysis and Stevens Johnson syndrome, increased suicide risk, and incidents of aseptic meningitis, it is used with caution for patients with seizure or mood disorders. There is good evidence that lamotrigine is not effective for neuropathic pain and that the potential harms are likely to outweigh the benefits, therefore it is not recommended for most patients.

d. **Antidepressants:** are classified into a number of categories based on their chemical structure and their effects on neurotransmitter systems. Their effects on depression are attributed to their actions on disposition of norepinephrine and serotonin at the level of the synapse; although these synaptic actions are immediate, the symptomatic response in depression is delayed by several weeks. When used for chronic pain, the effects may in part arise from treatment of underlying depression, but may also involve additional

neuromodulatory effects on endogenous opioid systems, raising pain thresholds at the level of the spinal cord.

Pain responses may occur at lower drug doses with shorter times to symptomatic response than are observed when the same compounds are used in the treatment of mood disorders. Neuropathic pain, diabetic neuropathy, post-herpetic neuralgia, and cancer-related pain may respond to antidepressant doses low enough to avoid adverse effects that often complicate the treatment of depression. First line drugs for neuropathic pain are the tricyclics with the newer formulations having better side effect profiles. SNRIs are considered second line drugs due to their costs and the number needed to treat for a response. SSRIs are used generally for depression rather than neuropathic pain and should not *be combined* with moderate to high-dose tricyclics.

All patients being considered for anti-depressant therapy should be evaluated and continually monitored for suicidal ideation and mood swings.

i. Tricyclics and other agents.

(e.g., amitriptyline, nortriptyline, doxepin, desipramine, imipramine, trazodone.

- A) Description – Serotonergics, typically tricyclic antidepressants (TCAs), are utilized for their serotonergic properties as increasing CNS serotonergic tone can help decrease pain perception in non-antidepressant dosages. Amitriptyline is known for its ability to repair Stage 4 sleep architecture, a frequent problem found in chronic pain patients and to treat depression, frequently associated with chronic pain. However, higher doses may produce more anticholinergic side effects than newer tricyclics such as nortriptyline and desipramine. Doxepin and trimipramine also have sedative effects.
- B) Indications – As of the time of this guideline writing, some formulations are FDA approved for depression and anxiety. For the purposes of this guideline, they are recommended for neuropathic pain and insomnia. They are not a recommended drug treatment for depression. There is good evidence that gabapentin is not superior to amitriptyline. Given the cost of gabapentin, it is recommended that patients who are medically appropriate to undergo a trial of lower cost tricyclic before use of gabapentin.
- C) Major Contraindications – Cardiac disease or dysrhythmia, glaucoma, prostatic hypertrophy, seizures, high suicide risk, uncontrolled hypertension and orthostatic hypotension. A screening cardiogram may be done for those 40 or older, especially if higher doses are used.
- D) Dosing and Time to Therapeutic Effect – Varies by specific tricyclic. Low dosages, less than 100 mg are commonly used for chronic pain and/or insomnia. Lower doses decrease side effects and cardiovascular risks.

- E) Major Side Effects – Side effects vary according to the medication used, however, the side effect profile for all of these medications is generally higher in all areas except GI distress, which is more common among the SSRIs and SNRIs. Anticholinergic side effects include, but not limited to, dry mouth, sedation, orthostatic hypotension, cardiac arrhythmia, urinary retention, and weight gain. Patients should also be monitored for suicidal ideation and drug abuse.
 - F) Drug Interactions – Tramadol (may cause seizures, both also increase serotonin/norepinephrine, so serotonin syndrome is a concern), clonidine, cimetidine, sympathomimetics, valproic acid, warfarin, carbamazepine, bupropion, anticholinergics, and quinolones.
 - G) Recommended Laboratory Monitoring – Renal and hepatic function. EKG for those on high dosages or with cardiac risk.
- ii. Selective serotonin reuptake inhibitors (SSRIs) (e.g., citalopram, fluoxetine, paroxetine, and sertraline) are not recommended for neuropathic pain. They may be used for depression.
 - iii. Selective Serotonin Norepinephrine Reuptake Inhibitor SSNRI and Serotonin Norepinephrine Reuptake Inhibitors (SNRI).
 - A) Description – Venlafaxine, duloxetine and milnacipran
 - B) Indications – At the time of this guideline writing, formulations of duloxetine has been FDA approved for treatment of diabetic neuropathic pain and chronic musculoskeletal pain. There is good evidence that it is superior to placebo for neuropathic pain at doses of 60mg or 120mg. There is some evidence that it is comparable to pregabalin and gabapentin.

As of the time of this guideline writing, formulations of venlafaxine hydrochloride is FDA approved for generalized anxiety disorder. There is some evidence that it is modestly effective in diabetic neuropathic pain at doses of 150 to 225 mg. There is no evidence of superiority over tricyclics.

As of the time of this guideline writing, formulations of milnacipran have been FDA approved for treatment of fibromyalgia and has a success rate similar to imipramine. It is not recommended in patients as a first or second line treatment and is reserved for patients who fail other regimes due to side effects.
 - C) Relative Contraindications – Seizures, eating disorders.

- D) Major Side Effects – Depending on the drug, but commonly includes dry mouth, nausea, fatigue, constipation, and abnormal bleeding. Serotonin syndrome is also a risk. GI distress, drowsiness, sexual dysfunction less than other classes. Hypertension and glaucoma (venlafaxine). Cardiac issues with venlafaxine and withdrawal symptoms unless tapered. Studies show increased suicidal ideation and attempts in adolescents and young adults. Patients should also be monitored for suicidal ideation.
- E) Drug Interactions – Drug specific.
- F) Laboratory Monitoring – Drug specific. Hepatic and renal monitoring, venlafaxine may cause cholesterol or triglyceride increases.

iv. Atypical Antidepressants/Other Agents. May be used for depression however are not for neuropathic pain.

- e. **Hypnotics and Sedatives:** Sedative and hypnotic drugs decrease activity and induce drowsiness and moderate agitation in some individuals. Many other medications, such as antihistamines and antidepressants also produce these side effects. Due to the addiction potential, withdrawal symptoms, and sedating side effects benzodiazepines and other similar drugs found in this class, are not generally recommended. They should be used with extreme caution when the patient is on chronic opioids management. When used, extensive patient education should be documented. Some of these medications have long half lives; sleep apnea can occur or be aggravated on these medications. Many unintentional drug deaths are related to concomitant opioid and benzodiazepine drug use. Retrograde amnesia can occur and is implicated in “sleep driving,” “sleep eating” and other activities.

Most insomnia in chronic pain patients should be managed primarily through behavioral interventions with medications as secondary measures (refer to Therapeutic Procedures, Non-Operative, Disturbances of Sleep, Section G.4.).

- i. Zaleplon; Eszopiclone; Zolpidem.
 - A) Description – Nonbenzodiazepine hypnotic.
 - B) Indications – As of the time of this guideline writing, formulations of zaleplon, eszopiclone and zolpidem have been FDA approved for insomnia.
 - C) Dosing and Time to Therapeutic Effect – Time of onset is 30 to 60 minutes.
 - D) Major Side Effects – Dizziness, dose-related amnesia.
 - E) Drug Interactions – Increases sedative effect of other central nervous system (CNS) depressant drugs.

F) Laboratory Monitoring - none required, based on individual patient history.

- ii. Benzodiazepine-based hypnotics including temazepam and flurazepam. Neither is recommended because of habit-forming potential, withdrawal symptoms, and sedating side effects. Flurazepam has an active metabolite with a very long half-life, resulting in drug accumulation and next-day somnolence, and should be avoided.

f. Marijuana:

At the time of this guidelines writing, marijuana use is illegal under federal law and cannot be recommended for use in this guideline. The Colorado statute also states that insurers are not required to pay for marijuana.

Marijuana produces many cannabinoids. Only a few of these substances have been explored in detail. Cannabis is currently procured in Colorado through a registry program. Products sold cannot be evaluated for pharmaceutically appropriate content or strength. THC content has increased from 2% in 1980 to 8.5% in 2007, thus making it difficult to correctly determine effects of a specific plant on an individual. Because smoked marijuana reaches its effect quickly, it is thought that most smokers titrate their dosage when using higher potency agents.

There are only two oral pharmaceutical cannabinoid products on the market. These medications were developed initially for nausea due to oncological drug therapy but have been trialed in other settings and are described below. A buccal spray is accepted in Europe and Canada and may be approved by the FDA for use with neuropathic pain. Initial studies were done on neuropathic pain associated with multiple sclerosis.

There are a number of studies evaluating the health effects of cannabinoids. Cannabis is associated with the subsequent development of psychosis in adolescents and can cause transient episodes of paranoia and psychotic symptoms in some individuals. It is not known whether or not the association with psychosis is causal. Cannabis increases heart rate in a dose related fashion and some studies suggest it may increase the risk for myocardial infarction in those with cardiovascular disease. Because smoked marijuana contains many of the same carcinogens as smoked tobacco, it has been postulated that cancer risk may be increased in heavy marijuana smokers. However, the association has not been established epidemiologically. There appears to be an increase in respiratory infections although there is no clear disposition for chronic obstructive lung disease in regular cannabis smokers. Cannabis dependence occurs in some users. In some individuals, withdrawal symptoms have been demonstrated after 20 days of high dose use and consist of decreased mood and appetite with irritability, insomnia, anxiety and depression.

Unlike alcohol and many other sedating drugs of abuse, marijuana does not appear to be lethal at any dose consumed by heavier users when used in isolation, unlike alcohol, probably because it is not a respiratory depressant. Some studies have shown a decrease in reaction time and some association with motor vehicle accidents. However, the risk appears to be less than ½ the risk of driving under alcohol intoxication. There is only one study that evaluated the use of marijuana in conjunction with chronic opioid management, thus no recommendations can be made to clinicians regarding this combination.

Clinicians should keep in mind that there are an increasing number of deaths due to the toxic misuse of opioids with other medications and alcohol. Drug screening is a mandatory component of chronic opioid management. It is appropriate to screen for alcohol use and have a contractual policy regarding alcohol use during chronic opioid management as alcohol use in combination with opioids is more likely to contribute to death or accidents than marijuana.

The contraindications and major side effects for cannabinoid are listed below. No laboratory monitoring is necessary.

- Relative Contraindications – history of psychosis or risk factors for psychosis, seizure history, cardiovascular risk history, history of addiction, hypersensitivity to cannabinoids.
- Major Side Effects – Dizziness or fatigue, rapid heart rate, dry mouth, euphoria, Less common effects- paranoia or hallucinations, seizures. A withdrawal reaction can occur when high doses are discontinued. It may include sweating and rhinorrhea with anorexia.
- Psychological reactions: intoxication from cannabis frequently results in impaired motor coordination, euphoria, anxiety, sensation of slowed time, impaired judgment, social withdrawal, and hallucinations. Psychotic and anxiety disorders can occur from the use of cannabis. Paranoid ideation ranging from suspiciousness to frank delusions, hallucinations and depersonalization or derealization have been reported. Some of these findings may be related to the higher level of THC (delta-9-tetrahydrocannabinol) found in the marijuana currently sold.

i. Dronabinol:

- A) Description – Dronabinol is a synthetic delta-9-tetrahydrocannabinol, which is also a naturally occurring component of Cannabis Sativa L. (Marijuana).
- B) Indications – As of the time of this guideline writing, formulations of this drug have been FDA approved for nausea and vomiting with cancer therapy and weight loss associated with AIDS.
- C) Dosing and Time to Therapeutic Effect – 2.5 mg twice a day titrated up to 20 mg total per day.

ii. Nabilone:

- A) Description – Nabilone is a synthetic cannabinoid which is also a naturally occurring component of Cannabis Sativa L. (Marijuana).
- B) Indications – As of the time of this guideline writing, formulations of nabilone have been FDA approved for nausea and vomiting with cancer therapy.

- C) Dosing and Time to Therapeutic Effect –1 to 2 mg twice a day titrated up to 6 mg per day.

iii. Nabiximols:

- A) Description –tetrahydrocannabinol (THC) and cannabidiol (CBD) in a one to one ratio, plus other components of cannabis extracts such as terpenoids and flavonoids mixed in a tincture. In the UK, nabiximols has just been approved and launched as a prescription medicine for spasticity due to multiple sclerosis. In Canada, nabiximols is approved under Health Canada’s Notice of Compliance with Conditions (NOC/c) policy for the relief of neuropathic pain and advanced cancer pain. It has not been approved in the US as of the time of this guideline writing. This drug is not intended to provide the euphoria produced with smoking marijuana.
- B) Indications – In other countries for neuropathic pain and spasticity of MS, cancer pain. There is some evidence that nabiximols can modestly decrease peripheral neuropathic pain with allodynia in some patients who were concomitantly treated with opioids or anticonvulsants, however, the drop out rate for those who continued the medication longer term was high.
- C) Dosing and Time to Therapeutic Effect – Spray administered under the tongue. Up to 8 sprays every 3 hours with a maximum of 48 per day.

g. Nonsteroidal Anti-Inflammatory Drugs (NSAIDs):

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) are useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs and the response of the individual injured worker to a specific medication is unpredictable. For this reason a range of NSAIDs may be tried in each case with the most effective preparation being continued. Patients should be closely monitored for adverse reactions. The US Food and Drug Administration advise all NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Administration of proton pump inhibitors, histamine 2 blockers, or a prostaglandin analog misoprostol along with these NSAIDs may reduce the risk of duodenal and gastric ulceration but do not impact possible cardiovascular complications. There is good evidence that naproxen has a more favorable cardiovascular risk profile than other NSAIDs when used over a long period for chronic pain. Due to the cross-reactivity between aspirin and NSAIDs, NSAIDs should not be used in aspirin-sensitive patients, and should be used with caution in all asthma patients. NSAIDs are associated with abnormal renal function, including renal failure, as well as, abnormal liver function. Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent upon the patient’s age, general health status and should be within parameters listed for each specific medication. Complete blood

count (CBC), liver and renal function should be monitored at least every six months in patients on chronic NSAIDs and initially when indicated.

i. Non-selective Nonsteroidal Anti-Inflammatory Drugs.

Includes NSAIDs and acetylsalicylic acid (aspirin). Serious GI toxicity, such as bleeding, perforation, and ulceration can occur at any time, with or without warning symptoms in patients treated with traditional NSAIDs. Physicians should inform patients about the signs and/or symptoms of serious gastrointestinal toxicity and what steps to take if they occur. Anaphylactoid reactions may occur in patients taking NSAIDs. NSAIDs may interfere with platelet function. Fluid retention and edema have been observed in some patients taking NSAIDs.

- ❖ Optimal Duration: 1-2 weeks.
- ❖ Maximum Duration: chronic use is not generally recommended but may be appropriate in select cases if monitored regularly. Use of these substances long-term (3 days per week or greater) is associated with rebound pain upon cessation.

ii. Selective Cyclo-oxygenase-2 (COX-2) Inhibitors.

COX-2 inhibitors are more recent NSAIDs and differ in adverse side effect profiles from the traditional NSAIDs. The major advantages of selective COX-2 inhibitors over traditional NSAIDs are that they have less gastrointestinal toxicity and no platelet effects. COX-2 inhibitors can worsen renal function in patients with renal insufficiency; thus, renal function may need monitoring.

COX-2 inhibitors should not be first-line for low risk patients who will be using an NSAID short-term but are indicated in select patients for whom traditional NSAIDs are not tolerated. Serious upper GI adverse events can occur even in asymptomatic patients. Patients at high risk for GI bleed include those who use alcohol, smoke, are older than 65, take corticosteroids or anti-coagulants, or have a longer duration of therapy. Celecoxib is contraindicated in sulfonamide allergic patients.

- ❖ Optimal Duration: 7 to 10 days.
- ❖ Maximum Duration: chronic use is not generally recommended but may be appropriate in select cases if monitored regularly. Use of these substances long-term (3 days per week or greater) is associated with rebound pain upon cessation.

h. **Opioids:** are the most powerful analgesics. Their use in acute pain and moderate-to-severe cancer pain is well accepted. Their use in chronic

nonmalignant pain, however, is fraught with controversy and lack of scientific research.

General Information: Opioids include some of the oldest and most effective drugs used in the control of severe pain. The discovery of opioid receptors and their endogenous peptide ligands has led to an understanding of effects at the binding sites of these naturally occurring substances. Most of their analgesic effects have been attributed to their modification of activity in pain pathways within the central nervous system; however, it has become evident that they also are active in the peripheral nervous system. Activation of receptors on the peripheral terminals of primary afferent nerves can mediate anti-nociceptive effects, including inhibition of neuronal excitability and release of inflammatory peptides. Some of their undesirable effects on inhibiting gastrointestinal motility are peripherally mediated by receptors in the bowel wall.

The central nervous system actions of these drugs account for much of their analgesic effect and for many of their other actions, such as respiratory depression, drowsiness, mental clouding, reward effects, and habit formation. With respect to the latter, it is crucial to distinguish between three distinct phenomena: tolerance, dependence, and addiction.

- Tolerance refers to a state of adaptation in which exposure to a drug over time causes higher doses of that drug to be required in order to produce the same physiologic effect and/or markedly diminished effect with continued use of the same amount that drug.
- Dependence refers to a set of disturbances in body homeostasis that leads to withdrawal symptoms, which can be produced with abrupt discontinuation, rapid reduction, decreasing blood levels, and/or by administration of an antagonist.
- Addiction is a primary, chronic, neurobiological disease, with genetic, psychological, and environmental factors influencing its development and manifestations. It is a behavioral pattern of drug craving and seeking which leads to a preoccupation with drug procurement and an aberrant pattern of use. The drug use is frequently associated with negative consequences.

Tolerance and dependence are physiological phenomena, are expected with the continued administration of opioids, and should not deter physicians from their appropriate use. Before increasing the opioid dose due to a presumption of physiologic tolerance, the physician should review other possible causes for the decline in analgesic effect. Consideration should be given to possible new psychological stressors or an increase in the activity of the nociceptive pathways. Other possibilities include new pathology, low testosterone level that impedes delivery of opioids to the central nervous system, drug diversion, or abusive use of the medication.

The use of opioids is well accepted in treating cancer pain, where nociceptive mechanisms are generally present due to ongoing tissue destruction, expected survival may be short, and symptomatic relief is emphasized more than functional outcomes. In chronic non-malignant pain, by contrast, tissue destruction has generally ceased, meaning that central and neuropathic mechanisms frequently overshadow nociceptive processes. Expected survival in

chronic pain is relatively long and return to a high-level of function is a major goal of treatment. Therefore, approaches to pain developed in the context of malignant pain may not be transferable to chronic non-malignant pain. Opioids are generally not the best choice of medication for controlling neuropathic pain. Tricyclics, SNRIs, and anticonvulsants should be tried before considering opioids for neuropathic pain.

In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs. While maximum efficacy is modest, they may reduce pain sufficiently to permit adequate function. When these drugs do not satisfactorily reduce pain, medications specific to the diagnosis should be used, (e.g. neuropathic pain medications as outlined in Medications section).

Most studies show that only around 50% of patients tolerate opioid side effects and receive an acceptable level of pain relief. Depending on the diagnosis and other agents available for treatment the incremental benefit can be small. Patients should have a thorough understanding of the need to pursue many other pain management techniques in addition to medication use in order to function with chronic pain. They should also be thoroughly aware of the side effects and how to manage them. Common side effects are drowsiness, constipation, nausea and possible testosterone decrease with longer term use.

Physicians should be aware that deaths from unintentional drug overdoses exceed the number of deaths from motor vehicle accidents in the US. Most of these deaths are due to the use of opioids, usually in combination with other respiratory depressants such as alcohol or benzodiazepines. The prevalence of drug abuse in the population of patients undergoing pain management varies according to region and other issues. A recent study indicated that ¼ of patients being monitored for chronic opioid use have abused drugs occasionally, and ½ of those have frequent episodes of drug abuse. Eighty per-cent of patients admitted to a large addiction program reported that their first use of opioids was from prescribed medication.

Choice of Opioids:

There is no evidence that one long-acting opioid is more effective than another, nor more effective than other types of medications, in improving function or pain. There is some evidence that long-acting oxycodone and oxymorphone have equal analgesic effects and side effects, although the milligram dose of oxymorphone is ½ that of oxycodone. There is no evidence that long-acting opioids are superior to short-acting opioids for improving function or pain or causing less addiction. Long-acting opioids are generally preferred for chronic opioid management as they are thought to result in a less pronounced euphoria state and are thus less likely to lead to addiction. They may result in better tolerance for the sedative and cognitive effects of opioids. However, due to the lack of evidence physicians may choose to use short-acting opioids in some patients. Long-acting opioids should not be used for the treatment of acute, sub-acute or post-operative pain, as this is likely to lead to drug dependence and difficulty tapering the medication. Additionally, there is a potential for respiratory depression to occur. When choosing longer acting opioids for chronic pain management it is reasonable to consider cost given the lack of superiority profiles for one medication over another. The Food and Drug Administration (FDA) requires that manufacturers develop Risk Evaluation and Mitigation Strategies (REMS) for most opioids. Physicians should carefully review the plans or educational materials provided under this program.

Addiction and abuse potentials of commonly prescribed opioid drugs may be estimated in a variety of ways, and their relative ranking may depend on the measure which is used. Hydrocodone is the most commonly prescribed opioid in the general population, and is one of the most commonly abused opioids in the population; however, the abuse rate per 1000 prescriptions is lower than the corresponding rates for extended release oxycodone, hydromorphone, and methadone. Extended release oxycodone appears to be the most commonly abused opioid, both in the general population and in the abuse rate per 1000 prescriptions. Tramadol, by contrast, appears to have a lower abuse rate than for other opioids. Newer drug formulations such as oxycodone, have been assumed to be relatively abuse-resistant, but their abuse potential is unknown and safety cannot be assumed in the absence of sound data.

Tapentadol is a new mu opioid agonist which also inhibits serotonin and norepinephrine reuptake activity. It is currently available in an intermediate release formulation and may be available as extended release if FDA approved. Due to its dual activity it can cause seizures or serotonin syndrome, particularly when taken with other SSRIs, SNRIs, tricyclics, or MAO inhibitors. It has not been tested in patients with severe renal or hepatic damage. It has similar opioid abuse issues as other opioid medication; however, it is promoted as having fewer GI side effects, such as constipation. Further studies may be needed to verify this finding. There is good evidence that extended release tapentadol is more effective than placebo and comparable to oxycodone. In that study the percent of patients who achieved 50% or greater pain relief was placebo, 18.9%, tapentadol, 27.0%, and oxycodone, 23.3%. There is some evidence that tapentadol can reduce pain to a moderate degree in diabetic neuropathy, average difference 1.4/10 pain scale, with tolerable adverse effects. Tapentadol is not recommended as a first line opioid for chronic, subacute or acute pain due to the cost, lack of superiority over other analgesics and need for further testing to assess GI effects in comparison to other medications. It may be appropriate for patients who cannot tolerate other opioids due to GI side effects.

Methadone requires special precautions. It may cause cardiac arrhythmias due to QT prolongation and has been linked with a greater number of deaths due to its prolonged half life. Propoxyphene has been withdrawn from the market due to cardiac effects including arrhythmias.

Fentanyl is not generally recommended for use with musculoskeletal chronic pain patients. It has been associated with a number of deaths and has high addiction potential. Fentanyl should never be used transbuccally in this population.

Meperidine should not be used for chronic pain; it and its active metabolite, normeperidine, present a serious risk of seizure and hallucinations. It is not a preferred medication for acute pain as its analgesic effect is similar to codeine.

Buprenorphine may be used for opioid addiction or habituation treatment in patients with chronic pain, it is not recommended for most chronic pain patients due to methods of administration, reports of euphoria in some patients, and lack of proof for improved efficacy in comparison with other opioids. It may be appropriate for some patients at high risk for addiction and should be used in consultation with an addiction medicine specialist.

Doses of opioids in excess of 120 mg morphine equivalent have been observed to be associated with increased duration of disability, even when adjusted for injury severity in injured workers with acute low back pain and thus any use above 120 mg should be very closely monitored. Doses in excess of 200 mg

should be avoided. Higher doses are more likely to be associated with hypogonadism and the patient should be informed of this risk. Higher doses of opioids also appear to contribute to the euphoric effect.

Health care professionals and their patients must be particularly conscientious regarding the potential dangers of combining over-the-counter acetaminophen with prescription medications that also contain acetaminophen. Opioid and acetaminophen combination medication are limited due to the acetaminophen component. Total acetaminophen dose per day should not exceed 4 grams per 24-hour period due to possible liver damage.

Physiologic Responses to Opiates: Physiologic responses to opiates are influenced by variations in genes which code for opiate receptors, cytochrome P450 enzymes, and catecholamine metabolism. Interactions between these gene products significantly affect opiate absorption, distribution, and excretion. Hydromorphone, oxycodone, and morphine are metabolized through the glucuronide system. Other opioids generally use the cytochrome P450 system. Allelic variants in the mu opiate receptor may cause increased analgesic responsiveness to lower drug doses in some patients. The genetic type can predict either lower or higher needs for opioids. For example, at least 10% of Caucasians lack the CYP450 2D6 enzyme that converts codeine to morphine. In some cases genetic testing for cytochrome P450 type may be helpful. When switching patients from codeine to other medications assume the patient has little or no tolerance to opioids. Many gene-drug associations are poorly understood and of uncertain clinical significance; the treating physician needs to be aware of the fact that the patient's genetic makeup may influence both the therapeutic response to drugs and the occurrence of adverse effects.

Physicians can expect chronic opioid patients to experience more pain, and require higher doses of opioids, peri-operatively than pre-operatively.

Risk Factors: Consultation or referral to a pain specialist should be considered when the pain persists but the underlying tissue pathology is minimal or absent and correlation between the original injury and the severity of impairment is not clear. Consider consultation if suffering and pain behaviors are present and the patient manifests risk behaviors described below, or when standard treatment measures have not been successful or are not indicated.

A psychological consultation including psychological testing (with validity measures) is indicated for all chronic pain patients as these patients are at high risk for unnecessary procedures and treatment and prolonged recovery.

Many behaviors have been found related to prescription-drug abuse patients. None of these are predictive alone, and some can be seen in patients whose pain is not under reasonable control; however, the behaviors should be considered warning signs for higher risk of abuse or addiction by physicians prescribing chronic opioids.

The following behaviors frequently seen in prescription drug - abusing patients should be considered warning signs for addiction and patients that are at high-risk when placed on chronic opioids. Consultation with an addiction specialist may be useful when patients present with these symptoms:

- Unusual knowledge of controlled substances.

- Request for specific controlled substances or claims of allergy or ineffectiveness to other medications.
- Demanding assessment or medication after usual clinic hours.
- Requesting more refills than scheduled, “losing” drugs.
- Signs of mood disorders or other psychiatric conditions.
- Physical signs of drug abuse.
- No interest in their diagnosis, fails to keep other treatment or consultation appointments.
- Feigns or exaggerates physical problems.
- Pressures physician by eliciting sympathy, guilt or direct threats.
- Subjective complaints exceed objective findings.
- Attempts to transfers care after a doctor refuses to fill prescription(s) for habit forming medication.

In one study four specific behaviors appeared to identify patients at risk for current substance abuse: increasing doses on their own, feeling intoxicated, early refills, and oversedating oneself. A positive test for cocaine also appeared to be related.

Recommendations for Opioid Use: When considering opioid use for moderate to moderately severe chronic pain, a trial of opioids must be accomplished as described below and the patient must have failed other chronic pain management regimes. Physicians should complete the education recommended by the FDA, risk evaluation and mitigation strategies (REMS) provided by drug manufacturing companies.

- i. General Indications – There must be a clear understanding that opioids are to be used for a limited term as a trial (see trial indications below). The patient should have a thorough understanding of all of the expectations for opioid use. The level of pain relief is expected to be relatively small, 2 to 3 points on a VAS pain scale, although in some individual patients it may be higher. For patients with a high response to opioid use, care should be taken to assure that there is no abuse or diversion occurring. The physician and patient must agree upon defined functional goals as well as pain goals. If functional goals are not being met the opioid trial should be reassessed. The full spectrum of side effects should be reviewed. The contract signed by the patient must clarify under what term the opioids will be tapered. See section iii. D below.
- ii. Therapeutic Trial Indications – A therapeutic trial of opioids should not be employed unless the patient has begun multi-disciplinary pain management.

Chronic use of opioids should not be prescribed until the following have been met:

- A) The failure of pain management alternatives by a motivated patient including active therapies, cognitive behavioral therapy, pain self-management techniques, and other appropriate medical techniques.
 - B) Physical and psychological and/or psychiatric assessment including a full evaluation for alcohol or drug addiction, dependence or abuse, performed by two specialists including the authorized treating physician and a specialist with expertise in chronic pain. The patient should be stratified as to low, medium or high risk for abuse based on behaviors and prior history of abuse. High risk patients are those with active substance abuse of any type or a history of prescription opioid abuse. These patients should generally not be placed on chronic opioids. If it is deemed appropriate to do so, physician addiction specialists should be monitoring the care. Patients with a past history of substance abuse or other psychosocial risk factors should be co-managed with a physician addiction specialist.
 - C) Urine drug screening for substances of abuse and substances currently prescribed. Clinicians should keep in mind that there is an increasing number of deaths due to the toxic misuse of opioids with other medications and alcohol. Drug screening is a mandatory component of chronic opioid management. It is appropriate to screen for alcohol use and have a contractual policy regarding alcohol use during chronic opioid management as alcohol use in combination with opioids is more likely to contribute to death or accidents than marijuana.
 - D) Physician Prescription Drug Monitoring Program review.
 - E) Informed, written, witnessed consent by the patient including the aspects noted above.
 - F) The trial, usually with a short-acting agent first, should document sustained improvement of pain control, at least a 30% reduction, and of functional status, including return-to-work and/or increase in activities of daily living. Frequent follow-up at least every 2 to 4 weeks may be necessary to titrate dosage and assess clinical efficacy.
- iii. On-Going, Long-Term Management after a successful trial should include:
- A) Prescriptions from a single practitioner.
 - B) Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects.

- C) Ongoing effort to gain improvement of social and physical function as a result of pain relief.
- D) Contract detailing the following:
- Side effects anticipated from the medication.
 - Requirement to continue active therapy.
 - Need to achieve functional goals including return to work for most cases.
 - Reasons for termination of opioid management, referral to addiction treatment, or for tapering opioids (tapering is usually over 30 days). Examples to be included in the contract include, but are not limited to:
 - Diversion of medication.
 - Lack of functional effect at higher doses.
 - Non-compliance with other drug use.
 - Drug screening showing use of drugs outside of the prescribed treatment or evidence of non-compliant use of prescribed medication.
 - Requests for prescriptions outside of the defined time frames.
 - Lack of adherence identified by pill count, excessive sedation, or lack of functional gains.
 - Excessive dose escalation with no decrease in use of short-term medications.
 - Apparent hyperalgesia.

Contracts should be written at a 6th grade reading level to accommodate the majority of patients.

- E) Use of drug screening initially, randomly at least once a year and as deemed appropriate by the prescribing physician. Drug screening is suggested for any patients who have been receiving opioids for 90 days. A discussion regarding how screens positive for marijuana or alcohol will be handled should be included in the opioid contract. The concept of opioid misuse encompasses a variety of problems distinct from the development of addiction, such as nonmedical use, diversion, consultation with multiple prescribers, and unintentional overdose.

It appears that users of prescription opioids who also experienced depression or anxiety disorders were more

likely to abuse opioids. Urine testing, when included as one part of a structured program for pain management, has been observed to reduce abuse behaviors in patients with a history of drug misuse. Clinicians should keep in mind that there is an increasing number of deaths due to the toxic misuse of opioids with other medications and alcohol. Drug screening is a mandatory component of chronic opioid management. It is appropriate to screen for alcohol use and have a contractual policy regarding alcohol use during chronic opioid management as alcohol use in combination with opioids is more likely to contribute to death or accidents than marijuana.

Physicians should recognize that occasionally patients may use non-prescribed substances because they have not obtained sufficient relief on the prescribed regime.

Although drug screens done for chronic pain management should not be routinely available to employers, as screens are part of the treatment record to which employers have limited access, patients should be aware that employers might obtain the records through attorneys or the insurer.

- F) Use limited to two oral opioids: a long-acting opioid for maintenance of pain relief and a short-acting opioid for limited rescue use when pain exceeds the routine level. If more than two opioids are being considered for long-term use, a second opinion from specialist who is Board Certified in Addiction, or Pain Medicine is strongly recommended. Short-acting “rescue” medications should be used with caution in patients with a potential for abuse. Buccal-delivered medications should not be used in this population. Transdermal medication use is generally not recommended.
- G) Use of acetaminophen-containing medications in patients with liver disease should be limited, including over the counter medications. Acetaminophen dose should not exceed 4 grams per day for short-term use nor 250 mg/day for long-term use in healthy patients. A safer chronic dose may be 1800mg/day.
- H) Continuing review of overall therapy plan with regard to non opioid means of pain control and functional status.
- I) Monitoring of behavior for signs of possible substance abuse indicating an increased risk for addiction and possible need for consultation with an addiction specialist.
- J) Tapering of opioids may be necessary due to the development of hyperplasias, decreased effects from an opioid, lack of compliance with the opioid contract, or intolerance of side effects. Some patients appear to

experience allodynia or hyperalgesia on chronic opioids. This premise is supported by a study of normal volunteers who received opioid infusions and demonstrated an increase in secondary hyperalgesia. This is thought to be relatively uncommon and more frequently associated with methadone. Options for treating this include withdrawing the patient from opioids and reassessing their condition. In some cases the patient will improve when off of the opioid. In other cases another opioid may be substituted.

- K) Inpatient treatment may be required for addiction or opioid tapering in complex cases. Refer to Section F.6, Interdisciplinary Rehabilitation Programs for detailed information on inpatient criteria.
- iv. Relative Contraindications – Extreme caution should be used in prescribing controlled substances for workers with one or more “relative contraindications”: Consultation with a pain or addiction specialist may be useful in these cases.
- A) History of alcohol or other substance abuse, or a history of chronic, benzodiazepine use.
 - B) Sleep apnea – if patient has symptoms of sleep apnea diagnostic tests should be pursued prior to chronic opioid use.
 - C) Off work for more than six months with minimal improvement in function from other active therapy.
 - D) Severe personality disorder or other known severe psychiatric disease.
- v. General Contraindications. The following are high risk warning signs for possible drug abuse or addiction. Patients with these findings should have a consultation by a pain and or addiction specialist.
- A) Active alcohol or other substance abuse.
 - B) Untreated mood or psychotic disorders (e.g., depression).
 - C) Decreased physical or mental function with continued opioid use.
 - D) Addictive behaviors. Warning signs include but are not limited to:
 - 1) Preoccupation with drugs.
 - 2) Refusal to participate in medication taper.

- 3) Reporting that nothing but a specific opioid works.
 - 4) Strong preference for short-acting over long-acting opioids.
 - 5) Use of multiple prescribers and pharmacies.
 - 6) Use of street drugs or other patient's drugs.
 - 7) Not taking medications as prescribed.
 - 8) Loss of medications more than once, and/or
 - 9) Criminal behaviors to obtain drugs, i.e., forged prescriptions.
- vi. Dosing and Time to Therapeutic Effect – Oral route is the preferred route of analgesic administration because it is the most convenient and cost-effective method of administration. Transbuccal administration should be avoided. When patient's dosage exceeds 120 mg of morphine per day and/or the patient is sedentary with minimal function, consideration should be given to lowering the dosage. Consultation may be necessary. When patients cannot take medications orally, rectal and transdermal routes should be considered because they are also relatively noninvasive. However, careful consideration should be given to the possible abuse potential of these forms of administration.
- vii. Major Side Effects – There is great individual variation in susceptibility to opioid-induced side effects and clinicians should monitor for these potential side effects. Common initial side-effects include nausea, vomiting, drowsiness, unsteadiness, and confusion. Occasional side-effects include dry mouth, sweating, pruritus, hallucinations, and myoclonus. Rare side effects include respiratory depression and psychological dependence. Constipation and nausea/vomiting are common problems associated with long-term opioid administration and should be anticipated, treated prophylactically, and monitored constantly. Stool softeners, laxatives and increased dietary fluid may be prescribed. Chronic sustained release opioid use is associated with decreased testosterone in males and females and estradiol in pre-menopausal females. Patients should be asked about changes in libido, sexual function, and fatigue.
- viii. Sedation - Driving and other tasks – Although some studies have shown that patients on chronic opioids do not function worse than patients not on medication, caution should be exerted and patients should be counseled never to mix opioids with the use of alcohol or other sedating medication. When medication is increased or trials are begun patients should not drive for at least 5 days. Chronic untreated pain and disordered sleep can also impair driving abilities.

- ix. Drug Interactions – Patients receiving opioid agonists should not be given a mixed agonist-antagonist such as pentazocine butorphanol because doing so may precipitate a withdrawal syndrome and increase pain.

All sedating medication, especially benzodiazepines should be avoided or limited to very low doses. Over the counter medications such as antihistamines, diphenhydramine, and prescription medications such as hydroxyzine should be avoided. Alcohol should not be used.

- x. Recommended Laboratory Monitoring– Primary laboratory monitoring is recommended for acetaminophen/ aspirin/NSAIDs combinations (renal and liver function, blood dyscrasias), although combination opioids are not recommended for long-term use. Morphine and other medication may require renal testing and other screening.
- xi. Sleep Apnea Testing- Both obstructive and central sleep apnea is likely to be exaggerated by opioid use or may occur secondary to higher dose chronic opioid use and combination medication use, especially benzodiazepines and sedative hypnotics. Patients should be questioned about sleep disturbance and family members or sleeping partners questioned about loud snoring or gasping during sleep. If present, qualified sleep studies and sleep medicine consultation should be obtained. Portable sleep monitoring units are generally not acceptable for diagnosing primary central sleep apnea. Type 3 portable units with 2 airflow samples and a O² saturation device may be useful for monitoring respirator depression secondary to opioids although there are no studies on this topic.
- xi. Regular consultation of the Prescription Drug Monitoring Program (PDMP) – Physicians should review their patient on the system whenever drug screens are done. This information should be used in combination with the drug screening results, functional status of the patient and other laboratory findings to review the need for treatment and level of treatment appropriate for the patient. There is a separate billing code created by the DOWC to cover this service. Refer to Rule 18, Medical Fee Schedule.
- xiii. Addiction – If addiction occurs, patients may require treatment, Refer to treatment section. After detoxification they may need long-term treatment with naltrexone, an antagonist which can be administered in a long-acting form or buprenorphine which requires specific education per the DEA.
- xiv. Potentiating Agents – There is some evidence that dextromethorphan does not potentiate the effect of morphine opioids and therefore is not recommended to be used with opioids.

- i. **Skeletal Muscle Relaxants:** are most useful for acute musculoskeletal injury or exacerbation of injury. Chronic use of benzodiazepines or any muscle relaxant is not recommended due to their habit-forming potential,

seizure risk following abrupt withdrawal, and documented contribution to deaths of patients on chronic opioids due to respiratory depression.

- i. Baclofen (intrathecal)
 - A) Description – May be effective due to stimulation of Gamma Aminobutyric Acid (GABA) receptors.
 - B) Indications – Pain from muscle rigidity. As of the time of this guideline writing, formulations of baclofen injection have been FDA approved for the management of severe spasticity of a spinal cord or cerebral origin
 - C) Side Effects –, exacerbation of psychotic disorders, may precipitate seizures in epileptics, dry mouth, and sexual dysfunction.
 - D) Recommended Laboratory Monitoring – Renal and hepatic function.

- ii. Cyclobenzaprine
 - A) Description – Structurally related to tricyclics.
 - B) Indications – Acute or exacerbated chronic pain associated with muscle spasm. As of the time of this guideline writing, formulations of this drug are FDA approved as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. It should only be used for short periods (2 to 3 weeks) because of lack of evidence for effectiveness with prolonged use.
 - C) Major Contraindications – Cardiac dysrhythmias
 - D) Dosing and Time to Therapeutic Effect – Variable, onset of action is 1 hour.
 - E) Major Side Effects – Sedation, anticholinergic, blurred vision. Patients should also be monitored for suicidal ideation and drug abuse.
 - F) Drug Interactions – Contraindicated for use with MAO inhibitors; interacts with tramadol, duloxetine, escitalopram, and fluoxetine. Likely interactions with other SRI'S and SNRI'S. Drug interactions are similar when used with tricyclics. Refer also to tricyclics.
 - G) Recommended Laboratory Monitoring – Hepatic and renal function.

- ii. Carisoprodol- This medication should not be used in chronic pain or CRPS patients due to its addictive nature secondary to the active metabolite meprobamate.

- iii. Metaxalone
 - A) Description – Central acting muscle relaxant.
 - B) Indications – Muscle spasm. As of the time of this guideline writing, formulations of metaxalone have been FDA approved as an adjunct to rest, physical therapy and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions.
 - C) Major Contraindications – significantly impaired renal or hepatic disease, pregnancy, and disposition to drug induced hemolytic anemia.
 - D) Dosing and Time to Therapeutic Effect – Onset of action 1 hour.
 - E) Major side effects – sedation, hematologic abnormalities.
 - F) Drug interactions – other sedating drugs (e.g. opioids, benzodiazepines)
 - G) Recommended Laboratory Monitoring – Hepatic Function, CBC.

- ii. Tizanidine
 - A) Description – Alpha 2 adrenergic agonist.
 - B) Indications – Spasticity, musculoskeletal disorders. As of the time of this guideline writing, formulations of tizanidine have been FDA approved for the management of spasticity.
 - C) Major Contraindications – concurrent use with ciprofloxacin or fluvoxamine; or hepatic disease.
 - D) Dosing and Time to Therapeutic Effect – 4 mg/day orally and gradually increase in 2-4 mg increments on an individual basis over 2-4 weeks; maintenance, 8 mg orally every 6-8 hr (max dose 36 mg/day)
 - E) Major Side Effects – Hypotension, sedation, hepatotoxicity, hallucinations and psychosis, dry mouth.
 - F) Drug Interactions – Alcohol can increase sedation, concurrent use with ciprofloxacin or fluvoxamine contraindicated. Several others increase tizanidine plasma concentrations - (e.g. oral contraceptives, verapamil, and cimetidine). Use with caution with other alpha agonists and other antihypertensives as they may increase the risk of hypotension.

- G) Laboratory Monitoring – Hepatic function, blood pressure.

j. Topical Drug Delivery:

- i. Description – Topical medications, such as lidocaine and capsaicin, may be an alternative treatment for neuropathic disorders and is an acceptable form of treatment in selected patients.
- ii. Indications – Neuropathic pain for most agents. Episodic use of NSAIDs and salicylates for joint pain. Patient selection must be rigorous to select those patients with the highest probability of compliance. Many patients do not tolerate the side effects for some medication or the need for frequent application.
- iii. Dosing and Time to Therapeutic Effect –All topical agents should be prescribed with strict instructions for application and maximum number of applications per day to obtain the desired benefit and avoid potential toxicity. There is no evidence that topical agents are more or less effective than oral medications. For most patients, the effects of long-term use are unknown and thus these medications be better used episodically.
- iv. Side Effects – Localized skin reactions may occur, depending on the medication agent used.
- v. Topical Agents.
 - a) Capsaicin – As of the time of this guideline writing, formulations of capsaicin have been FDA approved for management of pain associated with post-herpetic neuralgia. Capsaicin offers a safe and effective alternative to systemic NSAID therapy. Although it is quite safe, effective use of capsaicin is limited by the local stinging or burning sensation that typically dissipates with regular use, usually after the first 7 to 10 days of treatment. Patients should be advised to apply the cream on the affected area with a plastic glove or cotton applicator and to avoid inadvertent contact with eyes and mucous membranes.

There is good evidence that low dose capsaicin (0.075%) applied 4 times per day will decrease pain up to 50%. There is also good evidence that a high dose (8%) capsaicin patch applied for 60 minutes can decrease post herpetic neuralgic pain for 3 months and thus may be useful in other chronic neuropathies. The high dose patch is preceded by the application of a lidocaine patch and many patients require a schedule II opioid immediately after the treatment.
 - b) Ketamine and Tricyclics – Topical medications, such as the combination of ketamine and amitriptyline have been proposed as an alternative treatment for neuropathic

disorders including CRPS. A study using a 10% concentration showed no signs of systemic absorption. This low-quality study demonstrated decreased allodynia at 30 minutes for some CRPS patients. However, as of the time of this guideline writing, neither tricyclic nor ketamine topicals are FDA approved for topical use in neuropathic pain.

Furthermore, there is good evidence that neither 2% topical amitriptyline nor 1% topical ketamine reduces neuropathic pain syndromes. Low dose topical ketamine and topical amitriptyline are not recommended to be used in patients with neuropathic pain syndromes, including CRPS. Physiologically, it is possible that topical tricyclics and a higher dose of ketamine could have some effect on neuropathic pain. The use of topical tricyclics and/or ketamine should be limited to patients with neuritic and/or sympathetically mediated pain with documented supporting objective findings such as allodynia and/or hyperalgesia. Continued use of these agents beyond the initial prescription requires documentation of effectiveness, including functional improvement, and/or decreased use of other medications, particularly decreased use of opiates or other habituating medications.

- c) Lidocaine – As of the time of this guideline writing formulations of lidocaine (patch form) have been FDA approved for pain associated with post-herpetic neuralgia. Evidence is mixed for long-term use of lidocaine topically. Physicians should always take into account the blood level that may be achieved with topical use as toxic levels have been reported. There is some evidence that a 5% lidocaine patch may be used as a secondary option for patients with focal neuropathic pain. A 30 to 50% pain reduction may be achieved in those who tolerate the patch. Up to three patches may be used simultaneously for twelve hours per day. It should only be applied to intact skin. Metered dose 8% pump sprays have also been used and usually require a three times per day reapplication. There is some evidence that the 8% sprays are effective for short-term, 2 week use. However, the effects of long-term use are unknown.
- d) Topical Salicylates and Nonsalicylates –have been shown to be effective in relieving pain in acute musculoskeletal conditions and single joint osteoarthritis. Topical salicylate and nonsalicylates achieve tissue levels that are potentially therapeutic, at least with regard to COX inhibition. Other than local skin reactions, the side effects of therapy are minimal, although not non-existent and the usual contraindications to use of these compounds needs to be considered. Local skin reactions are rare and systemic effects were even less common. Their use in

patients receiving warfarin therapy may result in alterations in bleeding time. Overall, the low level of systemic absorption can be advantageous; allowing the topical use of these medications when systemic administration is relatively contraindicated such as is the case in patients with hypertension, cardiac failure, or renal insufficiency. There is good evidence that diclofenac gel reduces pain and improves function in mild-to-moderate hand osteoarthritis. As of the time of this guideline writing, formulations of diclofenac gel has been FDA approved for acute pain due to minor strains, pains, and contusions; and for relief of pain due to osteoarthritis of the joints amenable to topical treatment, such as those of the knees and hands.

- e) Other Compounded Topical Agents: At the time this guideline was written, no studies identified evidence for the effectiveness of compounded topical agents other than those recommended above. Therefore, other compounded topical agents are not generally recommended. In rare cases they may be appropriate for patients who prefer a topical medication to chronic opioids or have allergies or side effects from other more commonly used oral agents.
- f) Prior authorization is required for all agents that have not been recommended above. Continued use requires documentation of effectiveness including functional improvement and/or decrease in other medications.

k. Tramadol

- A) Description – An opioid partial agonist that does not cause GI ulceration, or exacerbate hypertension or congestive heart failure. It also inhibits the reuptake of norepinephrine and serotonin which may contribute to its pain relief mechanism. Side effects similar to opioid opioid side effects and may limit its use. They include nausea, sedation and dry mouth.
- B) Indications – Mild to moderate pain relief. As of the time of this guideline writing, formulations of tramadol has been FDA approved for management of moderate to moderately severe pain in adults. This drug has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs. There is some evidence that it alleviates neuropathic pain following spinal cord injury. However, given the effectiveness of other drug classes for neuropathic pain, tramadol should be considered a second line medication. It may be useful for patients who cannot tolerate tricyclic antidepressants.
- C) Contraindications – Use cautiously in patients who have a history of seizures or who are taking medication that may lower the seizure threshold, such as MAO inhibitors, SSRIs, and TCAs. Not recommended in

those with prior opioid addiction. Has been associated with deaths in those with an emotional disturbance or concurrent use of alcohol or other opioids. Significant renal and hepatic dysfunction requires dosage adjustment.

- D) Side Effects – May cause impaired alertness or nausea. This medication has physically addictive properties and withdrawal may follow abrupt discontinuation.
- E) Drug Interactions – Opioids, sedating medications, any drug that affects serotonin and/or norepinephrine (e.g. SNRI'S, SRI'S, MAOI'S, TCA'S).
- F) Laboratory Monitoring – Renal and hepatic function.

- 8. **ORTHOTICS/PROSTHETICS/EQUIPMENT** Devices and adaptive equipment are rarely necessary for CRPS patients as motion is to be encouraged. Specific devices may be useful in rare cases to aid in return to work duties.
- 9. **PATIENT EDUCATION** Patients should be educated on their specific injury, assessment findings, and plan of treatment and encouraged to take an active role in establishing functional outcome goals. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of prolonging the beneficial effects of rehabilitation, as well as facilitating self-management of symptoms and prevention of secondary disability.

In some cases, educational intervention combined with exercises may achieve results comparable to surgical intervention for patients who have undergone previous surgery. There is some evidence that, for patients who had undergone previous surgery for disc herniation and continued to experience low back pain for at least one year, educational lectures and materials provided to the patients in conjunction with exercise programs yield similar results as indicated by Oswestry Disability scores to patients who had undergone posterolateral low back fusion. It should be noted that the rehabilitation program included individual and group discussions targeted to assuring patients that participation in ordinary activities would not cause harm. Treatment period was 25 hours per week for three weeks.

Patient education is an interactive process that provides an environment where the patient not only acquires knowledge but also gains an understanding of the application of that knowledge. Therefore, patients should be able to describe and/or will need to be educated on:

- a. The treatment plan.
- b. Indications for and potential side effects of medications.
- c. Their home exercise program.
- d. Expected results of treatment.
- e. Tests to be performed, the reasons for them and their results.
- f. Activity restrictions and return-to-work status.

- g. Home management for exacerbations of pain.
- h. Procedures for seeking care for exacerbations after office hours.
- i. Home self-maintenance program.
- j. Patient responsibility to communicate with all medical providers and the employer, and
- k. Patient responsibility to keep appointments.
- l. The importance of taking medications exactly as prescribed.
- m. Basic physiology related to patient's diagnosis.

Educational efforts should also extend to family and other support persons, the case manager, the insurer and the employer as indicated to optimize the understanding of the patient and the outcome. Professional translators should be provided for non-English speaking patients to assure optimum communication. All education, teaching, and instruction given to the patient should be documented in the medical record.

Effects of education weaken over time; continuing patient education sessions will be required to maximize the patient's function. The effectiveness of educational efforts can be enhanced through attention to the learning style and receptivity of the patient. Written educational materials may reinforce and prolong the impact of verbal educational efforts. Overall, patient education should emphasize health and wellness, return to work and return to a productive life.

- ❖ Time to Produce Effect: Varies with individual patient.
- ❖ Frequency: At each visit.

10. **PERSONALITY/PSYCHOLOGICAL/PSYCHOSOCIAL/PSYCHIATRIC INTERVENTION**

Psychosocial treatment is a well-established therapeutic and diagnostic intervention with selected use in acute pain problems, and more widespread use in sub-acute and chronic pain populations. Psychosocial treatment is recommended as an important component in the total management of a patient with CRPS and should be implemented as soon as the problem is identified.

If a diagnosis consistent with the standards of the American Psychiatric Association Diagnostic Statistical Manual of Mental Disorders has been determined, the patient should be evaluated for the potential need for psychiatric medications. Use of any medication to treat a diagnosed condition may be ordered by the authorized treating physician or by the consulting psychiatrist. Visits for management of psychiatric medications are medical in nature and are not a component of psychosocial treatment. Therefore, separate visits for medication management may be necessary, depending upon the patient and medications selected.

Psychosocial interventions include psychotherapeutic treatments for mental health conditions, as well as behavioral medicine treatments for patients without psychiatric conditions, but who may need to make major life changes in order to

cope with pain or adjust to disability. Examples of these treatments include cognitive behavioral therapy, relaxation training, mindfulness training, and sleep hygiene training.

The screening or diagnostic workup should have clarified and distinguished between pre-existing, aggravated, and/or purely causative psychological conditions. Therapeutic and diagnostic modalities include, but are not limited to, individual counseling, and group therapy. Treatment can occur within an individualized model, a multi-disciplinary model, or within a structured pain management program.

A psychologist with a PhD, PsyD, EdD credentials, or a Psychiatric MD/DO may perform psychosocial treatments. Other licensed mental health providers or licensed health care providers with training in Cognitive Behavioral Therapy (CBT), or certified as a Cognitive Behavioral Therapist (CBT) working in consultation with a PhD, PsyD, EdD, or Psychiatric MD/DO; and with experience in treating chronic pain disorders in injured workers or certified as cognitive behavioral therapists may also perform treatment.

Cognitive behavioral therapy (CBT) refers to a group of psychological therapies that are sometimes referred to by more specific names, such as Rational Emotive Behavior Therapy, Rational Behavior Therapy, Rational Living Therapy, Cognitive Therapy, and Dialectic Behavior Therapy. Variations of CBT methods can be used to treat a variety of conditions, including chronic pain, depression, anxiety, phobias and PTSD. For patients with multiple diagnoses, more than one type of CBT might be needed. The CBT used in research studies is often “manualized CBT”, meaning that the treatment follows a specific protocol in a manual. In clinical settings, CBT may involve the use of standardized materials, but is also commonly adapted by a psychologist or psychiatrist to the patient’s unique circumstances. If the CBT is being performed by a non-mental health professional, a manual approach would be strongly recommended. CBT must be distinguished from neuropsychological therapies used to teach compensatory strategies to brain injured patients, which are also called “cognitive therapy.”

It should be remembered that most clinical trials on CBT exclude subjects who have significant psychiatric diagnoses. Consequently, the selection of patients for CBT should include the following considerations. CBT is instructive and structured, using an educational model with homework to teach inductive rational thinking. Because of this educational model, a certain level of literacy is assumed for most CBT protocols. Patients who lack the cognitive and educational abilities required by a CBT protocol are unlikely to be successful. Further, given the highly structured nature of CBT, it is more effective when a patient’s circumstances are relatively stable. For example, if a patient is about to be evicted, is actively suicidal, or coming to sessions intoxicated, these matters will generally preempt CBT treatment for pain, and require other types of psychotherapeutic response. Conversely, literate patients whose circumstances are relatively stable, but catastrophize or cope poorly with pain or disability are often good candidates for CBT for pain. Similarly, literate patients whose circumstances are relatively stable, but who exhibit unfounded medical phobias are often good candidates for CBT for anxiety.

There is good evidence that psychological interventions, especially CBT, are superior to no psychological intervention for chronic low back pain, and that self-regulatory interventions such as biofeedback and relaxation training may be equally effective. There is good evidence that 6 sessions of 1.5 hour group therapy focused on CBT skills improved function and alleviated pain in

uncomplicated subacute and chronic low back pain patients. There is some evidence that CBT provided in seven two-hour small group sessions can reduce the severity of insomnia in chronic pain patients. A Cochrane meta-analysis grouped very heterogeneous behavioral interventions and concluded that there is good evidence that CBT may reduce pain and disability but the effect size was uncertain. In total, the evidence clearly supports cognitive behavioral therapy and it should be offered to all chronic pain patients without other serious issues, as discussed above.

CBT is often combined with active therapy in an interdisciplinary program formal or informal. It must be coordinated with a psychologist or psychiatrist. Cognitive behavioral therapy can be done in a small group or individually and the usual number of treatments varies between 8 and 16 sessions.

Before CBT is done, the patient must have a full psychological evaluation. The CBT program must be done under the supervision of a PhD, PsyD, EdD, or Psychiatric MD/DO.

Psychological DSM Axis I disorders are common in chronic pain. One study demonstrated that the majority of patients who had failed other therapy and participated in a functional restoration program also suffered from major depression. However, in a program which included CBT and other psychological counseling the success rate for return to work was similar for those with and without a DSM IV diagnosis. This study further strengthens the argument for having some psychological intervention included in all chronic pain treatment plans.

For all psychological/psychiatric interventions, an assessment and treatment plan with measurable behavioral goals, time frames, and specific interventions planned, **must** be provided to the treating physician prior to initiating treatment. A status report **must** be provided to the authorized treating physician every two weeks during the initial more frequent treatment and monthly thereafter. The report should provide documentation of progress towards functional recovery and discussion of the psychosocial issues affecting the patient's ability to participate in treatment. The report should also address pertinent issues such as pre-existing, aggravated, and/or causative, as well as project realistic functional prognosis.

i. Cognitive Behavioral Therapy (CBT) or similar treatment:

- ❖ Time to Produce Effect: 6 to 8 1-2 hour session, group or individual, 1 hour individual or two-hour group.
- ❖ Maximum Duration: 16 sessions.

NOTE: Before CBT is done, the patient must have a full psychological evaluation. The CBT program must be done under the supervision of a PhD, PsyD, EdD, or Psychiatric MD/DO.

ii. Other psychological/psychiatric interventions:

- ❖ Time to Produce Effect: 6 to 8 weeks.
- ❖ Frequency: 1 to 2 times weekly for the first 2 weeks

(excluding hospitalization, if required), decreasing to 1 time per week for the second month. Thereafter, 2 to 4 times monthly with the exception of exacerbations which may require increased frequency of visits. Not to include visits for medication management:

- ❖ Optimum Duration: 2 to 6 months.
- ❖ Maximum: 6 months. Not to include visits for medication management. For select patients, longer psychological/psychiatric supervised treatment may be required, especially if there are ongoing medical procedures or complications. If counseling beyond 6 months is indicated, the management of psychosocial risks or functional progress must be documented. Treatment plan/progress must show severity.

11. **RESTRICTION OF ACTIVITIES** Continuation of normal daily activities is the recommendation for CRPS patients since immobility will negatively affect rehabilitation. Prolonged immobility results in a wide range of deleterious effects, such as a reduction in aerobic capacity and conditioning, loss of muscle strength and flexibility, increased segmental stiffness, promotion of bone demineralization, impaired disc nutrition, and the facilitation of the illness role.

Immobility may range from bed rest to the continued use of orthoses, such as cervical collars and lumbar support braces. While these interventions may have been ordered in the acute phase, the provider should be aware of their impact on the patient's ability to adequately comply with and successfully complete rehabilitation. There is strong evidence against the use of bed rest in acute low pain back cases without neurologic symptoms.

Patients should be educated to the detrimental effects of immobility versus the efficacious use of limited rest periods. Adequate rest allows the patient to comply with active treatment and benefit from the rehabilitation program. In addition, complete work cessation should be avoided, if possible, since it often further aggravates the pain presentation and promotes disability. Modified return-to-work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers with chronic pain.

12. **RETURN-TO-WORK**, and/or performance of work-related activities are one of the major components in chronic pain management and rehabilitation. There is some evidence that an integrated care program including workplace interventions and graded activity teaching that pain need not limit activity, is effective in returning patients with chronic low back pain to work, even with minimal reduction of pain. Return-to-work is a subject that should be addressed by each workers' compensation provider at the first meeting with the injured employee, and be updated at each additional visit. A return-to-work format should be part of a company's health plan, knowing that return-to-work can decrease anxiety, reduce the possibility of depression, and reconnect the worker with society.

Because a prolonged period of time off work will decrease the likelihood of return to work, the first weeks of treatment are crucial in preventing and/or reversing chronicity and disability mindset. In complex cases, experienced nurse case managers may be required to assist in return to work. Other services, including psychological evaluation and/or treatment, job site analysis, and vocational assistance may be employed.

The following should be considered when attempting to return an injured worker with chronic pain to work.

- a. **Job History Interview:** The authorized treating physician should perform a job history interview at the time of the initial evaluation and before any plan of treatment is established. Documentation should include the workers' job demands, stressors, duties of current job, and duties of job at the time of the initial injury. In addition, cognitive and social issues should be identified and treatment of these issues should be incorporated into the plan of care.
- b. **Coordination of Care:** Management of the case is a significant part of return to work and may be the responsibility of the authorized treating physician, occupational health nurse, risk manager, or others. Case management is a method of communication between the primary provider, referral providers, insurer, employer and employee. Because case management may be coordinated by a variety of professionals, the case manager should be identified in the medical record.
- c. **Communication:** is essential between the patient, authorized treating physician, employer and insurer. Employers should be contacted to verify employment status, job duties and demands, and policies regarding injured workers. In addition, availability of temporary and permanent restrictions, for what duration, as well as other placement options should be discussed and documented. All communications in the absence of the patient are required to be documented and made available to the patient.
- d. **Establishment of a Return-To-Work Status:** Return to work for persons with CRPS should be thought of as therapeutic, assuming that work is not likely to aggravate the basic problem or increase the discomfort. In most cases of chronic pain, the worker may not be currently working or even employed. The goal of return to work would be to implement a plan of care to return the worker to any level of employment with the current employer or to return them to any type of new employment.
- e. **Establishment of Activity Level Restrictions:** A formal job description for the injured/ill employee who is employed is necessary to identify physical demands at work and assist in the creation of modified duty. A jobsite evaluation may be utilized to identify tasks such as pushing, pulling, lifting, reaching above shoulder level, grasping, pinching, sitting, standing, posture, ambulatory distance and terrain, and if applicable, environment for temperature, air flow, noise and the number of hours that may be worked per day. Due to the lack of predictability regarding exacerbation of symptoms affecting function, an extended, occupationally focused functional capacity evaluation may be necessary to determine the patient's tolerance for job type tasks over a continuing period of time. Functional Capacity Evaluations should take place for 8 hours. Between one and three days after the evaluation, there should be a follow-up evaluation by the treating therapist and/or the authorized treating physician to assess the patient's status. When prescribing the FCE, the physician must assess the probability of return to work against the potential for exacerbation of the work related condition. Work restrictions assigned by the authorized treating physician may be temporary or permanent. The case manager should continue to seek out

modified work until restrictions become less cumbersome or as the worker's condition improves or deteriorates.

- f. **Rehabilitation and Return to Work:** As part of rehabilitation, every attempt should be made to simulate work activities so that the authorized treating physician may promote adequate job performance. The use of ergonomic or adaptive equipment, therapeutic breaks, and interventional modalities at work may be necessary to maintain employment.

- g. **Vocational Assistance:** Formal vocational assistance is a generally accepted intervention and can assist disabled persons to return to viable employment. Assisting patients to identify vocational goals will facilitate medical recovery and aid in the maintenance of MMI by (1) increasing motivation towards treatment and (2) alleviating the patient's emotional distress. Chronic pain patients will benefit most if vocational assistance is provided during the interdisciplinary rehabilitation phase of treatment. To assess the patient's vocational capacity, a vocational assessment utilizing the information from occupational therapy and physical therapy assessments may be utilized to identify rehabilitation program goals, as well as optimize both patient motivation and utilization of rehabilitation resources. This can be extremely helpful in decreasing the patient's fear regarding an inability to earn a living which can add to their anxiety and depression.

Recommendations to employers and employees of small businesses: employees who are diagnosed with chronic pain may not be able to perform any jobs for which openings exist. Temporary employees may fill those slots while the employee functionally improves. Some small businesses hire other workers and if the injured employee returns to the job, the supervisor/owner may have an extra employee. To avoid this, it is suggested that case managers be accessed through the payer or third party administrator. Case managers may assist with resolution of these problems, as well as assist in finding modified job tasks, or find jobs with reduced hours, etc., depending upon company philosophy and employee needs.

Recommendations to employers and employees of mid-sized and large businesses are encouraged by the Division to identify modified work within the company that may be available to injured workers with chronic pain who are returning to work with temporary or permanent restrictions. To assist with temporary or permanent placement of the injured worker, it is suggested that a program be implemented that allows the case manager to access descriptions of all jobs within the organization.

- 13. **THERAPY — ACTIVE** The following active therapies are widely used and (unless otherwise noted) accepted methods of care for a variety of work-related injuries. Active therapy is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range-of-motion, and can alleviate discomfort. All active therapy plans should be made directly with patients in the interest of achieving long-term individualized goals.

Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual and/or tactile instruction(s). Active therapy is intended to promote independence and self-reliance in managing the

physical pain as well as to improve the functional status in regard to the specific diagnosis and general conditioning and well-being. At times, a provider may help stabilize the patient or guide the movement pattern but the energy required to complete the task is predominately executed by the patient. Therapy in this section should not be merely a repeat of previous therapy but should focus specifically on the individual goals and abilities of the patient with CRPS.

The goal of active therapy is to teach the patient exercises that they can perform regularly on their own. Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Follow-up visits to reinforce and monitor progress and proper technique are recommended. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices.

Since CRPS and SMP patients frequently have additional myofascial pain generators, other active therapies not listed may be used in treatment. Refer to the Division's Chronic Pain Medical Treatment Guidelines for therapies and timeframe parameters not listed. The following active therapies are listed in alphabetical order:

- a. **Activities of Daily Living (ADL):** are instruction, active-assisted training, and/or adaptation of activities or equipment to improve a person's capacity in normal daily activities such as self-care, work re-integration training, homemaking and driving.
 - ❖ Time to Produce Effect: 4 to 5 treatments.
 - ❖ Frequency: 3 to 5 times per week.
 - ❖ Optimum Duration: 4 to 6 weeks.
 - ❖ Maximum Duration: 6 weeks.

- b. **Aquatic Therapy:** is a well-accepted treatment which consists of the therapeutic use of aquatic immersion for therapeutic exercise to promote strengthening, core stabilization, endurance, range-of-motion, flexibility, body mechanics, and pain management. Aquatic therapy is the implementation of active therapeutic procedures (individual or group) in a swimming or therapeutic pool heated to 88 to 92 degrees. The water provides a buoyancy force that lessens the amount of force of gravity applies to the body, and the pool should be large enough to allow full extremity range-of-motion and full erect posture. The decreased gravity effect allows the patient to have a mechanical advantage increases the likelihood of successful therapeutic exercise. Multiple limb involvement, weight bearing problems, and vasomotor abnormalities are frequently treated with water exercise. Indications for individuals who may not tolerate active land-based or full-weight-bearing therapeutic procedures, or who require augmentation or other therapy. The therapy may be indicated for individuals who:
 - cannot tolerate active land-based or full-weight bearing therapeutic procedures.

- require increased support in the presence of proprioceptive deficit.
- are at risk of compression fracture due to decreased bone density.
- have symptoms that are exacerbated in a dry environment.
- would have a higher probability of meeting active therapeutic goals than in a dry environment.

The pool should be large enough to allow full extremity range of motion and fully erect posture. Aquatic vests, belts and other devices can be used to provide stability, balance, buoyancy, and resistance.

- ❖ Time to Produce Effect: 4 to 5 treatments.
- ❖ Frequency: 3 to 5 times per week.
- ❖ Optimum Duration: 4 to 6 weeks.
- ❖ Maximum Duration: 6 Weeks. Multiple limb involvement may require longer intervention.

A self-directed program is recommended after the supervised aquatics program has been established, or, alternatively a transition to a self-directed dry environment exercise program.

- c. **Functional Activities:** are well-established interventions which involve the use of therapeutic activity to enhance mobility, body mechanics, employability, coordination, and sensory motor integration.

- ❖ Time to Produce Effect: 4 to 5 treatments.
- ❖ Frequency: 3 to 5 times per week.
- ❖ Optimum Duration: 4 to 6 weeks.
- ❖ Maximum Duration: 6 weeks.

- d. **Gait Training:** Indications include the need to promote normal gait pattern with assistive devices and/or to reduce risk of fall or loss of balance. This may include instruction in safety and proper use of assistive devices and gait instruction on uneven surfaces and steps (with or without railings).

- ❖ Time to Produce Effect: 1 to 6 sessions.
- ❖ Frequency: 1 to 3 times per week.
- ❖ Optimum Duration: 2 weeks. Could be needed intermittently as changes in functional status occur.
- ❖ Maximum Duration: 1 month.

- e. **Mirror Therapy- Graded Motor Imagery:** is a several week program that is accomplished through patient participation. It usually begins with limb laterality recognition, imagined motion, and mirror movements. Each phase gradually increases the number of repetitions. Therapy visits are once a week in the last phases and the treatment is performed at home at least 30 minutes per day. There is some evidence that this therapy improves function and pain in CRPS I patients. Therapy usually lasts 4-6 weeks for training and oversight. Most of the program is accomplished through patient participation at home. Time to produce effect is not known.
- ❖ Training period 4 to 8 lessons.
 - ❖ Optimum duration 4-6 weeks with two follow-up visits.
- f. **Neuromuscular Re-education:** is the skilled application of exercise with manual, mechanical, or electrical facilitation to enhance strength, movement patterns, neuromuscular response, proprioception, kinesthetic sense, coordination, education of movement, balance, and posture. Indications include the need to promote neuromuscular responses through carefully timed proprioceptive stimuli, to elicit and improve motor activity in patterns similar to normal neurologically developed sequences, and improve neuromotor response with independent control.
- ❖ Time to Produce Effect: 6 treatments.
 - ❖ Frequency: 1 to 3 times per week.
 - ❖ Optimum Duration: 4 to 8 weeks.
 - ❖ Maximum Duration: 8 to 12 weeks.
- f. **Stress Loading:** is considered a reflex and sensory integration technique involving the application of a compressive load and a carry load. It is carried out in a consistent, progressive manner and integrated as part of a home program. Use of this technique may increase symptoms initially, but symptoms generally subside with program consistency. This technique is used for upper as well as lower extremities
- ❖ Time to Produce Effect: 3 weeks.
 - ❖ Frequency: 2 to 3 times per week.
 - ❖ Optimum Duration: 4 to 6 weeks and concurrent with an active daily home exercise program.
 - ❖ Maximum Duration: 6 to 10 weeks.
- h. **Therapeutic Exercise:** with or without mechanical assistance or resistance, may include isoinertial, isotonic, isometric and isokinetic types of exercises. Indications include the need for cardiovascular fitness, reduced edema, improved muscle strength; improved connective tissue strength and integrity, increased bone density, promotion of circulation to enhance soft tissue healing, improvement of muscle

recruitment, improved proprioception, and coordination, and increased range of motion are used to promote normal movement patterns. Can also include alternative/complementary exercise movement therapy (with oversight of a physician or appropriate healthcare professional).

Therapeutic exercise programs should be tissue specific to the injury and address general functional deficits as identified in the diagnosis and clinical assessment. Patients should be instructed in and receive a home exercise program that is progressed as their functional status improves. Upon discharge, the patient would be independent in the performance of the home exercise program and would have been educated in the importance of continuing such a program. Educational goals would be to maintain or further improve function and to minimize the risk for aggravation of symptoms in the future.

- ❖ Time to Produce Effect: 2 to 6 treatments.
- ❖ Frequency: 3 to 5 times per week.
- ❖ Optimum Duration: 4 to 8 weeks and concurrent with an active daily home exercise program.
- ❖ Maximum Duration: 8 to 12 weeks of therapist oversight. Home exercise should continue indefinitely.

- h. **Work Conditioning:** These programs are work-related, outcome-focused, individualized treatment programs. Objectives of the program includes, but are not limited to, improvement of cardiopulmonary and neuromusculoskeletal functions (strength, endurance, movement, flexibility, stability, and motor control functions), patient education, and symptom relief. The goal is for patients to gain full or optimal function and return to work. The service may include the time-limited use of modalities, both active and passive, in conjunction with therapeutic exercise, functional activities, general conditioning body mechanics, and lifting techniques re-training. The patient should be assisted in learning to pace activities to avoid exacerbations.

These programs are usually initiated once re-conditioning has been completed but may be offered at any time throughout the recovery phase. It should be initiated when imminent return of a patient to modified- or full-duty is not an option, but the prognosis for returning the patient to work at completion of the program is at least fair to good.

- ❖ Length of Visit: 1 to 2 hours per day.
- ❖ Frequency: 2 to 5 visits per week.
- ❖ Optimum Duration: 2 to 4 weeks.
- ❖ Maximum Duration: 6 weeks. Participation in a program beyond 6 weeks must be documented with respect to need and the ability to facilitate positive symptomatic and functional gains.

- i. **Work Simulation:** is a program where an individual completes specific work-related tasks for a particular job and return to work. Use of this

program is appropriate when modified duty can only be partially accommodated in the work place, when modified duty in the work place is unavailable, or when the patient requires more structured supervision. The need for work place simulation should be based upon the results of a functional capacity evaluation and/or jobsite analysis.

- ❖ Length of Visit: 2 to 6 hours per day.
- ❖ Frequency: 2 to 5 visits per week.
- ❖ Optimum Duration: 2 to 4 weeks.
- ❖ Maximum Duration: 6 weeks. Participation in a program beyond 6 weeks must be documented with respect to need and the ability to facilitate positive symptomatic and functional gains.

14. **THERAPY—PASSIVE** Most of the following passive therapies and modalities are generally accepted methods (unless otherwise noted) of care for a variety of work-related injuries. Passive therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They should be used adjunctively with active therapies such as postural stabilization and exercise programs to help control swelling, pain, and inflammation during the active rehabilitation process. Please refer to Section B. 4. General Guideline Principles, Active Interventions. Passive therapies may be used intermittently as a therapist deems appropriate or regularly if there are specific goals with objectively measured functional improvements during treatment. Or if there are episodes of acute pain superimposed upon a chronic pain problem.

On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care and co-morbidities may extend durations of care. Having specific goals with objectively measured functional improvement during treatment can support extended durations of care. It is recommended that if after 6 to 8 visits no treatment effect is observed, alternative treatment interventions, further diagnostic studies or further consultations should be pursued.

The following passive therapies are listed in alphabetical order:

- a. **Continuous Passive Motion (CPM)**: is rarely indicated in CRPS but may occasionally be warranted if the patient shows signs of contracture despite active therapy.
- ❖ Time to Produce Effect: 4 to 6 treatments.
 - ❖ Frequency: Varies, between 2 to 3 times per day and 1 time per week.
 - ❖ Optimum Duration: 4 treatments.

- ❖ Maximum Duration: 6 treatments. Provide home unit with improvement.
- b. **Fluidotherapy:** Used primarily for desensitization and to facilitate increased active range of motion. Thermal heat conduction and convection is advantageous for vasodilation, muscle relaxation, and preparation for stress and activity (exercise).
- ❖ Time to Produce Effect: 3 treatments.
 - ❖ Frequency: 3 times per week.
 - ❖ Optimum Duration: 2 months.
 - ❖ Maximum Duration: 2 months as a primary therapy or intermittently as an adjunct therapy to other procedures.
- d. **Paraffin Bath:** Indications include the need to enhance collagen extensibility before stretching, reduce muscle guarding, and to prepare for functional restoration activities.
- ❖ Time to Produce Effect: 1 to 2 treatments.
 - ❖ Frequency: 1 to 3 times per week as an adjunct treatment to other procedures. May use daily if available at home.
 - ❖ Optimum Duration: 2 weeks.
 - ❖ Maximum Duration: 3 to 4 weeks. If effective, purchase a home unit.
- e. **Desensitization:** is accomplished through sensory integration techniques. Concurrent desensitization techniques are generally accepted as a treatment for CRPS. Home techniques using soft cloths of various textures, massage, and vibrators may be beneficial in reducing allodynia and similar sensory abnormalities.
- ❖ Time to Produce Effect: 6 treatments.
 - ❖ Frequency: 3 times per week and concurrent with home exercise program.
 - ❖ Optimum Duration: 3 weeks with reinforcement of home program.
 - ❖ Maximum Duration: 1 month.
- f. **Superficial Heat Therapy:** Superficial heat is a thermal agent applied to raise the body tissue temperature. It is indicated before exercise to elevate the pain threshold, alleviate muscle spasm, and promote increased movement. Heat packs can be used at home as an extension of therapy in the clinic setting.
- ❖ Time to Produce Effect: Immediate.

- ❖ Frequency: 1 to 3 times per week.
- ❖ Optimum Duration: 2 weeks as primary or intermittently as an adjunct to other therapeutic procedures.
- ❖ Maximum Duration: 2 weeks. Home use as a primary modality may continue at the providers' discretion.

H. THERAPEUTIC PROCEDURES – OPERATIVE

When considering operative intervention in CRPS management, the treating physician must carefully consider the inherent risk and benefit of the procedure. All operative intervention should be based on a positive correlation with clinical findings, the clinical course, and diagnostic tests. A comprehensive assessment of these factors should have led to a specific diagnosis with positive identification of the pathologic condition. Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions.

Surgical procedures are seldom meant to be curative and would be employed in conjunction with other treatment modalities for maximum functional benefit. Functional benefit should be objectively measured and includes the following:

- a. Return-to-work or maintaining work status.
- b. Fewer restrictions at work or performing activities of daily living.
- c. Decrease in usage of medications prescribed for the work-related injury.
- d. Measurable functional gains, such as increased range of motion or a documented increase in strength.

Education of the patient should include the proposed goals of the surgery, expected gains, risks or complications, and alternative treatment.

Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician. If a treating physician recommends a specific smoking cessation program peri-operatively, this should be covered by the insurer. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels. The surgeon will make the final determination as to whether smoking cessation is required prior to surgery.

Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

1. NEUROSTIMULATION

- a. Description: Spinal cord stimulation (SCS) is the delivery of low-voltage electrical stimulation to the spinal cord or peripheral nerves to inhibit or block the sensation of pain. The system uses implanted electrical leads and a battery powered implanted pulse generator.

Some evidence shows that SCS is superior to re-operation and conventional medical management for severely disabled patients who have failed conventional treatment and have Complex Regional Pain

Syndrome (CRPS I). These findings may persist at three years of follow-up in patients who had an excellent initial response and who are highly motivated.

It is particularly important that patients meet all of the indications before a permanent neurostimulator is placed because some literature has shown that workers' compensation patients are less likely to gain significant relief than other patients. As of the time of this guideline writing, spinal cord stimulation devices have been FDA approved as an aid to in the management of chronic intractable pain of the trunk and/or limbs, including unilateral and bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

Refer to Section, F. 3. Diagnostic Components of Confirmed CRPS, for the definition of confirmed CRPS which requires two positive diagnostic tests.

While there is no evidence demonstrating effectiveness for use of SCS with for CRPS II, it is generally accepted that SCS can be used for patients who have this condition. SCS may be most effective in patients with CRPS I or II who have not achieved relief with oral medications, rehabilitation therapy, or therapeutic nerve blocks, and in whom the pain has persisted for longer than 6 months

Particular technical expertise is required to perform this procedure and is available in some neurosurgical, rehabilitation, and anesthesiology training programs and fellowships. Physicians performing this procedure must be trained in neurostimulation implantation and participate in ongoing training workshops on this subject, such as those sponsored by the International Spine Intervention Society (ISIS) or as sponsored by implant manufacturers. Surgical procedures should be performed by surgeons, usually with a neurosurgical or spinal background.

- b. Complications: Serious, less common complications include spinal cord compression, paraplegia, epidural hematoma, epidural hemorrhage, undesirable change in stimulation, seroma, CSF leakage, infection, erosion, and allergic response. Other complications consist of dural puncture, hardware malfunction or equipment migration, pain at implantation site, loss of pain relief, chest wall stimulation, and other surgical risks. In recent studies device complication rates have been reported to be 25% at 6 months, 32% at 12 months, and 45% at 24 months. The most frequent complications are reported to be electrode migration (14%) and loss of paresthesia (12%).
- c. Surgical Indications: Patients with established CRPS I or II with persistent functionally limiting pain who have failed conservative therapy including active and/or passive therapy, pre-stimulator trial psychiatric evaluation and treatment, medication management, and therapeutic injections. Prior authorization is required. Habituation to opioid analgesics in the absence of a history of addictive behavior does not preclude the use of SCS. Patients with severe psychiatric disorders, and issues of secondary gain are not candidates for the procedure. Approximately, one third to one half of patients who qualify for SCS can expect a substantial reduction in pain relief; however, it may not influence allodynia, and hypesthesia. Patients' expectations need to be realistic, and therefore, patients should understand that the SCS

intervention is not a cure for their pain but rather a masking of their symptomatology which might regress over time. There appears to be a likely benefit of up to 3 years. Patients must meet the following criteria in order to be considered for neurostimulation:

- i. Confirmed CRPS I or II who have significant functional limitations from neuropathic pain involving the hand or foot after greater than 6 months of conventional management (Refer to Section, F. 3. Diagnostic Components of Confirmed CRPS, for the definition of confirmed CRPS which requires two positive diagnostic tests).
- ii. A comprehensive psychiatric or psychological evaluation *prior* to the stimulator trial has been performed. This evaluation should include a standardized detailed personality inventory with validity scales (such as MMPI-2, MMPI-2-RF, or PAI); pain inventory with validity measures (for example, BHI 2, MBMD); clinical interview and complete review of the medical records. Before proceeding to a spinal stimulator trial the evaluation should find the following:
 - No indication of falsifying information, or of invalid response on testing; and
 - No primary psychiatric risk factors or “red flags” (e.g. psychosis, active suicidality, or addiction), severe depression. (Note that tolerance and dependence to opioid analgesics are not addictive behaviors and do not preclude implantation); and
 - A level of secondary risk factors or “yellow flags” (e.g. moderate depression, job dissatisfaction, dysfunctional pain cognitions) judged to be below the threshold for compromising the patient’s ability to benefit from neurostimulation; and
 - The patient is cognitively capable of understanding and operating the neurostimulation control device; and
 - The patient is cognitively capable of understanding and appreciating the risks and benefits of the procedure; and
 - The patient has demonstrated a history of motivation in and adherence to prescribed treatments.

The psychologist or psychiatrist performing these evaluations should not be an employee of the physician performing the implantation. This evaluation must be completed, with favorable findings, before the trial is scheduled.

- iii. All reasonable surgical and non-surgical treatment has been exhausted; and

- iv. The topography of pain and its underlying pathophysiology are amenable to stimulation coverage (the entire painful extremity area has been covered); and
- v. A successful neurostimulation screening test of at least 3 to 7 days.

For a spinal cord neurostimulation screening test, a temporary lead is implanted at the level of pain and attached to an external source to validate therapy effectiveness. A screening test is considered successful if the patient meets both of the following criteria: (a) experiences a 50% decrease in CRPS pain, which may be confirmed by visual analogue scale (VAS) or Numerical Rating Scale (NRS), and (b) demonstrates objective functional gains or decreased utilization of pain medications. Objective, measurable, functional gains should be evaluated by an occupational therapist and/or physical therapist and the primary treating physician prior to and before discontinuation of the trial.

d. Contraindications:

- Unsuccessful SCS test – inability to obtain objective, documented, functional improvement or reduction of pain.
- Those with cardiac pacemakers should be evaluated on an individual basis as some may qualify for surgery.
- Patient who are unable to properly operate the system.
- Patients who are anti-coagulated and cannot be without anticoagulation for a few days (e.g. patients with artificial heart valves).
- Patients with frequent severe infections.
- Patients for whom a future MRI of a body part below the head is planned. MRI of the head is permissible with some manufacturers.

e. Operative Treatment: Implantation of stimulating leads connected by extensions to either an implanted neurostimulator or an implanted receiver powered by an external transmitter. The procedure may be performed either as an open or a percutaneous procedure, depending on the presence of epidural fibrosis and the anatomical placement required for optimal efficacy. During the final procedure the patient must be awakened to establish full coverage from the placement of the lead. One of the most common failures is misplaced leads. Functional improvement is anticipated for up to 3 years or longer when objective functional improvement has been observed during the time of neurostimulation screening exam.

f. Post-operative Considerations: MRI is contraindicated after placement of neurostimulators except for cranial imaging with some models.

- g. Post-operative Therapy: Active and/or passive therapy should be employed to improve function. Implantable stimulators will require frequent monitoring such as adjustment of the unit and replacement of batteries. Estimated battery life of SCS implantable devices is usually 5 – 10 years depending on the manufacturer.

2. PERIPHERAL NERVE STIMULATION

There are no randomized controlled studies for this treatment. This modality should only be employed with a clear nerve injury or when the majority of pain is clearly in a nerve distribution in patients who have completed 6 months of other appropriate therapy including pre-trial psychosocial evaluation and treatment. A screening trial should take place over 3 to 7 days and is considered successful if the patient meets both of the following criteria: (a) experiences a 50% decrease in pain, which may be confirmed by Visual Analogue Scale (VAS) or Numerical Rating Scale (NRS) and (b) demonstrates objective functional gains or decreased utilization of pain medications. Objective, measurable, functional gains should be evaluated by an occupational therapist and/or physical therapist and the primary treating physician prior to and before discontinuation of the trial. It may be used for proven occipital, ulnar, median and other isolated nerve injuries.

- 3. INTRATHECAL DRUG DELIVERY Not generally recommended. Requires prior authorization. Due to conflicting studies in this population and complication rate for long-term use, it may be considered only in very rare occasions when dystonia and spasticity are dominant features or when pain is not able to be managed using any other non-operative treatment. As of the time of this guideline writing, specific brands of drug infusion systems have been FDA approved for the following: chronic intraspinal (epidural and intrathecal) infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, chronic infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intrathecal infusion of baclofen for the management of severe spasticity.

- a. Description: This mode of therapy delivers small doses of medications directly into the cerebrospinal fluid.
- b. Complications: Intrathecal delivery is associated with significant complications, such as infection, catheter disconnects, CSF leak, arachnoiditis, pump failure, nerve injury, and paralysis.

Typical adverse events reported with opioids (ie, respiratory depression, tolerance, and dependence), or spinal catheter-tip granulomas that might arise during intrathecal morphine or hydromorphone treatment have not currently been recorded for ziconotide. The most common presentation of an intraspinal mass is a sudden increase in dosage required for pain relief, with new neurologic defects secondary to a mass effect. Technical errors can lead to drug overdose which can be life-threatening.

Surveys have shown technical problems requiring surgical correction in 18% to 40% of patients. CSF leakage may occur with multiple dural punctures. Since the needle is larger than the spinal catheter, there may be incomplete tissue sealing around the catheter. The function of the

pump depends on its electronic power source, which may be disrupted by the magnet of an MRI; therefore, after the patient has an MRI, the pump should be checked to ensure that it does not need to be restarted. The delivery rate can be affected by atmospheric pressure and body temperature.

- c. **Indications:** Clinical studies are conflicting, regarding long-term, effective pain relief in patients with non-malignant pain. The Division does not generally recommend the use of intrathecal drug delivery systems in injured workers with chronic pain. Due to the complication rate for long-term use, it may be considered only in very rare occasions when dystonia and spasticity are dominant features or when pain is not able to be managed using any other non-operative treatment. This treatment must be prior authorized and have the recommendation of at least one physician experienced in chronic pain management in consultation with the primary treating physician. The procedure should be performed by physicians with documented experience. This small eligible sub-group of patients must meet all of the following indications:
- i. A diagnosis of a specific physical condition known to be chronically painful has been made on the basis of objective findings; and
 - ii. All reasonable surgical and non-surgical treatment has been exhausted including failure of conservative therapy including active and/or passive therapy, medication management, or therapeutic injections; and
 - iii. Pre-trial psychiatric or psychological evaluation has been performed (as for SCS) and has demonstrated motivation and long-term commitment without issues of secondary gain. Significant personality disorders must be taken into account when considering a patient for IDD and other major procedures; and
 - iv. There is no evidence of current addictive behavior. (Tolerance and dependence to opioid analgesics are not addictive behaviors and do not preclude implantation); and
 - v. A successful trial of continuous infusion by a percutaneous spinal infusion pump for a minimum of 24 hours. A screening test is considered successful if the patient (a) experiences a 50% decrease in pain, which may be confirmed by VAS, and (b) demonstrates objective functional gains or decreased utilization of pain medications. Functional gains should be evaluated by an occupational therapist and/or physical therapist prior to and before discontinuation of the trial.
- d. **Contraindications:** Infection, body size insufficient to support the size and weight of the implanted device. Patients with other implanted programmable devices should be given these pumps with caution since interference between devices may cause unintended changes in infusion rates.

4. **SYMPATHECTOMY** Including use of phenol or radiofrequency.

Description – Destruction of part of the sympathetic nervous system, which is not generally accepted or widely used. Long-term success with this pain relief treatment is poor. Expected duration of pain relief is 3 to 5 months. There is currently a lack of evidence supporting long-term pain relief and increased pain can result. This procedure is generally not recommended and requires prior authorization. It may be considered for patients who are unable to return to normal activities of daily living when using the other non-operative treatments (as listed in Section G, Non-operative Procedures) and who meet the strict indications below.

Indications – Single extremity CRPS-I with a significant amount of sympathetically mediated ischemia and distal pain only. The procedure should not be done if the proximal extremity is involved. Local anesthetic Stellate Ganglion Block or Lumbar Sympathetic Block consistently gives 90 to 100 percent relief each time a technically good block is performed and results in a temperature difference between the affected and the unaffected extremity of at least 1 degree Celsius. The procedure may be considered for individuals who have limited duration of relief from blocks. Permanent neurological complications are common.

5. **AMPUTATION**

Amputation is not recommended in CRPS except in cases of gangrene.

I. MAINTENANCE MANAGEMENT

Successful management of chronic pain conditions results in fewer relapses requiring intense medical care. Failure to address long-term management as part of the overall treatment program may lead to higher costs and greater dependence on the health care system. Management of CRPS continues after the patient has met the definition of maximum medical improvement (MMI). MMI is declared when a patient's condition has plateaued and the authorized treating physician believes no further medical intervention is likely to result in improved function. When the patient has reached MMI, a physician must describe in detail the maintenance treatment.

Maintenance care in CRPS requires a close working relationship between the carrier, the providers, and the patient. Providers and patients have an obligation to design a cost-effective, medically appropriate program that is predictable and allows the carrier to set aside appropriate reserves. Carriers and adjusters have an obligation to assure that medical providers can design medically appropriate programs. A designated primary physician for maintenance team management is recommended.

Maintenance care will be based on principles of patient self-management. When developing a maintenance plan of care, the patient, physician and insurer should attempt to meet the following goals:

- a. Maximal independence will be achieved through the use of home exercise programs or exercise programs requiring special facilities (e.g., pool, health club) and educational programs.
- b. Modalities will emphasize self-management and self-applied treatment.
- c. Management of pain or injury exacerbations will emphasize initiation of active therapy techniques and may occasionally require anesthetic injection blocks.
- d. Dependence on treatment provided by practitioners other than the authorized treating physician will be minimized.
- e. Periodic reassessment of the patient's condition will occur as appropriate.
- f. Patients will understand that failure to comply with the elements of the self-management program or therapeutic plan of care may affect consideration of other interventions.

The following are Specific Maintenance Interventions and Parameters:

1. **HOME EXERCISE PROGRAMS AND EXERCISE EQUIPMENT** Most patients have the ability to participate in a home exercise program after completion of a supervised exercise rehabilitation program. Programs should incorporate an exercise prescription including the continuation of an age-adjusted and diagnosis-specific program for aerobic conditioning, flexibility, stabilization, and strength. Some patients may benefit from the purchase or rental of equipment to maintain a home exercise program. Determination for the need of home equipment should be based on medical necessity to maintain MMI, compliance

with an independent exercise program, and reasonable cost. Before the purchase or long-term rental of equipment, the patient should be able to demonstrate the proper use and effectiveness of the equipment. Effectiveness of equipment should be evaluated on its ability to improve or maintain functional areas related to activities of daily living or work activity. Home exercise programs are most effective when done 3 to 5 times a week. Prior to purchasing the equipment a therapist and/or exercise specialist who has treated the patient should visit a facility with the patient to assure proper use of the equipment. Occasionally, compliance evaluations may be made through a 4 week membership at a facility offering similar equipment.

2. **EXERCISE PROGRAMS REQUIRING SPECIAL FACILITIES** Some patients may have higher compliance with an independent exercise program at a health club versus participation in a home program. All exercise programs completed through a health club facility should focus on the same parameters of an age-adjusted and diagnosis-specific program for aerobic conditioning, flexibility, stabilization, and strength. Prior to purchasing a membership, a therapist and/or exercise specialist who has treated the patient should visit a facility with the patient to assure proper use of the equipment. Selection of health club facilities should be limited to those able to track attendance and utilization, and provide records available for physician and insurer review.
 - ❖ Frequency: 2 to 3 times per week.
 - ❖ Maximum Maintenance Duration: 3 months. Continuation beyond 3 months should be based on functional benefit and patient compliance. Health club membership should not extend beyond 3 months if attendance drops below 2 times per week on a regular basis.
3. **PATIENT EDUCATION MANAGEMENT** Educational classes, sessions, or programs may be necessary to reinforce self-management techniques. This may be performed as formal or informal programs, either group or individual.
 - ❖ Maintenance Duration: 2 to 6 educational visits during one 12 month period.
4. **PSYCHOLOGICAL MANAGEMENT** An ideal maintenance program will emphasize management options implemented in the following order: (a) individual self-management (pain control, relaxation and stress management, etc.), (b) group counseling, (c) individual counseling by a psychologist or psychiatrist, and (d) inpatient treatment. Exacerbation of the injury may require psychological treatment to restore the patient to baseline. In those cases, use treatments and timeframe parameters listed in the Biofeedback and Psychological Evaluation or Intervention sections.
 - ❖ Maintenance Duration: 6 to 10 visits during the first year and 4 to 6 visits per year thereafter. In cases of significant exacerbation, refer to the psychological treatment section in Therapeutic Procedures, Non-operative, Section G.
5. **NON-OPIOID MEDICATION MANAGEMENT** In some cases, self-management of pain and injury exacerbations can be handled with medications, such as those listed in the Medication section. Physicians must follow patients who are on any chronic medication or prescription regimen for efficacy and side effects.

Laboratory or other testing may be appropriate to monitor medication effects on organ function.

- ❖ Maintenance Duration: Usually, four medication reviews within a 12 month period. Frequency depends on the medications prescribed. Laboratory and other monitoring as appropriate.

6. **VITAMIN C:** There is some evidence that Vitamin C 500mg taken for 50 days after a wrist fracture may help to prevent CRPS. It may be useful to prescribe vitamin C to patients who historically have had or currently have CRPS if they suffer a fracture in order to prevent exacerbation of CRPS.
7. **OPIOID MEDICATION MANAGEMENT-** As compared with other painful conditions there may be a role for chronic augmentation of the maintenance program with opioid medications. In selected cases, scheduled medications may prove to be the most cost effective means of insuring the highest function and quality of life; however, inappropriate selection of these patients may result in a high degree of iatrogenic illness. A patient should have met the criteria in the opioids section of these guidelines before beginning maintenance opioids. Laboratory or other testing may be appropriate to monitor medication effects on organ function. The following management is suggested for maintenance opioids:
 - a. The medications should be clearly linked to improvement of function, not just pain control. All follow-up visits should document the patient's ability to perform routine functions satisfactorily. Examples include the abilities to perform: work tasks, drive safely, pay bills or perform basic math operations, remain alert and upright for 10 hours per day, or participate in normal family and social activities. If the patient is not maintaining reasonable levels of activity the patient should usually be tapered from the opioid and tried on a different long-acting opioid.
 - b. A low dose opioid medication regimen should be defined, which may minimally increase or decrease over time. Dosages will need to be adjusted based on side effects of the medication and objective function of the patient. A patient may frequently be maintained on additional non-opioid medications to control side effects, treat mood disorders, or control neuropathic pain; however, only one long-acting opioid and one short-acting opioid for rescue use should be prescribed in most cases. Buccally absorbed opioids are not appropriate for these non-malignant pain patients. Transdermal medication use is generally not recommended.
 - c. All patients on chronic opioid medication dosages need to sign an appropriate opioid contract with their physician for prescribing the opioids.
 - d. The patient must understand that continuation of the medication is contingent on their cooperation with the maintenance program. Use of non-prescribed drugs may result in tapering of the medication. The clinician should order random drug testing at least annually and when deemed appropriate to monitor medication compliance.
 - e. Patients on chronic opioid medication dosages must receive them through one prescribing physician.

- ❖ Maintenance Duration: Up to 12 visits within a 12 month period to review the opioid plan. Laboratory and other monitoring as appropriate.

8. **THERAPY MANAGEMENT-** Some treatment may be helpful on a continued basis during maintenance care if the therapy maintains objective function and decreases medication use. With good management, exacerbations should be uncommon; not exceeding two times per year and using minimal or no treatment modality beyond self-management. On occasion, exacerbated conditions may warrant durations of treatment beyond those listed below. Having specific goals with objectively measured functional improvement during treatment can support extended durations of care. It is recommended that if after 6 to 8 visits no treatment effect is observed, alternative treatment interventions should be pursued.

- ❖ Active Therapy, Acupuncture, or Manipulation Maintenance Duration: 10 visits [for each treatment] during the first year and then decreased to 5 visits per year thereafter.

9. **INJECTION THERAPY**

a. **Sympathetic Blocks** - These injections are considered appropriate if they increase function for a minimum of 4 to 8 weeks. Maintenance blocks are combined with and enhanced by the appropriate neuro-pharmacological medication(s) and an active self-management exercise program. It is anticipated that the frequency of the maintenance blocks may increase in the cold winter months or with stress.

- ❖ Maintenance Duration: Not to exceed 4 to 6 blocks in a 12 month period for a single extremity and to be separated by no less than 4 week intervals. Increased frequency may need to be considered for multiple extremity involvement or for acute recurrences of pain and symptoms. For treatment of acute exacerbations, consider 2 to 6 blocks with a short time interval between blocks.

b. **Trigger Point Injections** - These injections may occasionally be necessary to maintain function in those with myofascial problems. They are generally not recommended for CRPS as it is a neuropathic syndrome. Refer to the Division's Chronic Pain Medical Treatment Guidelines for treatment parameters.

- ❖ Maintenance Duration: Not more than 4 injections per session not to exceed 4 sessions per 12 month period.

10. **PURCHASE OR RENTAL OF DURABLE MEDICAL EQUIPMENT-** It is recognized that some patients may require ongoing use of self-directed modalities for the purpose of maintaining function and/or analgesic effect. Purchase or rental of modality based equipment should be done only if the assessment by the physician and/or therapist has determined the effectiveness, compliance, and improved or maintained function by its application. It is generally felt that large expense purchases such as spas, whirlpools, and special mattresses are not necessary to maintain function beyond the areas listed above.

- ❖ Maintenance Duration: Not to exceed 3 months for rental equipment.