

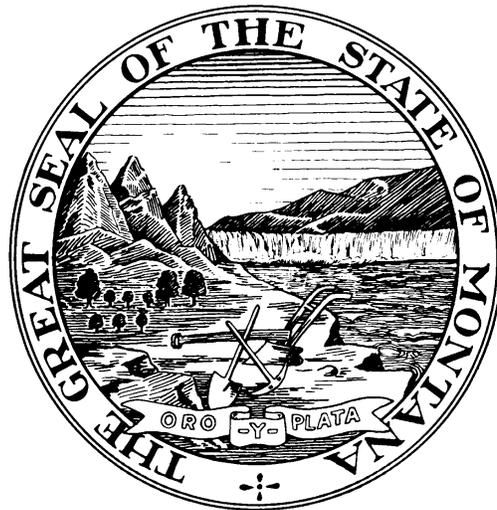
Chronic Pain Disorder

Montana Utilization and Treatment Guidelines

Effective July 1, 2014

**Presented by:
State of Montana**

**Department of Labor and Industry
EMPLOYMENT RELATIONS DIVISION**



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B. General Guideline Principles

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

1. APPLICATION OF GUIDELINES The Department provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the providers, payers, and patients through the Administrative Rules of Montana in lieu of more costly litigation, parties may wish to request an independent medical review from the Department's Medical Director prior to submitting a Petition for a Workers' Compensation Mediation Conference.

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 and disability. An education-based paradigm should start with communication providing reassuring information to the patient. A more in-depth education within a treatment regime employing functional restorative and innovative programs of prevention and rehabilitation is optimal. A treatment plan should address issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.

3. TREATMENT PARAMETER DURATION Timeframes 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 timeframes 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 Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.

6. FUNCTIONAL IMPROVEMENT GOALS should be consistently addressed. Positive patient response 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 (ROM), strength, endurance activities of daily living 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 timeframe, whenever possible. It is important to note that timeframes may not be pertinent to 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 be released to return to work with specific physical activity limitations clearly spelled out per the specific job requirement. Release to “sedentary” or “light duty” is not a specific physical limitation. 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 understand 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 health care professional with ergonomic experience, an occupational health nurse, a physical therapist, an occupational therapist, a vocational rehabilitation specialist, or an industrial hygienist.

11. DELAYED RECOVERY Strongly consider a psychological evaluation, if not previously provided, as well as initiating interdisciplinary rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after an injury. The Department 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. CARE BEYOND MAXIMUM MEDICAL IMPROVEMENT (MMI) should be declared when a patient’s condition has plateaued to the point where the authorized treating physician no longer believes further medical intervention is likely to result in improved function. However, some patients may require treatment after MMI has been declared in order to maintain their functional state. The recommendations in this guideline are for pre-MMI care and are not intended to limit post-MMI treatment.

C. Introduction to Chronic Pain

The International Association for the Study of Pain (IASP) defines pain as "an unpleasant sensory and emotional experience with actual or potential tissue damage." Pain is a complex experience embracing physical, mental, social, and behavioral processes that often compromises the quality of life of many individuals. Pain is an unpleasant subjective perception usually in the context of tissue damage.

Pain is subjective and cannot be measured or indicated objectively. Pain evokes negative emotional reactions such as fear, anxiety, anger, and depression. People usually regard pain as an indicator of physical harm, despite the fact that pain can exist without tissue damage and tissue damage can exist without pain. Many people report pain in the absence of tissue damage or any likely pathophysiologic cause. There is no way to distinguish their experience from that due to actual tissue damage. If they regard their experience as pain and they report it the same way as pain caused by tissue damage, it should be accepted as pain.

Pain can generally be classified as:

- Nociceptive which includes pain from visceral origins or damage to other tissues. Myofascial pain is a nociceptive type of pain characterized by myofascial trigger points limited to a specific muscle or muscles.
- Neuropathic including that originating from brain, peripheral nerves or both; and
- Psychogenic that originates in mood, characterological, social, or psychophysiological processes.

Recent advances in the neurosciences reveal additional mechanisms involved in chronic pain. In the past, pain was seen as a sensation arising from the stimulation of pain receptors by damaged tissue, initiating a sequence of nerve signals ending in the brain and there recognized as pain. A consequence of this model was that ongoing pain following resolution of tissue damage was seen as less physiological and more psychological than acute pain with identifiable tissue injury. Current research indicates that chronic pain involves additional mechanisms that cause: 1) neural remodeling at the level of the spinal cord and higher levels of the central nervous system; 2) changes in membrane responsiveness and connectivity leading to activation of larger pain pathways; and 3) recruitment of distinct neurotransmitters.

Changes in gene function and expression may occur, with lasting functional consequences. These physiologic functional changes cause chronic pain to be experienced in body regions beyond the original injury and to be exacerbated by little or no stimulation. The chronic pain experience clearly represents both psychologic and complex physiologic mechanisms, many of which are just beginning to be understood.

Chronic Pain is defined as "pain that persists for at least 30 days beyond the usual course of an acute disease or a reasonable time for an injury to heal or that is associated with a chronic

pathological process that causes continuous pain (e.g., reflex sympathetic dystrophy)." The very definition of chronic pain describes a delay or outright failure to relieve pain associated with some specific illness or accident. Delayed recovery should prompt a clinical review of the case and a psychological evaluation by the health care provider. Referral to a recognized pain specialist for further evaluation is recommended. Consideration may be given to new diagnostic testing or a change in treatment plan.

The term "chronic pain syndrome" has been used and defined in a variety of ways that generally indicate a belief on the part of the health care provider that the patient's pain is inappropriate or out of proportion to existing problems or illness. Use of the term "chronic pain syndrome" should be discontinued because the term ceases to have meaning due to the many different physical and psychosocial issues associated with it. Instead, practitioners should use the nationally accepted terminology indicated in the definition section and/or the psychiatric diagnosis of "Pain Disorder" and the subtypes according to established standards of the American Psychiatric Association (APA).

The International Association for the Study of Pain (IASP) offers taxonomy of pain, which underscores the wide variety of pathological conditions associated with chronic pain. This classification system may not address the psychological and psychosocial issues that occur in the perception of pain, suffering, and disability and may require referral to psychiatric or psychological clinicians. These issues should be documented with preference to the diagnostic categories of the Diagnostic and Statistical Manual of Mental Disorders (DSM), published by the American Psychiatric Association including the subcategories of pain disorder and any other applicable diagnostic categories (i.e., depressive, anxiety, and adjustment disorders). Pain disorder associated with general medical condition may be used for treatment; however, it may not be used to establish impairment therefore, more specific DSM coding of the condition is required when appropriate.

Chronic pain is a phenomenon not specifically relegated to anatomical or physiologic parameters. The prevailing biomedical model (which focuses on identified disease pathology as the sole cause of pain) cannot capture all of the important variables in pain behavior. While diagnostic labels may pinpoint contributory physical and/or psychological factors and lead to specific treatment interventions that are helpful, a large number of patients defy precise taxonomic classification. Furthermore, such diagnostic labeling often overlooks important social contributions to the chronic pain experience. Failure to address these operational parameters of the chronic pain experience may lead to incomplete or faulty treatment plans. The term "pain disorder" is perhaps the most useful term in the medical literature today, in that it captures the multi-factorial nature of the chronic pain experience.

It is recognized that some health care practitioners, by virtue of their experience, additional training, and/or accreditation by pain specialty organizations, have much greater expertise in the area of chronic pain evaluation and treatment than others. Referrals for the treatment of chronic pain should be to such recognized specialists. Chronic pain treatment plans should be monitored and coordinated by pain medicine physicians with such specialty training.

Most acute and some chronic pain problems are adequately addressed in other Department

treatment guidelines, and are generally beyond the scope of these guidelines. However, because chronic pain is more often than not multi-factorial, involving more than one pathophysiologic or mental disorder, some overlap with other guidelines is inevitable. These guidelines are meant to apply to any patient who fits the operational definition of chronic pain discussed at the beginning of this section.

D. Definitions

1. **ADDICTION** 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.
2. **AFTERSENSATION** Refers to the abnormal persistence of a sensory perception, provoked by a stimulus even though the stimulus has ceased.
3. **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.
4. **ANALGESIA** Absence of pain in response to stimulation that would normally be painful.
5. **BIOPSYCHOSOCIAL** A term that reflects the multiple facets of any clinical situation; namely, the biological, psychological, and social situation of the patient.
6. **CENTRAL PAIN** Pain initiated or caused by a primary lesion or dysfunction in the central nervous system.
7. **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.
8. **DEPENDENCE** 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.
9. **DYSESTHESIA** An abnormal sensation described by the patient as unpleasant. As with paresthesia, dysesthesia may be spontaneous or evoked by maneuvers on physical examination.

10. **HYPERALGESIA** Refers to an exaggerated pain response from a usually painful stimulation.
11. **HYPERESTHESIA (POSITIVE SENSORY PHENOMENA)** 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.
12. **HYPERPATHIA** A condition of altered perception such that stimuli which would normally be innocuous, if repeated or prolonged, result in severe explosive persistent pain.
13. **HYPOALGESIA** Diminished pain perception in response to a normally painful stimulus.
14. **HYPOESTHESIA (NEGATIVE SENSORY PHENOMENA)** (also hypesthesia), Diminished sensitivity to stimulation.
15. **MALINGERING** Intentional feigning of illness or disability in order to escape work or gain compensation. The differential diagnosis could be factitious disorder or somatoform disorder.
16. **MYOFASCIAL PAIN** A regional pain characterized by tender points in taut bands of muscle that produce pain in a characteristic reference zone.
17. **MYOFASCIAL TRIGGER POINT** A physical sign in a muscle which includes a) exquisite tenderness in a taut muscle band; and b) referred pain elicited by mechanical stimulation of the trigger point. The following findings may be associated with myofascial trigger points: 1) Local twitch or contraction of the taut band when the trigger point is mechanically stimulated; 2) Reproduction of the patient's spontaneous pain pattern when the trigger point is mechanically stimulated; 3) Weakness without muscle atrophy; 4) Restricted range of motion of the affected muscle; and 5) Autonomic dysfunction associated with the trigger point such as changes in skin or limb temperature.
18. **NEURALGIA** Pain in the distribution of a nerve or nerves.
19. **NEURITIS** Inflammation of a nerve or nerves.
20. **NEUROGENIC PAIN** Pain initiated or caused by a primary lesion, dysfunction, or transitory perturbation in the peripheral or central nervous system.
21. **NEUROPATHIC PAIN** Pain due to an injured or dysfunctional central or peripheral nervous system.
22. **NEUROPATHY** A disturbance of function or pathological change in a nerve: in one nerve, (mononeuropathy) in several nerves, (mononeuropathy multiplex); **OR** diffuse and bilateral, (polyneuropathy). Neuropathy should be associated with objective findings such as consistent sensory abnormalities, consistent motor findings (e.g. weakness, atrophy,

fasciculations, muscle cramping) and/or neuropathic abnormalities on EMG/nerve conduction testing.

23. **NOCICEPTOR** A receptor preferentially sensitive to a noxious stimulus or to a stimulus which would become noxious if prolonged.
24. **PAIN BEHAVIOR** The non-verbal 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.
25. **PAIN THRESHOLD** The smallest stimulus perceived by a subject as painful during laboratory testing. The term also loosely applies to the biological variation among human beings in sensing and coping with pain.
26. **PARESTHESIA** An abnormal sensation that is not described as pain. It can be either a spontaneous sensation (such as pins and needles) or a sensation evoked from non-painful or painful stimulation, such as light touch, thermal, or pinprick stimulus on physical examination.
27. **PERIPHERAL NEUROPATHIC PAIN** Pain initiated or caused by a primary lesion or dysfunction in the peripheral nervous system.
28. **SOMATIC DYSFUNCTION** Somatic dysfunction is impaired or altered function of related components of the somatic (body framework) system which includes skeletal, arthroal, and myofascial structures.
29. **SUMMATION** Refers to abnormally painful sensation to a repeated stimulus although the actual stimulus remains constant. The patient describes the pain as growing and growing as the same intensity stimulus continues.
30. **SYMPATHETICALLY MAINTAINED PAIN (SMP)** A pain that is maintained by sympathetic efferent innervations or by circulating catecholamines.
31. **TENDER POINTS** Tenderness on palpation at a tendon insertion, muscle belly or over bone. Palpation should be done with the thumb or forefinger, applying pressure approximately equal to a force of 4 kilograms (blanching of the entire nail bed).
32. **TOLERANCE** 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 of drug.

E. Initial Evaluation and Diagnostic Procedures

The Department 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.

E.1. History-taking and Physical Examination

History-taking and physical examination are generally accepted, well-established and widely used procedures that establish the foundation/basis for and dictate 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. The medical records should reasonably document the following:

E.1.a Medical History

As in other fields of medicine, a thorough patient history is an important part of the evaluation of chronic pain. In taking such a history, factors influencing a patient's 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:

1. General Information – General items requested are name, sex, age, birth date, etc.
2. Level of Education – The level of patients' education may influence response to treatment.
3. 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.
4. Current Employment Status
5. Marital Status
6. 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.
7. 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.

8. Belief System – The patient may refuse various treatments or may have an altered perception of his pain due to his particular beliefs.
9. 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.
10. Past and Present Psychological Problems
11. History of Abuse – Physical, emotional, sexual.
12. History of Disability in the Family
13. Sleep Disturbances
14. Causality: How did this injury occur? Was the problem initiated by a work-related injury or exposure?

E.1.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.

1. Site of Pain – localization and distribution of the pain help determine the type of pain the patient has (i.e., central versus peripheral).
2. Pain diagram drawings to document the distribution of pain
3. 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.
4. Duration
5. Place of onset. Circumstances during which the pain began (e.g. an accident, an illness, a stressful incident or spontaneous onset)
6. Pain Characteristics – Such as burning, shooting, stabbing, and 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
7. List of activities which aggravate or exacerbate, ameliorate, or have no effect on the level of pain.
8. 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?

E.1.c Medical Management History

1. Prior Treatment – Chronological review of medical records including previous medical evaluations and response to treatment interventions. In other words, what has been tried and which treatments have helped?
2. Prior Surgery – If the patient has had prior surgery specifically for the pain, he/she is less likely to have a positive outcome.
3. Medications – 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 Prescription Drug Registry through the Montana Board of Pharmacy.
4. Review of Systems Check List – Determine if there is any interplay between the pain complaint and other medical conditions.
5. Psychosocial Functioning - Determine if 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. Other confounding psychosocial issues may be present, including 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 chronic pain should be referred for a full psychosocial evaluation.
6. Diagnostic Tests – All previous radiological and laboratory investigations should be reviewed.
7. Pre-existing Conditions – Treatment of these conditions is appropriate when the pre-existing condition affects recovery from chronic pain.
8. Family history pertaining to similar disorders.

E.1.d Substance Use/Abuse

1. Alcohol use
2. Smoking History and use of nicotine replacements
3. History of current and prior prescription and street drug use or abuse
4. The use of caffeine or caffeine containing beverages
5. 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.1.e Other Factors Affecting Treatment Outcome

1. Compensation/Disability/Litigation
2. Treatment Expectations – What does the patient expect from treatment: complete relief of pain or reduction to a more tolerable level?

E.1.f Physical Examination

1. Neurologic Evaluation – Includes cranial nerves survey, muscle tone and strength, atrophy, detailed sensory examination (see below), motor evaluation (station, gait, coordination) reflexes (normal tendon reflexes and presence or absence of abnormal reflexes such as frontal lobe release signs or upper motor neuron signs, cerebellar testing and provocative neurological maneuvers.
2. Sensory Evaluation – A detailed sensory examination is crucial in evaluating a patient with chronic pain complaints. Quantitative sensory testing, such as Semmes-Weinstein, may be useful tools in determining sensory abnormalities. The examination should determine if the following sensory signs are present and consistent on repeated examination:
 - A) Hyperalgesia
 - B) Hyperpathia
 - C) Paresthesia
 - D) Dysesthesia
 - E) Mechanical Allodynia – static versus dynamic
 - F) Thermal Allodynia
 - G) Hypoesthesia
 - H) Hyperesthesia
 - I) Summation
3. Musculoskeletal Evaluation – Range of motion, segmental mobility, musculoskeletal provocative maneuvers, palpation, observation, and functional activities. All joints, muscles, ligaments, and tendons should be examined for asymmetry, swelling, laxity, and tenderness. A portion of the musculoskeletal evaluation is the myofascial examination. The myofascial examination includes palpating soft tissues for evidence of tightness and trigger points.
4. Evaluation of Nonphysiologic Findings
 - A) If applicable, Waddell Signs, which include 5 categories of clinical signs (1) tenderness- superficial and non-anatomic, (2) pain with simulation: axial loading and rotation, (3) regional findings: sensory and motor inconsistent with nerve root patterns (4) distraction /inconsistency in straight leg raising findings, and (5) over-reaction to physical examination maneuvers. Significance may be attached to positive findings in 3 out of 5 of these categories, but not to isolated findings. Waddell advocates considering Waddell's signs prior to recommending a surgical procedure. These signs should be measured routinely to identify patients requiring further assessment (i.e., biopsychosocial) prior to undergoing back surgery.

It is generally agreed that Waddell signs are associated with decreased functional performance and greater subjective pain levels, though they provide no information on the etiology of pain. Waddell Signs cannot be used to predict or diagnose malingering. The presence of 3 out of 5 signs may most appropriately be viewed as a “yellow flag”, or screening test, alerting clinicians to those patients who require a more comprehensive approach to their assessment and care plan. Therefore, for chronic back pain, a psychosocial evaluation is highly recommended to be part of the total evaluation of the patient. Refer to Section E. 2, Personality/Psychological/Psychosocial Evaluation for Pain Management.

B) Variabilities on formal exam including variable sensory exam, inconsistent tenderness, and/or swelling secondary to extrinsic sources.

C) Inconsistencies between formal exam and observed abilities of range of motion, motor strength, gait and cognitive/emotional state should be noted in the assessment.

D) Observation of consistencies between pain behavior, affect and verbal pain rating, and affect and physical re-examination.

E.2 Personality/Psychological/Psychosocial Evaluation for Pain Management

Personality/Psychological/Psychosocial Evaluation 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 and chronic pain 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 interventions are indicated for patients diagnosed with chronic pain. 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 chronic pain, 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 psychometric testing 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 diagnostic information.

All patients who are diagnosed as having chronic pain are highly recommended to 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 chronic pain conditions.

E.2.a Qualifications

1. 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 chronic pain disorders in injured workers.
2. Psychometric tests may 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.

E.2.b Clinical Evaluation

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

1. 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.
 - A) Nature of injury
 - B) Psychosocial circumstances of the injury
 - C) Current symptomatic complaints
 - D) Extent of medical corroboration
 - E) Treatment received and results
 - F) Compliance with treatment
 - G) Coping strategies used, including perceived locus of control, catastrophizing, and risk aversion
 - H) Perception of medical system and employer
 - I) History of response to prescription medications
2. Health History
 - A) Nature of injury

- B) Medical history
 - C) Psychiatric history
 - D) History of alcohol or substance abuse
 - E) Activities of daily living
 - F) Previous injuries, including disability, impairment, and compensation
3. Psychosocial history
 - A) Childhood history, including abuse/neglect
 - B) Educational history
 - C) Family history, including disability
 - D) Marital history and other significant adulthood activities and events
 - E) Legal history, including criminal and civil litigation
 - F) Employment history
 - G) 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
 - H) Signs of pre-injury psychological dysfunction
 - I) Current interpersonal relations, support, living situation
 - J) Financial history
 4. Mental status exam including cognition, affect, mood, orientation, thinking, and perception. May include mini mental status exam or frontal assessment battery if appropriate
 5. Assessment of any danger to self or others.
 6. Psychological test results, if performed
 7. Current psychiatric diagnosis consistent with the standards of the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders.
 8. Pre-existing psychiatric conditions. Treatment of these conditions is appropriate when the pre-existing condition affects recovery from chronic pain.
 9. Causality (to address medically probable cause and effect, distinguishing pre-existing psychological symptoms, traits and vulnerabilities from current symptoms).
 10. Treatment recommendations with respect to specific goals, frequency, timeframes, and expected outcomes.

E.2.c 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. The report should include symptom validity, effort, and likelihood to respond to invasive treatment. While there is no general agreement as to which

psychometric tests should be specifically recommended for psychological evaluations of chronic pain conditions, standardized tests are preferred over those which are not for assessing diagnosis.

In contrast, non-standardized tests can be useful for “positive” 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 chronic pain 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. If the identified reading level of the injured worker is below the sixth grade, then oral administration of these tests may be warranted. Examples of frequently used psychometric tests performed include, but not limited to the following:

Comprehensive Inventories for Medical Patients

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

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, somatic preoccupation, and help 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 on patients with chronic pain or injury and on community members, with reference groups for six other subcategories of injured patients.

B) Millon Behavioral Medical Diagnostic (MBMD™)

What it measures – Updated version of the Millon Behavioral Health Inventory (MBHI). Provides information on Coping Styles (introversive, 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.

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 part of a comprehensive evaluation, can screen for a broad range of DSM diagnoses.

Characteristics – Standardized test normaled on psychiatric patients.

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

What it measures – Original scale constructs, such as hysteria and psychesthenia 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-RF®).

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. The new version is designated MMPI-2-RF.

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

D) Personality Assessment Inventory (PAI)

What it measures – A good measure of general psychopathology. Measures 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.

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) 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.

C) 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.

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

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.

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.

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 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 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 professional evaluation to verify diagnosis.

Characteristics – Non-standardized test without norms.

E.3 Diagnostic Studies

Imaging of the spine and/or extremities is a generally accepted, well-established, and widely used diagnostic procedure when specific indications, based on history and physical examination, are present. Physicians should refer to individual Department guidelines for specific information about specific testing procedures. Test should be performed to rule in or out specific diagnoses.

1. Radiographic Imaging, MRI, CT, bone scan, radiography, and other special imaging studies may provide useful information for many musculoskeletal disorders causing chronic pain. Most imaging is likely to demonstrate aging changes which are usually not pathologic. Refer to specific guidelines for details. Patients should be informed before the test is performed about the purpose of the exam, e.g. to rule out unsuspected cancer, and the likelihood that nonpathologic aging changes will be found.
2. Electrodiagnostic studies may be useful in the evaluation of patients with suspected myopathic or neuropathic disease and may include Nerve Conduction Studies (NCS), Standard Needle Electromyography, or Somatosensory Evoked Potential (SSEP). The evaluation of electrical studies is difficult and should be relegated to specialists who are well trained in the use of this diagnostic procedure.
3. Special Testing Procedures may be considered when attempting to confirm the current diagnosis or reveal alternative diagnosis. In doing so, other special tests may be performed at the discretion of the physician.
4. Testing for complex regional pain syndrome (CRPS-I) or sympathetically maintained pain (SMP) is described in the Department's Complex Regional Pain Syndrome Medical Treatment Guidelines.

E.4 Laboratory Testing

Laboratory testing is 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:

1. Complete Blood Count (CBC) with differential can detect infection, blood dyscrasias, and medication side effects;

2. Erythrocyte sedimentation rate, rheumatoid factor, antinuclear antigen (ANA), human leukocyte antigen (HLA), and C-reactive protein can be used to detect evidence of a rheumatologic, infection, or connective tissue disorder;
3. 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);
4. Serum calcium, phosphorous, uric acid, alkaline phosphatase, and acid phosphatase can detect metabolic bone disease;
5. Urinalysis to detect bacteria (usually with culture and sensitivity), calcium, phosphorus, hydroxyproline, or hematuria;
6. Liver and kidney function may be performed for baseline testing and monitoring of medications; and
7. Toxicology Screen. Serum and/or urine may be performed as appropriate. A blood alcohol level may also be appropriate if alcohol abuse is suspected.

E.5 Injections - Diagnostic

E.5.a Spinal Diagnostic Injections

Diagnostic injections should not be done merely to identify all possible pain generators. The indications for the diagnostic injections must be met and a specific therapeutic goal clarified to justify the need for further diagnostic injections.

Description — generally accepted, well-established procedures. These injections may be useful for localizing the source of pain, and may have added therapeutic value when combined with injection of therapeutic medication(s). Each diagnostic injection has inherent risks, 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 indicating strong suspicion for pathologic condition(s) and the source of pain symptoms.

Because injections are invasive with an inherent risk, the number of diagnostic procedures should be limited in any individual patient to those most likely to be primary pain generators. Patients should not receive all of the diagnostic blocks listed merely in an attempt to identify 100% of the pain generators.

The interpretation of the test results are primarily based on functional change, symptom report, and pain response (via a recognized pain scale before and at an appropriate time after the injection). The diagnostic significance of the test result should be evaluated in conjunction with clinical information and the results of other diagnostic procedures. Injections with local anesthetics of differing duration may be used to support a diagnosis. In some cases, injections at

multiple levels may be required to accurately diagnose cervical conditions. Refer to Section F.5 on Injections – Therapeutic for information on specific injections.

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the diagnostic value of the procedure is evident to other reviewers. This entails, at a minimum, documentation of patient response immediately following the procedure with details of any symptoms with a response and the degree of response. Additionally, a log must be recorded as part of the medical record which documents response, if any, on an hourly basis for, at a minimum, the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, neck, leg, or arm pain). The physician must identify the local anesthetic used and the expected duration of response for diagnostic purposes.

Multiple injections provided at the same session without staging may seriously dilute the diagnostic value of these procedures. Physicians must carefully weigh the diagnostic value of the procedure against the possible therapeutic value.

Special Requirements for Diagnostic Injections - Since multi-planar, fluoroscopy during procedures is required to document technique and needle placement, an experienced physician should perform the procedure. Permanent images are required to verify needle placement for all spinal procedures. The subspecialty disciplines of the physicians performing injections may be varied, including, but not limited to: anesthesiology, radiology, surgery, or physiatry. The physician who performs spinal injections for low back pain should document hands-on training through workshops of the type offered by organizations such as the International Spine Intervention Society (ISIS) and/or completed fellowship training with interventional training. The physician who performs spinal injections for cervical pain should have completed fellowship training in pain medicine with interventional training, or its equivalent. Physicians performing spinal injections for low back and cervical pain should obtain fluoroscopy training and must also have appropriate training in radiation safety, usually overseen by a radiation safety officer.

Complications - General complications of diagnostic injections may include transient neurapraxia, nerve injury, infection, headache, vasovagal effects, as well as epidural hematoma, permanent neurologic damage, dural perforation and CSF leakage, and spinal meningeal abscess. Severe complications of cervical injections are remote but can include spinal cord damage, quadriplegia, and/or death. Injections at a C2-C3 level frequently cause temporary neuritis with ataxia.

Contraindications - Absolute contraindications to 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 of diagnostic injections may include: (a) allergy to contrast or shellfish, (b) poorly controlled Diabetes Mellitus and/or hypertension. Drugs affecting coagulation require restriction from use. Decisions regarding the number of restricted days should be made in consultation with the prescribing physician and other knowledgeable experts.

Specific Diagnostic Injections - In general, relief should last for at least the duration of the local anesthetic used and should significantly relieve pain and result in functional improvement. Refer to Section F.5 Injections-Therapeutic for information on other specific therapeutic injections. The following injections are used primarily for diagnosis:

E.5.a.i Medial Branch Blocks

Medial Branch Blocks are primarily diagnostic injections, used to determine whether a patient is a candidate for radiofrequency medial branch neurotomy (also known as facet rhizotomy). ISIS suggests controlled blocks – using either placebo or anesthetics with varying lengths of activity (i.e., bupivacaine longer than lidocaine). To be a positive diagnostic block, the patient should report a reduction of pain of 80% or greater relief from baseline for the length of time appropriate for the local anesthetic used. In almost all cases, this will mean a reduction of pain to 1 or 2 on the visual analog scale (VAS) 10-point scale correlated with functional improvement. The patient should also identify activities of daily living (which may include measurements of range of motion) that are impeded by their pain and can be observed to document functional improvement in the clinical setting. Ideally, these activities should be assessed throughout the observation period for function. The observer should not be the physician who performed the procedure. It is suggested that this be recorded on a form similar to ISIS recommendations.

A separate comparative block on a different date should be performed to confirm the level of involvement. A comparative block uses anesthetics of varying lengths of activity. Medial Branch blocks are probably not helpful to determine the likelihood of success for spinal fusion.

- Frequency and Maximum Duration: May be repeated once for comparative blocks. Limited to 4 levels.

E.5.a.ii Transforaminal Injections

Transforaminal Injections are useful in identifying spinal pathology. When performed for diagnosis, small amounts of local anesthetic up to a total volume of 1.0 cc should be used to determine the level of nerve root irritation. A positive diagnostic block should result in a positive diagnostic functional benefit and an 80% reduction in nerve-root generated pain appropriate for the anesthetic used as measured by accepted pain scales (such as a VAS).

- Time to produce effect: Less than 30 minutes for local anesthesia; corticosteroids up to 72 hours for most patients
- Frequency and Maximum Duration: Once per suspected level. Limited to two levels

E.5.a.iii Zygapophyseal (Facet) Blocks

Facet blocks are generally accepted but should not be considered diagnostic blocks for the purposes of determining the need for a rhizotomy (radiofrequency medial branch neurotomy), nor should they be done with medial branch blocks.

These blocks should not be considered a definitive diagnostic tool. They may be used

diagnostically to direct functional rehabilitation programs. A positive diagnostic block should result in a positive diagnostic functional benefit and an 80% reduction in pain appropriate for the anesthetic used as measured by accepted pain scales (such as a Visual Analog Scale). They then may be repeated per the therapeutic guidelines when they are accompanied by a functional rehabilitation program. (Refer to Section F. 5. a. Therapeutic Spinal Injections).

- Time to produce effect: Less than 30 minutes for local anesthesia; corticosteroids up to 72 hours for most patients
- Frequency and Maximum Duration: Once per suspected level, limited to two levels

E.5.a.iv Atlanto-Axial and Atlanto-Occipital Injections

Atlanto-Axial and Atlanto-Occipital Injections are generally accepted for diagnosis and treatment but do not lend themselves to denervation techniques owing to variable neuroanatomy. Injection of this articulation is complicated by the proximity of the vertebral artery, which may be tortuous at the level of the C1 joint. Inadvertent injection of the vertebral artery may cause respiratory arrest, seizure, stroke, or permanent neurological sequelae. Only practitioners skilled in these injections should perform them.

- Frequency and Maximum Duration: Once per side

E.5.a.v Sacroiliac Joint Injection

Description - a generally accepted injection of local anesthetic in an intra-articular fashion into the sacroiliac joint under fluoroscopic guidance. Long-term therapeutic effect has not yet been established.

Indications - Primarily diagnostic to rule out sacroiliac joint dysfunction versus other pain generators. Intra-articular injection can be of value in diagnosing the pain generator. There should be documented relief from previously painful maneuvers (e.g., Patrick's test) and at least 80% pain relief on post-injection physical exam (as measured by accepted pain scales such as VAS) correlated with functional improvement. Sacroiliac joint blocks should facilitate functionally directed rehabilitation programs.

- Time to produce effect: Up to 30 minutes for local anesthetic
- Frequency and Maximum Duration: 1

E.5.b Other Diagnostic Injections

These injections are frequently employed in assessing the type of pain a patient may be having. They also aid in ascertaining possible mechanisms and origins of the pain as well as the site of the pain source. Some diagnostic injections have therapeutic properties that may be used to both diagnose and treat chronic pain. In those cases, refer to Section F.5 Injections-Therapeutic for specific information regarding these injections.

Description - generally accepted, well-established procedures. These injections may be useful

for localizing the source of pain, and may have added therapeutic value when combined with injection of therapeutic medication(s). Each diagnostic injection has inherent risks, 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 indicating strong suspicion for pathologic condition(s) and the source of pain symptoms.

The interpretation of the test result is primarily based upon pain response; the diagnostic significance of the test result should be evaluated in conjunction with clinical information and the results of other diagnostic procedures. 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 F.5 Injections-Therapeutic for information on specific injections.

Special Requirements for Diagnostic Injections - Since fluoroscopic, arthrographic and/or CT guidance during procedures is required to document technique and needle placement, an experienced physician should perform the procedure. The subspecialty disciplines of the physicians may be varied, including, but not limited to: anesthesiology, radiology, surgery, or physiatry. The practitioner should have experience in ongoing injection training workshops provided by organizations such as the International Spine Injection Society (ISIS). In addition, practitioners should obtain fluoroscopy training and must have the appropriate training in radiation safety, usually overseen by a radiation safety officer.

Complications - General complications of diagnostic injections may include transient neurapraxia, nerve injury, infection, headache, vasovagal effects, as well as epidural hematoma, permanent neurologic damage, dural perforation and CSF leakage, and spinal meningeal abscess. Severe complications of cervical injections are remote but can include spinal cord damage, quadriplegia, and/or death.

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 of diagnostic injections may include: (a) allergy to contrast or shellfish, (b) poorly controlled Diabetes Mellitus 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.

Specific Diagnostic Injections - In general, relief should last for at least the duration of the local anesthetic used and give significant relief of pain. Refer to Section F.5 Injections-Therapeutic for information on other specific therapeutic injections. The following injections are used primarily for diagnosis:

1. Sympathetic Injections: are diagnostic injections that may be used in suspected cases of CRPS-I. Refer to the Department's Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy Medical Treatment Guidelines for specific information regarding the use of these injections.
2. Peripheral Nerve Blocks: are diagnostic injections that may be used in for specific nerve injury or entrapment syndromes. Not all peripheral nerve blocks require fluoroscopy. On occasion they are used for treatment in chronic pain or CRPS. Repeat injection for treatment should be based on functional changes. These injections are usually limited to 3 injections per site per year.

E.6 Special Tests

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.

E.6.a Computer-Enhanced Evaluations

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.

E.6.b Functional Capacity Evaluation (FCE)

Functional Capacity Evaluation (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. This test may also be known as Physical Capacity Evaluation, Functional Capacity Assessment, and Work Capacity Evaluation. 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; and (i) validity of effort and reproducibility. Standardized national guidelines (such as National Institute for Occupational Safety and Health (NIOSH)) should be used as the basis for FCE recommendations.

When an 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 or to determine permanent work restrictions. Prior authorization is required for FCEs performed during treatment.

E.6.c Job Site Evaluation

Job Site Evaluation is a comprehensive analysis of the physical, mental, and sensory components of a specific job. The goal of the Job Site 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 by a qualified individual (e.g., physical therapist, occupational therapist, vocational rehabilitation counselor, nurse case manager, etc.).

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 practitioner 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.

E.6.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 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.6.e Work Tolerance Screening (Fitness for Duty)

Work Tolerance Screening 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.

F. Therapeutic Procedures - Non-operative

Non-operative therapeutic rehabilitation is applied to patients with 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:

1. 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 F.12 Return-to-Work in this section for detailed information.
2. 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
 - Measurable functional gains, such as increased range of motion or documented increase in strength.
3. 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.
4. Psychological or psychosocial screening should be performed on all chronic pain patients.

The following procedures are listed in alphabetical order.

F.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 on myofascial trigger points. Refer to Section F.5.d Trigger Point Injections.

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.

F.1.a Acupuncture

Acupuncture without electrical stimulation 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.

F.1.b Acupuncture with Electrical Stimulation

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.

There is some evidence that a combination of electrical acustimulation to the wrist combined with neck stretching and strengthening exercises for 30 minutes two times per week for a period of about 4 weeks demonstrates more improvement in chronic neck pain and patient self-confidence in performing functional activities than neck exercises alone for up to one month.

F.1.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 Therapy-Active

(Therapeutic Exercise) and F.14 Therapy-Passive (Massage and Superficial Heat and Cold Therapy) for a description of these adjunctive acupuncture modalities and time frames.

F.1.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 or functional gains. Such care should be re-evaluated and documented with each series of treatments.

F.2 Biofeedback

Biofeedback is a generally well-accepted 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 psychophysiological 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, auditorially, 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:

1. **Electromyogram (EMG):** Used for self-management of pain and stress reactions involving muscle tension.
2. **Skin Temperature:** Used for self-management of pain and stress reactions, especially vascular headaches.
3. **Respiration Feedback (RFB):** Used for self-management of pain and stress reactions via breathing control.
4. **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 phenomena 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 psychophysiological indicator of health.
5. **Heart Rate Variability (HRV):** Used for self-management of stress via managing cardiac reactivity.
6. **Electrodermal Response (EDR,):** Used for self-management of stress involving palmar sweating or galvanic skin response.
7. **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 must 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 psychophysiological therapy which integrates biofeedback with psychotherapy, should be either Biofeedback Certification Institute of America (BCIA) certified or practicing within the scope of their training. All other 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 unlicensed 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 or functional gains.

F.3 Complementary Alternative Medicine

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 evidence, 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:

1. **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.
2. **Mind-Body Interventions:** These include practices such as hypnosis, meditation, bioenergetics, and prayer. Reflexology does not appear to relieve low back pain.
3. **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.
4. **Body-Based Therapy:** Included in this category are the practices of Yoga and Rolfing bodywork.
5. **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 generally not recommended on a maintenance basis.

F.4 Disturbances of Sleep

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 by opioid and hypnotic use. This should be investigated diagnostically (refer to Section F.7.i, 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 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:

1. Maintaining a regular sleep schedule, retiring and rising at approximately the same time on weekdays and weekends.
2. Limiting naps to 30 minutes twice a day or less.

3. Avoiding caffeinated beverages after lunchtime.
4. Making the bedroom quiet and comfortable, eliminating disruptive lights, sounds, television sets, and keeping a bedroom temperature of about 65°F.
5. Avoiding alcohol or nicotine within two hours of bedtime.
6. Avoiding large meals within two hours of bedtime.
7. Exercising vigorously during the day, but not within two hours of bedtime, since this may raise core temperature and activate the nervous system.
8. Associating the bed with sleep and sexual activity only, using other parts of the home for television, reading and talking on the telephone.
9. Leaving the bedroom when unable to sleep for more than 20 minutes, retuning to the bedroom when ready to sleep again.
10. Reducing time in bed to estimated typical sleeping time.
11. Arising at a regular time each day, regardless of the number of hours slept.
12. 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 melatonic 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.

F.5 Injections - Therapeutic

When considering the use of injections in chronic pain 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.

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the diagnostic value of the procedure is evident to other reviewers. This entails, at a minimum, documentation of patient response immediately following the procedure with details of any symptoms with a response and the degree of response. Additionally, a log must be recorded as part of the medical record which documents response, if any, on an hourly basis for,

at a minimum, the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, neck, leg, or arm pain). The physician must identify the local anesthetic used and the expected duration of response for diagnostic purposes.

Finally, reassessment of the patient's status in terms of functional improvement should be documented after each injection. Any continued use of injections should be monitored using objective measures such as:

1. Return-to-work or maintaining work status.
2. Fewer restrictions at work or performing activities of daily living
3. Decrease in usage of medications related to the work injury
4. 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, especially for repeat procedures.

F.5.a Therapeutic Spinal Injections

Description – The following injections are considered to be reasonable treatment for patients with chronic pain. Other injections not listed may be beneficial. Therapeutic spinal injections may be used after initial conservative treatments, such as physical and occupational therapy, medication, manual therapy, exercise, acupuncture, etc., have been undertaken. Therapeutic injections should be used only after imaging studies and diagnostic injections have established pathology. Injections are invasive procedures that can cause serious complications; thus clinical indications and contraindications should be closely adhered to. The purpose of spinal injections is to facilitate active therapy by providing short-term relief through reduction of pain and inflammation. All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients should have had prior to injections, is essential and will frequently require a repeat of the sessions previously ordered (Refer to Section F. 13, Therapy-Active). Injections, by themselves, are not likely to provide long-term relief. Rather, active rehabilitation with modified work achieves long-term relief by increasing active ROM, strength, and stability. If the first injection does not provide a diagnostic response with temporary and sustained pain relief substantiated by accepted pain scales, (i.e., 80% pain reduction), and improvement in function, similar injections should not be repeated. Cervical injections are

invasive procedures that can cause catastrophic complications. Refer to the Cervical Spine Injury guideline for more specific contraindications.

Considerations – For all spinal injections (excluding trigger point, botulinum toxin, and occipital or peripheral nerve blocks) multi-planar fluoroscopy, during procedures is required to document technique and needle placement, and should be performed by a physician experienced in the procedure. Permanent images are required to verify needle placement. The subspecialty disciplines of the physicians may be varied, including, but not limited to: anesthesiology, radiology, surgery, or physiatry. The practitioner who performs injections for low back pain should document hands on training through workshops of the type offered by organizations such as the International Spine Intervention Society (ISIS) and/or completed fellowship training with interventional training. The practitioner who performs injections for cervical pain should have completed fellowship training in pain medicine with interventional training, or its equivalent. Practitioners who perform spinal injections should obtain fluoroscopy training and must also have appropriate training in radiation safety.

Complications – General complications of these spinal injections may include transient neurapraxia, local pain, nerve injury, infection, headache, urinary retention and vasovagal effects; epidural hematoma, permanent neurologic damage, dural perforation and cerebral spinal fluid (CSF) leakage, and/or spinal meningeal abscess may also occur; Permanent paresis, anaphylaxis and arachnoiditis have been rarely reported with the use of epidural steroids. With steroid injections, there may be a dose-dependent suppression of the hypothalamic-pituitary adrenal axis lasting between one and three months. For cervical injections, severe complications are remote but can include spinal cord damage, quadriplegia, and/or death.

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.

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.

F.5.a.i Epidural Steroid Spinal Injections

Description – Epidural steroid injections (ESI) deliver corticosteroid into the epidural space. The purpose of ESI is to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs. ESI uses three approaches: transforaminal, translaminar (midline), and caudal.

Needle Placement – Multi-planar fluoroscopic imaging is required for all transforaminal

epidural steroid injections. Injection of contrast dye is necessary to verify needle placement and flow of medication into the epidural space. Permanent images are required to verify needle placement.

Indications for Acute Exacerbations – There is some evidence that epidural steroid injections are effective for patients with radicular pain or radiculopathy (sensory or motor loss in a specific dermatome or myotome). They are not recommended for chronic axial pain. There is some evidence that ESI injections in the low back are not effective for spinal stenosis without radicular findings. Additionally, there is some evidence in studies of the lumbar spine that patients who smoke or who have pain unaffected by rest or activity are less likely to have a successful outcome from ESIs.

Indications for Chronic Radicular Pain - Injections for chronic radiculopathy are rarely appropriate. Steroid injections are thought to act by decreasing the acute/subacute swelling and chemical reaction resulting from a disc herniation. Herniated discs in a chronic state would not benefit from this type of treatment. There is some evidence that about 50% of patients with chronic radicular pain will have a clinically meaningful decrease in pain and disability lasting at least 3 months from one injection of anesthetic or anesthetic with steroids. Generally, epidural injections should be limited to acute exacerbations of radicular pain at the same location as the work-related injury. There may be a small sub-population of patients with chronic radiculopathy who receive benefit from an injection. Repeated injections are frequently unnecessary and should only be done when documented functional improvement occurs, which may include a return to baseline function or ability to continue working. A positive result would include a return to baseline function, return to increased work duties, and a measurable improvement in physical activity goals including return to baseline after an exacerbation and achieved for at least 3 months.

- Time to Produce Effect: Local anesthetic, less than 30 minutes; corticosteroid, 48 to 72 hours for 80% of patients and 72 hours to 2 weeks for 20% of patients.
- Frequency: One or more divided levels can be injected in one session. Whether injections are repeated depends upon the patient's response to the previous injection session. For acute documented recurrent disc herniation with new radicular intensity, subsequent injection sessions may occur after 1 to 2 weeks if patient response has been favorable. If the first injection does not provide a diagnostic response of temporary and sustained pain relief (at least 2 to 6 weeks) substantiated by accepted pain scales (i.e., 80% pain reduction as measured by tools such as VAS) and improvement in function, similar injections should not be repeated.

For chronic radiculopathy, injections may be repeated only if a functional documented response lasts for 3 months. Patients should be reassessed after each injection session for an 80% improvement in pain (as measured by accepted pain scales) and evidence of functional improvement. A positive result would include a return to baseline function, return to increased work duties, and a measurable improvement in physical activity goals including return to baseline after an exacerbation.

- Optimum/Maximum Duration: No more than 4 in 1 year. Injections may only be repeated when the above functional and time goals are met. Repeated injections with steroids

should be done with caution especially in patients who have received other steroid injections or oral steroid therapy as higher yearly total doses of steroids may be associated with an increase in osteoporosis.

F.5.a.ii Zygapophyseal (Facet) Injection

Description – A generally accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid. Medial branch nerve blocks may be diagnostic only. There is conflicting evidence to support a long-term therapeutic effect using facet injections. There is no justification for a combined facet and medial branch block.

Indications – Patients with pain 1) suspected to be facet in origin based on exam findings and 2) affecting activity; OR patients who have refused a rhizotomy; OR patients who have facet findings with a throacic component. In these patients, facet injections may be occasionally useful in facilitating a functionally-directed rehabilitation program and to aid in identifying pain generators. Patients with recurrent pain should be evaluated with more definitive diagnostic injections, such as medial nerve branch injections, to determine the need for a rhizotomy. Because facet injections are not likely to produce long-term benefit by themselves, and are not the most accurate diagnostic tool, they should not be performed at more than two levels.

Zygapophyseal injections have almost no role in acute and subacute low back and thus are only permitted in chronic low back pain if there is indication in low back pain/cervical guideline that the patient meets the criteria for a diagnostic injection.

Patients should be reassessed after each injection session for an 80% improvement in pain (as measured by accepted pain scales) and evidence of functional improvement for 6 months. A positive result would include a return to base line function, return to increased work duties, and measurable improvement in physical activity goals including return to baseline after an exacerbation.

- Time to produce effect: Low back pain: 48 to 72 hours for corticosteroid. Up to 30 minutes for local anesthetic; corticosteroid up to 72 hours.
- Frequency: 1 injection per level with diagnostic response. If the first injection does not provide a diagnostic response of temporary and sustained pain relief substantiated by accepted pain scales (i.e., 80% pain reduction substantiated by tools such as VAS) and improvement in function, similar injections should not be repeated. At least 4 to 6 weeks of functional benefit should be obtained with each therapeutic injection.
- Optimum/Maximum Duration: 2 for each applicable joint per year. Injections may only be repeated when the above functional and time goals are met.

F.5.a.iii Sacroiliac Joint Injection

Description – A generally accepted injection of local anesthetic in an intra-articular fashion into the sacro-iliac joint under radiographic guidance. May include the use of corticosteroids. Long-term therapeutic effect has not yet been established.

Indications – Primarily diagnostic to rule out sacroiliac joint dysfunction vs. other pain generators. Intra-articular injection can be of value in diagnosing the pain generator. There should be documented relief from previously painful maneuvers (e.g., Patrick’s test) on post-injection physical exam. These injections may be repeated if they result in increased documented functional benefit for at least 6 weeks and at least 80% initial improvement in pain scales as measured by accepted pain scales (such as VAS). Sacroiliac joint blocks should facilitate a functionally directed rehabilitation program.

SI joint injections are only permitted in chronic low back pain if there is strong evidence per the indications in low back pain guideline that the patient meets the criteria for a diagnostic injection.

A successful injection should document relief from previously painful maneuvers (e.g., Patrick’s test) on post-injection physical exam. Patients should be reassessed after each injection session for an 80% improvement in pain (as measured by accepted pain scales) and evidence of functional improvement for 6 months. A positive result would include a return to base line function, return to increased work duties, and a measurable improvement in physical activity goals including return to baseline after an exacerbation.

- Time to Produce Effect: Approximately 30 minutes for local anesthetic; 48 to 72 hours for corticosteroid.
- Optimum/Maximum Duration: 2 per year. Injections may only be repeated when the above functional and time goals are met.

F.5.a.iv Intradiscal Steroid Therapy

Intradiscal steroid therapy consists of injection of a steroid preparation into the intervertebral disc under fluoroscopic guidance at the time of discography. There is good evidence that it is not effective in the treatment of suspected discogenic back pain and its use is not recommended.

F.5.b Radio Frequency Medial Branch Neurotomy/Facet Rhizotomy

Description — A procedure designed to denervate the facet joint by ablating the corresponding sensory medial branches. Continuous percutaneous radiofrequency is the method generally used.

There is good evidence to support Radio Frequency Medial Branch Neurotomy in the cervical spine but benefits beyond one year are not yet established. Evidence in the lumbar spine is conflicting; however, the procedure is generally accepted. In one study, 60% of patients maintained at least 90% pain relief at 12 months. Radio frequency Medial Branch Neurotomy is the procedure of choice over alcohol, phenol, or cryoablation. Precise positioning of the probe using fluoroscopic guidance is required since the maximum effective diameter of the device is a 5x8 millimeter oval. Permanent images should be recorded to verify placement of the device.

Indications — Those patients with proven, significant, facetogenic pain. A minority of low back patients would be expected to qualify for this procedure. This procedure is not recommended for patients with multiple pain generators or involvement of more than 3 levels of medial branch nerves.

Individuals should have met all of the following indications: Pain of well-documented facet origin, typically with extension and/or rotation unresponsive to active and/or passive therapy, unresponsive to manual therapy, and in which a psychosocial screening has been performed (e.g., pain diagram, Waddell's signs, thorough psychosocial history, screening questionnaire). It is generally recommended that this procedure not be performed until three months of active therapy and manual therapy have been completed. All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients will have had prior to the procedure, is essential and will frequently require a repeat of the sessions previously ordered (Refer to Section F.13 Therapy-Active.)

All patients should have a successful response to a diagnostic medial nerve branch block and a separate comparative block. ISIS suggests controlled blocks using either placebo or anesthetics with varying lengths of activity (i.e., bupivacaine longer than lidocaine). To be a positive diagnostic block the patient should report a reduction of pain of 80% or greater from baseline for the length of time appropriate for the local anesthetic used. In almost all cases this will mean a reduction of pain to 1 or 2 on the VAS 10-point scale correlated with functional improvement. The patient should also identify activities of daily living (which may include measurements of range-of-motion) that are impeded by their pain and can be observed to document functional improvement in the clinical setting. Ideally, these activities should be assessed throughout the observation period for function. The observer should not be the physician who performed the procedure. It is suggested that this be recorded on a form similar to ISIS recommendations.

A separate comparative block on a different date should be performed to confirm the level of involvement. A comparative block uses anesthetics with varying lengths of activity.

Complications — Bleeding, infection, or neural injury. The clinician must be aware of the risk of developing a localized neuritis, or rarely, a deafferentation centralized pain syndrome as a complication of this and other neuroablative procedures.

Post-Procedure Therapy — Active therapy. Implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-procedure week, barring complications. Instruction and participation in a long-term home-based program of ROM, core strengthening, postural or neuromuscular re-education, endurance, and stability exercises should be accomplished over a period of four to ten visits post-procedure.

Requirements for Repeat Radiofrequency Medial Branch Neurotomy (or additional-level RF Neurotomies): In some cases pain may recur. Successful RF Neurotomy usually provides from six to eighteen months of relief.

Before a repeat RF Neurotomy is done, a confirmatory medial branch injection should be performed if the patient's pain pattern presents differently than the initial evaluation. The long-

term effects of repeat rhizotomies, especially on younger patients are unknown. There is a possibility that repeated denervation could result in premature degenerative changes. In addition the patient should always reconsider all of the possible permanent complications before consenting to a repeat procedure. There are no studies addressing the total number of RF neurotomies that should be done for a patient. The patient should document 6 to 18 months minimum improvement.

In occasional patients, additional levels of RF neurotomy may be necessary. The initial indications including repeat blocks and limitations apply.

- Optimum/Maximum duration twice in the first year after the initial rhizotomy and once a year after, up to 12 total. They may only be repeated when the patient demonstrates functional improvement

F.5.c.Dorsal Nerve Root Ganglion Radiofrequency Ablation

Percutaneous radiofrequency partial lesioning of the dorsal root ganglion is a procedure intended to decrease persistent impairing radicular pain. There is some evidence that continuous RF for lumbar radicular pain does not result in improved pain and functional outcomes. Follow up of patients who had a dorsal nerve root ganglia procedure for failed low back surgery reported 2 out of 13 patients had a 50% reduction in pain and were satisfied with the procedure at 2 years. Fifty per cent or more of the group also reported worse sensory and motor findings. There is some evidence from a small study that pulsed RF used in patients with chronic cervical radicular pain who demonstrated a 50% reduction in pain on a diagnostic block will provide at least a 50% pain relief for 3 months. Recurrence of pain is common after 3 months with no significant effect at 6 months. No significant improvement in general function was documented. Due to the combination of possible adverse side effects, time limited effectiveness, and mixed study results, this therapy is not recommended. American Society of Anesthesiologist practice guidelines do not recommend routine use. **This treatment is not recommended.**

F.5.d Trigger Point Injections

Description — Trigger point injections are a generally accepted treatment. Trigger point treatment can consist of dry needling or injection of local anesthetic, with or without corticosteroid, into highly localized, extremely sensitive bands of skeletal muscle fibers that produce local and referred pain when activated. There is conflicting evidence regarding the benefit of trigger point injections. A truly blinded study comparing dry needle treatment of trigger points is not feasible. There is no evidence that injection of medications improves the results of trigger point injections. Needling alone may account for some of the therapeutic response.

There is no indication for conscious sedation for patients receiving trigger point injections. The patient must be alert to help identify the site of the injection.

Indications – Trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other active treatment modalities. Trigger point injections should

be utilized primarily for the purpose of facilitating functional progress. Patients should continue in an aggressive aerobic and stretching therapeutic exercise program as tolerated throughout the time period they are undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problems and any abnormalities need to be ruled out prior to injection.

For acute exacerbations trigger point injections are indicated in those patients where well-circumscribed trigger points have been consistently observed, demonstrating a local twitch response characteristic radiation of pain pattern and local autonomic reaction, such as persistent hyperemia following palpation. Generally, these injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a 6-week time frame.

Complications – Potential but rare complications of trigger point injections include infection, pneumothorax, and anaphylaxis, penetration of viscera, neurapraxia and neuropathy. If corticosteroids are injected in addition to local anesthetic, there is a risk of local myopathy developing. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

Patients should be reassessed after each injection session for an 80% improvement in pain (as measured by accepted pain scales) and evidence of functional improvement for 3 months. A positive result would include a return to base line function, return to increased work duties, and measurable improvement in physical activity goals including return to baseline after an exacerbation.

- Time to Produce Effect: Local anesthetic 30 minutes; 24 to 48 hours for no anesthesia.
- Frequency: No more than 4 injection sites per session per week for acute exacerbations only, to avoid significant post-injection soreness.
- Optimum Duration/Maximum: 4 sessions per year. Injections may only be repeated when the above functional and time goals are met.

F.5.e Prolotherapy Injections

Description - also known as sclerotherapy, consists of a series of injections of hypertonic dextrose, with or without glycerine and phenol, into the ligamentous structures of the low back and other joints (e.g., it has been used for ‘stabilization’ of ankles, SI joints, etc.). Its proponents claim that the inflammatory response to the injections will recruit cytokine growth factors involved in the proliferation of connective tissue, stabilizing the ligaments of the low back or treated joints when these structures have been damaged by mechanical insults.

There are conflicting studies concerning the effectiveness of Prolotherapy in the low back. Lasting functional improvement has not been shown. The injections are invasive, may be painful to the patient, and are not generally accepted or widely used. **Therefore, the use of Prolotherapy for low back or other chronic joint pain is not recommended.**

F 5.f Epiduroscopy and Epidural Lysis of Adhesions

Epiduroscopy and Epidural Lysis of Adhesions is an investigational treatment of low back pain. It involves the introduction of a fiberoptic endoscope into the epidural space via the sacral hiatus. With cephalad advancement of the endoscope under direct visualization, the epidural space is irrigated with saline. Adhesiolysis may be done mechanically with a fiberoptic endoscope. The saline irrigation is performed with or without epiduroscopy and is intended to distend the epidural space in order to obtain an adequate visual field. It is designed to produce lysis of adhesions, which are conjectured to produce symptoms due to traction on painful nerve roots. Saline irrigation is associated with risks of elevated pressures which may impede blood flow and venous return, possibly causing ischemia of the cauda equina and retinal hemorrhage.

Other complications associated with instrumented lysis include catheter shearing, need for catheter surgical removal, infection (including meningitis), hematoma, and possible severe hemodynamic instability during application. Although epidural adhesions have been postulated to cause chronic low back pain, studies have failed to find a significant correlation between the level of fibrosis and pain or difficulty functioning. Studies of epidural lysis demonstrate no transient pain relief from the procedure. Given the low likelihood of a positive response, the additional costs and time requirement, and the possible complications from the procedure, epidural injection, or mechanical lysis, is not recommended.

Epiduroscopy- directed steroid injections are also not recommended as there is no evidence to support an advantage for using an epiduroscope with steroid injections.

F.5.g Botulinum Toxin (Botox) Injection

Description – Used to temporarily weaken or paralyze muscles. May reduce muscle pain in conditions associated with spasticity, dystonia, or other types of painful muscle spasm. Neutralizing antibodies develop in at least 4% of patients treated with botulinum toxin type A, rendering it ineffective. Several antigenic types of botulinum toxin have been described. Botulinum toxin type B, first approved by the Food and Drug Administration (FDA) in 2001, is similar pharmacologically to botulinum toxin type A. It appears to be effective in patients who have become resistant to the type A toxin. The immune responses to botulinum toxins type A and B are not cross-reactive, allowing type B toxin to be used when type A action is blocked by antibody. Experimental work with healthy human volunteers suggests that muscle paralysis from type B toxin is not as complete or as long lasting as that resulting from type A. The duration of treatment effect of botulinum toxin type B for cervical dystonia has been estimated to be 12 to 16 weeks. EMG needle guidance may permit more precise delivery of botulinum toxin to the target area.

There is strong evidence that botulinum toxin A has objective and asymptomatic benefits over placebo for cervical dystonia.

There is some evidence to support injections for electromyographically proven piriformis syndrome. Prior to consideration of botulinum toxin injection for piriformis syndrome, patients should have had marked (80% or better) but temporary improvement with three separate trigger point injections. To be a candidate for botulinum toxin injection for piriformis syndrome,

patients should have had symptoms return to baseline or near baseline despite an appropriate stretching program after trigger point injections. Botulinum toxin injections of piriformis should be performed by a physician experienced in this procedure and utilize either ultrasound, fluoroscopy, or EMG needle guidance. Botulinum toxin should be followed by limb strengthening and reactivation.

Indications – For conditions which produce chronic spasticity, dystonia, or piriformis syndrome. There should be evidence of limited range-of-motion prior to the injection. Refer to Traumatic Brain Injury (TBI) Medical Treatment Guidelines for indications regarding headache.

There is insufficient evidence to support its use other myofascial trigger points for longer-term pain relief and it is likely to cause muscle weakness or atrophy if used repeatedly. Examples of such consequences include subacromial impingement, as the stabilizers of the shoulder are weakened by repeated injections of trigger points in the upper trapezii. Therefore it is not recommended for use for other myofascial trigger points.

Complications – There is good evidence that cervical botulinum toxin A injections cause transient dysphagia and neck weakness. Allergic reaction to medications, dry mouth and vocal hoarseness may also occur. Rare systemic effects include flu-like syndrome, and weakening of distant muscle. There is an increased risk of systemic effects in patients with motor neuropathy or disorders of the neuromuscular junction.

- Time to produce effect: 24 to 72 hours post injection with peak effect by 4 to 6 weeks.
- Frequency: No less than 3 months between re-administration. Patients should be reassessed after each injection session for an 80% improvement in pain (as measured by accepted pain scales) and evidence of functional improvement for 3 months. A positive result would include a return to base line function, return to increased work duties, and measurable improvement in physical activity goals including return to baseline after an exacerbation.
- Optimum duration: 3 to 4 months.
- Maximum duration: Currently unknown. Repeat injections should be based upon functional improvement and therefore used sparingly in order to avoid development of antibodies that might render future injections ineffective. In most cases, not more than four injections are appropriate due accompanying muscle atrophy.

F.6 Interdisciplinary Rehabilitation Programs

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 Department 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 Department 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.

Outpatient interdisciplinary pain programs, whether formal or informal, should be comprised of the following dimensions:

1. **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.
2. **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.
3. **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 the Sections F.13 and F.14 of this guideline. All treatment timeframes may be extended based upon the patient's positive functional improvement.
4. **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.
5. **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 an occupational rehabilitation program (as described in this section). 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 Section F.12 Return-to-Work.
6. **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.
7. **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.

8. Vocational Assistance: Vocational assistance can define future employment opportunities or assist patients in obtaining future employment. Refer to Section F.12 Return-to-Work 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.

F.6.a Formal 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 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, 5 days/week; 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.

Occupational Rehabilitation

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 programs, 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, and 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 or functional gains.

F.6.b Informal 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 Department 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, 5 days/week; 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.

F.6.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: Full time programs- no less than 5 hours/day, 5 days/week; 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 gain.

F.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. The clinician may check the Montana Prescription Drug Registry (MPDR). 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 medications 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 appropriate trial varies widely depending on the drug. Certain medications may take several months to determine the efficacy, while others require only a few doses. It is recommended that patients with chronic nonmalignant pain 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. There is good evidence that glucosamine does not improve pain related disability in those with chronic low back pain and degenerative changes on radiologic studies; therefore, it is not recommended for chronic spinal or non-joint pain. For chronic pain related to joint osteoarthritis see specific extremity guidelines.

Opioid analgesics and other drugs of potential abuse such as sedative hypnotics or benzodiazepines may be used in properly selected cases for chronic pain patients, although total elimination of these medications is 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.

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 is frequently 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 SNRIs, 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, tramadol, and tapentadol. Other medications have few clinical trials to support them but may be helpful in some patients.

The preceding principles do not apply to chronic headache patients. These patients should be referred to a physician specializing in the diagnosis and treatment of headache and facial pain.

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 for individual cases. Clinicians should refer to informational texts or consult

a pharmacist before prescribing unfamiliar medications or when there is a concern for drug interactions.

The following drug classes are listed in alphabetical order, not in order of suggested use.

F.7.a Acetaminophen

1. Description -- Acetaminophen and paracetamol are sometimes considered nonspecific NSAIDs, although their effects on cyclooxygenase activity are minimal and they are not anti-inflammatory agents. Acetaminophen blocks the activation of COX by another enzyme, peroxidase. Acetaminophen has very weak anti-inflammatory activity and essentially no platelet inhibition because of the absence of peripheral COX activity, but it selectively inhibits brain prostaglandin synthesis where peroxide concentrations are low. That is why tissues with high levels of peroxidase (platelets and immune cells) are “resistant” to acetaminophen, but tissues with low levels of peroxidase (i.e., nerve and endothelial cells that participate in pain and fever) are “sensitive” to acetaminophen.
2. Indications -- Acetaminophen is somewhat recommended for treatment of chronic persistent pain and radicular pain syndromes, particularly in patients with contraindications for NSAIDs.
3. Major Side Effects -- Acetaminophen is hepatotoxic in high doses (>4g a day chronically or a single dose >7g) and may cause liver failure requiring transplantation. Risk is increased with ethanol consumption and malnutrition. Although it has a more benign adverse effect profile than NSAIDs, in the U.S. alone, acetaminophen misuse accounts for more than 100,000 calls to poison control centers, more than 56,000 emergency department visits and 2,600 hospitalizations.

F.7.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 presynaptic inhibition of motor neurons. Given limited experience with their use, they cannot be considered first-line or second-line analgesics for neurogenic pain, but a trial of their use may be warranted in some cases of refractory pain.

Clonidine (Catapres)

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 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, orthostatic hypotension, sexual dysfunction, thrombocytopenia, weight gain, agitation, rebound hypertension with cessation.
- F) Drug Interactions – Beta adrenergics, tricyclic antidepressants.
- G) Recommended Laboratory Monitoring – Renal function, blood pressure.

F.7.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, is a relatively non-significant enzyme inducer, 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.

Gabapentin (Neurontin)

- 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) Recommended Laboratory Monitoring – Renal function.

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 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.
- E) Major Side Effects – Dizziness, confusion, sedation, dry mouth, weight gain, and visual changes have been reported.
- F) Drug Interactions – Opioids, benzodiazepines, and alcohol.
- G) Laboratory Monitoring – Renal function, and platelets, and creatinine kinase as appropriate for individual cases.

Topiramate

- A) Description – Sulfamate substitute monosacchride.
- B) Indications – 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.

Lamotrigine

This anti-convulsant drug is not FDA approved 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.

F.7.d Antidepressants

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.

Tricyclics and older agents (e.g., amitriptyline [Elavil], nortriptyline [Pamelor, Aventyl], doxepin [Sinequan, Adapin], 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 cholinergic side effects than newer tricyclics such as nortriptyline and desipramine. Doxepin and trimipramine also have sedative effects.

B) Indications – 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 recommended as a 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, quinolones.

G) Recommended Laboratory Monitoring – Renal and hepatic function. EKG for those on high dosages or with cardiac risk.

Selective Serotonin Reuptake Inhibitors (SSRIs)

Selective serotonin reuptake inhibitors (SSRIs) (e.g., citalopram [Celexa], fluoxetine [Prozac], paroxetine [Paxil], sertraline [Zoloft]) are not recommended for neuropathic pain. They may be used for depression.

Selective Serotonin Nor-epinephrine Reuptake Inhibitor (SSNRI)/Serotonin Nor-epinephrine Reuptake Inhibitors (SNRI)

A) Description – Venlafaxine, duloxetine, and milnacipran.

B) Indications – At the time of this guideline writing, 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 has been FDA approved for generalized anxiety disorder. There is some evidence 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 - Depends 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 and drug abuse.

E) Drug Interactions – Drug specific.

F) Laboratory Monitoring – Drug specific. Hepatic and renal monitoring, venlafaxine may cause cholesterol or triglyceride increases.

Atypical Antidepressants/Other Agents

May be used for depression; however, are not appropriate for neuropathic pain only.

F.7.e. Herbal/Dietary Supplements

Botanical preparations have been used for centuries to remedy human illnesses, but only recently have been subjected to systematic study. Many medications currently manufactured by pharmaceutical firms are derivatives of compounds originally isolated from plants.

Clinical trials of folk remedies have been few in number, and often flawed by methodological problems. The lack of reliable data on the clinical and biological effects of herbal remedies often leads to inappropriate use. Patients commonly use non-standard remedies without discussing them with their physicians; when pharmacological interactions exist between herbs and prescription drugs, adverse effects may follow. Quality control varies between manufacturers, and because herbs are classified as dietary supplements, they are exempt from regulations governing standardization of ingredients. Physicians should ask all patients about their use of herbal medications and dietary supplements.

1. **Description** – The following herbs may be appropriate for patients who prefer herbs as an alternative to prescription analgesics or NSAIDs:
 - A) White Willow Bark – There is some evidence of the effectiveness of *Salix* (willow) bark extract in chronic low back pain. A principal ingredient is salicin, with salicylic acid as the principal metabolite. In doses of 240 mg of salicin daily, willow bark extract is more effective than placebo in alleviating pain and improving scores of physical impairment. This dose is approximately equivalent to 50 mg of acetylsalicylate, which cannot alone account for its analgesic effect. It is well tolerated, with gastrointestinal complaints occurring no more frequently than with placebo. In patients at risk for GI problems from NSAID drugs, willow bark may be an appropriate option.
 - B) Devil’s Claw Root – Extract of *Hapagophytum procumbens*, with the common name of devil’s claw root, have been used in parts of Europe for conditions of the musculoskeletal system, including osteoarthritis and low back pain. There is some evidence that it may relieve back pain more effectively than placebo, but functional improvement has not yet been shown. The doses used in clinical trials have consisted of 50 to 100 mg of harpagoside daily. Mild gastrointestinal upset has been reported at higher doses.
 - C) Phytodolor – A standardized extract of *Populus tremula* (aspen), *Fraxinus excelsior* (European ash), and *Solidago virgaurea* (goldenrod), Phytodolor may have anti-inflammatory properties through inhibition of cyclooxygenase pathways. In doses of up to 180 drops per day in 3 divided doses, it has shown superiority to placebo in osteoarthritis and epicondylitis when pain and grip strength were evaluated. Adverse effects were not reported to exceed those of placebo.
 - D) St. John’s Wort – An herbal extract of the flowering plant *Hypericum perforatum* commonly used in the treatment of mild to moderate depression, St. John’s Wort has been tested for effectiveness in neuropathic pain. There is some evidence that it lacks effectiveness on pain in polyneuropathy. The Department does not recommend its use as an alternative analgesic in chronic pain conditions. There is also some evidence that it is no more effective than placebo in the treatment of major depression. It should not be considered an antidepressant agent in patients requiring medical treatment of depression.

2. **Specific Drug Interactions** – Current regulations prohibit herb manufacturers from claiming that their products treat or prevent disease, but allow them to make claims about the product’s effect on body function. Because herbal products are biologically active, they may interact with prescription drugs and with one another. Much of what is known concerning drug interactions is based on case reports or case series, which commonly lack crucial documentation of concomitant medication use or positive identification of herbs involved.
 - A) Physicians should be aware that patients on warfarin should have international normalized ratio (INR) measured a week after starting to take any herbal preparation.
 - B) Ginkgo, ginseng, and garlic are commonly used for reasons unrelated to relief of pain; they interfere with platelet function, and patients who take them should have bleeding times monitored.
 - C) St. John’s Wort should not be combined with an SSRI, since a serotonin syndrome may result. St. John’s Wort induces the CYP3A4 hepatic enzyme, lowering levels of drugs metabolized by this system; these drugs include anticonvulsants, oral contraceptives, antiretroviral, and calcium channel blockers.
 - D) Kava, often used to alleviate anxiety, may potentiate benzodiazepine anxiolytics and produce excess sedation.
 - E) Herbal preparation usage during the perioperative period should be discouraged.

F.7.f Hypnotics and Sedatives

Sedative and hypnotic drugs decrease activity and induce drowsiness and may cause 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 and 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 Section F.4 Disturbances of Sleep).

Zaleplon (Sonata), Eszopiclone, Zolpidem (Ambien)

- A) Description – A 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 drug
- F) Laboratory Monitoring - none required, based on individual patient history.

Benzodiazepine-based hypnotics

Benzodiazepine-based hypnotics include 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.7.g NMDA Receptor Antagonists

1. Description – Numerous new compounds that specifically target mechanisms mediating neuropathic pain such as the N-methyl-D-aspartate (NMDA) receptor complex are currently in clinical trials. These compounds include dextromethorphan, amantadine, and memantine. Methadone is a mu agonist that also has affinity for the NMDA receptor. NMDA inhibitors purportedly help to prevent acute pain from progressing to chronic pain. These agents theoretically act by blocking receptors of neurotransmitters that are essential to long-term memories. They also are thought to potentially help reduce opioid tolerance and may enhance opioid analgesia.
2. Indications – Dextromethorphan for treatment of select patients (e.g., those who have failed NSAIDs, TCAs, and anti-convulsant agents) with peripheral diabetic neuropathy and, by inference, other peripheral neuropathies.
3. Dosing and Time to Therapeutic Effect – Doses used have ranged widely. In the successful trial, an average daily dose of 400mg was utilized. Dextromethorphan is recommended in doses that are on average at least 3 times higher than the antitussive dose, and carefully titrated to therapeutic effect. Duration of use for patients with chronic neuropathic pain should generally be limited to 2 or 3 months as there is not evidence of long-term safety, although longer periods of use may be reasonable.
4. Major Side Effects – The utility of these agents has been limited by their significant adverse-effect profile, which includes lightheadedness, dizziness, tiredness, headache, nervous floating sensation, bad dreams, and sensory changes. Dextromethorphan, amantadine, and memantine are better tolerated with lower CNS adverse effects than ketamine possibly due to a lower affinity for the NMDA receptor which plays a role in both normal physiological functions as well as pathological pain processing.

F.7.h 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 misoprostol, a prostaglandin analog, 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.

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 to 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.

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.

F.7.i Opioids

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 the 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.

It is highly recommended that prescribers of opioids follow the “Universal Precautions” as published, Gourlay et al 2005, including:

- Single prescriber/single pharmacy
- Opioid agreement between prescriber and patient
- Lowest possible effective dosing
- Random urine drug testing using liquid chromatography-tandem mass spectrometry (LC/MS)
- Pill counts
- Prescription Drug Monitoring Program access

It is also highly recommended that the prescribers of opioids follow a literature-based guideline such as:

- Washington State Agency Medical Directors Guideline
- American Society of Interventional Pain Physicians

- Canadian Guidelines
- Federation of State Medical Boards Model Policy

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.

Newer drug formulations such as oxymorphone, 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 hypo-gonadism 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, oxymorphone, 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 transfer 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.

1. 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 3.D below.

2. 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 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.

D) Montana Prescription Drug Registry Review (MPDR)

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.

3. On-Going, Long-Term Management – Actions 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:

1. Side effects anticipated from the medication;
2. Requirement to continue active therapy;
3. Need to achieve functional goals including return to work for most cases;
4. 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 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.

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 or 250 mg/day for long-term use in healthy patients. A safer chronic dose may be 180mg/day.

H) Continuing review of overall therapy plan with regard to nonopioid 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 hyperalgesia, decreased effects from an opioid, lack of compliance with the opioid contract, or intolerance of side effects. Consultation with a pain or addiction specialist may be useful in these cases. 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 in-patient criteria.

4. Relative Contraindications – Extreme caution should be used in prescribing controlled substances for workers with one or more “relative contraindications”:

- 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.

5. 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 patients’ 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.

6. 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 equivalent dose (MED) 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.

7. 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.

8. 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.

9. Drug Interactions – Patients receiving opioid agonists should not be given a mixed agonist-antagonist such as pentazocine or butorphanol Stadol 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

10. 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.

11. 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 O_2 saturation device may be useful for monitoring respirator depression secondary to opioids although there are no studies on this topic.

12. Montana Prescription Drug Registry (MPDR) --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.

13. 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.

14. 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

F.7.j Skeletal Muscle Relaxants

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.

Baclofen (Lioresal)

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.

Cyclobenzaprine (Flexeril)

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 SSRI'S and SNRI'S drug interactions are similar to those for tricyclics. Refer also to tricyclics

G) Recommended Laboratory Monitoring – Hepatic and renal function.

Carisoprodol (Soma)

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

Metaxalone (Skelaxin)

- 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

Tizanidine (Zanaflex)

- 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 to 4 weeks; maintenance, 8 mg orally every 6 to 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 other medications 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.

F.7.k Topical Drug Delivery

1. 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.
2. Indications – Neuropathic pain for most agents. Episodic use of NSAIDs and salicylates for or 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.

3. 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 may be better used episodically.
4. Side Effects – Localized skin reactions may occur, depending on the medication agent used.

5. 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 be applied only 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. 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.

F.7.1 Tramadol

Tramadol appears to have a lower abuse rate than for other opioids.

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 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 not be considered a first 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, SSRI'S, MAOI'S, and TCA'S).

F) **Laboratory Monitoring** – Renal and hepatic function.

F.7.m Other Agents

Glucosamine

There is good evidence that glucosamine does not improve pain related disability in those with chronic low back pain and degenerative changes on radiologic studies, therefore it is not recommended for chronic lower spinal or non-joint pain. For chronic pain related to joint osteoarthritis see specific extremity guidelines. Glucosamine should not be combined with chondroitin as it is ineffective.

F.8 Orthotics/Prosthetics/Equipment

Devices and adaptive equipment may be necessary in order to reduce impairment and disability, to facilitate medical recovery, to avoid re-aggravation of the injury, and to maintain maximum medical improvement. Indications would be to provide relief of the industrial injury or prevent further injury and include the need to control neurological and orthopedic injuries for reduced stress during functional activities. In addition, they may be used to modify tasks through instruction in the use of a device or physical modification of a device. Equipment needs may need to be reassessed periodically. Refer to F.12 Return-to-Work for more detailed information.

Equipment may include high and low technology assistive devices, computer interface or seating, crutch or walker training, and self-care aids. It should improve safety and reduce risk of re-injury. Standard equipment to alleviate the effects of the injury on the performance of activities of daily living may vary from simple to complex adaptive devices to enhance independence and safety. Certain equipment related to cognitive impairments may also be required.

Ergonomic modifications may be necessary to facilitate medical recovery, to avoid re-aggravation of the injury, and to maintain maximum medical improvement. Ergonomic evaluations with subsequent recommendations may assist with the patients return-to-work. (Refer to Section E.6.c Job Site Evaluation for further information.)

For chronic pain disorders, equipment such as foot orthoses or lumbar support devices may be helpful. The injured worker should be educated as to the potential harm from using a lumbar support for a period of time greater than which is prescribed. Harmful effects include de-conditioning of the trunk musculature, skin irritation, and general discomfort. Use of cervical collars is not recommended for chronic cervical myofascial pain. Special cervical orthosis and/or equipment may have a role in the rehabilitation of a cervical injury such as those injuries to a cervical nerve root resulting in upper extremity weakness or a spinal cord injury with some degree of paraparesis or tetraparesis. Use of such devices would be in a structured rehabilitation setting as part of a comprehensive rehabilitation program.

Fabrication/modification of orthotics, including splints, would be used when there is need to normalize weight-bearing, facilitate better motion response, stabilize a joint with insufficient muscle or proprioceptive/reflex competencies, to protect subacute conditions as needed during movement, and correct biomechanical problems. Orthotic/prosthetic training is the skilled instruction (preferably by qualified providers) in the proper use of orthotic devices and/or prosthetic limbs.

For information regarding specific types of orthotics/prosthetics/equipment, refer to individual medical treatment guidelines.

F.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:

1. The treatment plan;
2. Indications for and potential side effects of medications;
3. Their home exercise program;
4. Expected results of treatment;
5. Tests to be performed, the reasons for them and their results;
6. Activity restrictions and return-to-work status;
7. Home management for exacerbations of pain;
8. Procedures for seeking care for exacerbations after office hours;
9. Home self-maintenance program;
10. Patient responsibility to communicate with all medical providers and the employer; and
11. Patient responsibility to keep appointments.
12. The importance of taking medications exactly as prescribed.
13. Basic Physiology related to patient's diagnosis.

Educational efforts should also target 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

F.10 Personality/Psychological/Psychosocial Intervention

Psychosocial treatment is a well-established therapeutic and diagnostic intervention with selected use in acute pain problems, but with 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 chronic pain 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 behavior therapy (CBT), or certified as CBT therapists working in consultation with a PhD, PsyD, EdD, or Psychiatric MD/DO, and with experience in treating chronic pain disorders in injured workers 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 the most current DSM 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 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.

Cognitive Behavioral Therapy (CBT) or similar treatment:

- Time to produce effect: 6 to 8 total sessions, one-hour sessions for individuals, two-hour sessions for 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

Other Psychological/Psychiatric Interventions:

- Time to produce effect: 2 to 4 weeks
- Frequency: 1 to 5 times weekly for the first 4 weeks (excluding hospitalization, if required), decreasing to 1 to 2 times 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 duration: 6 to 12 months, not to include visits for medication management. For select patients, longer supervised treatment may be required and, if further counseling beyond 6 months is indicated, functional progress must be documented.

F.11 Restriction of Activities

Continuation of normal daily activities is the recommendation for chronic pain 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 back pain 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.

F.12 Return to Work

Return to work and/or work-related activities whenever possible is 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 one of the major components in chronic pain management. 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 and vocational assistance should be employed.

The Montana Department of Labor and Industry and workers' compensation insurers help Montana workers stay at work or return to work quickly after a work-related injury. Assistance can be requested by phone 406-444-1752 or by email at sawrtwrquest@mt.gov.

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

F.12.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.

F.12.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.

F.12.c Communication

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.

F.12.d Establishment of a Return-To-Work Status

Return to work for persons with chronic pain 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.

F.12.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 usually take place for 8 hours. Between one and three days after the evaluation, there may 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.12.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.

F.12.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 may be utilized to identify rehabilitation program goals, as well as optimize both patient motivation and utilization of rehabilitation resources. This may be extremely helpful in decreasing the patient's fear regarding an inability to earn a living which can add to their anxiety and depression.

F.12.h Recommendations to Employers and Employees of Small Businesses

Employers and employees of small businesses 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 and/or certified rehabilitation counselors (CRCs) be accessed through their insurer or third party administrators. 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.

F.12.i Recommendations to Employers and Employees of Mid-Sized and Large Businesses

Employers and employees of mid-sized and large businesses are encouraged by the Department 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

F.13 Therapy-Active

The following active therapies are widely used and 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 merely be a repeat of previous therapy but should focus specifically on the individuals goals and abilities of the patient with chronic pain.

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.

The following active therapies are listed in alphabetical order.

F.13.a Activities of Daily Living (ADL)

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

F.13.b Aquatic Therapy

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 applied 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 and more likely have a successful trial of therapeutic exercise. Indications are for individuals who may not tolerate active land-based or full weight bearing therapeutic procedures or who require augmentation of 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;
- 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

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

F.13.c Fear Avoidance Belief Training (FABT)

Fear Avoidance Belief Training (FABT) and principles are believed to be important in the management of patients with trigger points/myofascial pain. Inclusion of these principles in the course of exercise training or supervision appears highly desirable.

F.13.d Functional Activities

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

F.13.e Functional Electrical Stimulation

Functional Electrical Stimulation is an accepted treatment in which the application of electrical current to elicit involuntary or assisted contractions of atrophied and/or impaired muscles. Indications include muscle atrophy, weakness, and sluggish muscle contraction secondary to pain, injury, neuromuscular dysfunction, peripheral nerve lesion, or radicular symptoms. This modality may be prescribed for use at home when patients have demonstrated knowledge of how to self-administer and are in an independent exercise program.

- Time to produce effect: 2 to 6 treatments
- Frequency: 3 times per week
- Optimum duration: 8 weeks
- Maximum duration: 8 weeks. If beneficial, provide with home unit.

F.13.f Spinal Stabilization

Lumbar Stabilization is a generally well-accepted treatment. The goal of this therapeutic program is to strengthen the spine in its neural and anatomic position. The stabilization is dynamic which allows whole body movements while maintaining a stabilized spine. It is the

ability to move and function normally through postures and activities without creating undue vertebral stress.

- Time to produce effect: 4 to 8 treatments
- Frequency: 3 to 5 times per week
- Optimum duration: 4 to 8 weeks
- Maximum duration: 8 weeks

F.13.g Neuromuscular Re-education

Neuromuscular Re-education is a generally accepted treatment. It 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: 2 to 6 treatments
- Frequency: 3 times per week
- Optimum duration: 4 to 8 weeks
- Maximum duration: 8 weeks

F.13.h Therapeutic Exercise

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. May also include alternative/complementary exercise movement therapy (with oversight of a physician or appropriate healthcare professional).

There is some evidence that intensive exercise coupled with cognitive behavioral therapy is as effective for chronic un-operated low back pain as posterolateral fusion.

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

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.

F.13.i Work Conditioning

These programs are work-related, outcome-focused, individualized treatment programs. Objectives of the program include, 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.

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 six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

F.13.j Work Simulation

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 Job Site 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 six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

F.13.k Yoga

Yoga is a program that involves postures, stretches, breath control, and relaxation. Traditional yoga also involves rules for personal conduct, sense withdrawal, concentration, meditation, and self-realization and different versions are practiced. Yoga may be beneficial for select, highly motivated patients.

There is some evidence that Iyengar yoga, which avoids back bending, results in improved function and decreased chronic mechanical low back pain for up to 6 months. One quarter of the participants dropped out. Instruction occurred 2 times per week for 24 weeks and was coupled with home exercise.

- Time to produce effect: 2 to 6 treatments
- Frequency: 3 to 5 times per week
- Optimum duration: 4 to 8 weeks
- Maximum duration: 8 to 12 weeks

F.14 Therapy - Passive

Most of the following passive therapies and modalities are generally accepted methods 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.

F.14.a Electrical Stimulation (Unattended)

Transcutaneous Electrical Nerve Stimulation (TENS)— Indications include pain, inflammation, muscle spasm, atrophy, decreased circulation, and the need for osteogenic stimulation. Electrical stimulation, once applied, requires minimal on-site supervision by the physical or nonphysical provider and should include least one instructional session for proper application and use.

- A TENS home unit should be purchased if treatment is effective and frequent use is recommended. Time to produce effect: Immediate.
- Frequency: Variable
- Optimum duration: 3 sessions. If beneficial, provide with home unit.
- Maximum duration: 3 sessions.

F.14.b Iontophoresis

Iontophoresis is an accepted treatment which consists of the transfer of medication, including, but not limited to, steroidal anti-inflammatories and anesthetics, through the use of electrical stimulation. Indications include pain (Lidocaine), inflammation (hydrocortisone, salicylate), edema (mecholyly, hyaluronidase, salicylate), ischemia (magnesium, mecholyly, iodine), muscle spasm (magnesium, calcium), calcific deposits (acetate), scars and keloids (chlorine, iodine, acetate).

- Time to produce effect: 1 to 4 treatments
- Frequency: 3 times per week with at least 48 hours between treatments
- Optimum duration: 4 to 6 weeks
- Maximum duration: 6 weeks

F.14.c Manipulation

Manipulative Treatment (not therapy) is defined as the therapeutic application of manually guided forces by an operator to improve physiologic function and/or support homeostasis that has been altered by the injury or occupational disease, and has associated clinical significance.

There is good evidence that a combination of exercise and spinal manipulation is more effective than manipulation alone in relieving chronic neck pain, and that these advantages remain for more than one year after the end of treatment.

Conversely, there is some evidence that a combination of spinal manipulation and exercise is more effective than exercise alone in reducing pain and improving function of low back pain for one year.

There is good evidence that spinal manipulation has a small superiority to other common interventions (standard medical care, physiotherapy, and exercise alone) for chronic low back pain, making it comparable to other commonly accepted interventions for this indication.

The decision to refer a patient for spinal manipulation rather than for other treatments should be made on the basis of patient preference and relative safety, not on an expectation of a greater treatment effect. Manipulation may be indicated in patients who have not had an evaluation for manual medicine, or have not progressed adequately in an exercise program.

Manipulative treatments may be applied by osteopathic physicians (D.O.), chiropractors (D.C.), properly trained physical therapists (P.T.), properly trained occupational therapists (O.T.), or properly trained medical doctors (M.D.). Some popular and useful techniques include, but are not limited to, high velocity, low amplitude (HVLA), muscle energy (ME), strain-counterstrain (SCS), a balanced ligamentous tension (BLT) and myofascial release (MFR). Under these different types of manipulation exist many subsets of different techniques that can be described as a) direct- a forceful engagement of a restrictive/pathologic barrier, b) indirect- a gentle/non-forceful disengagement of a restrictive/pathologic barrier, c) the patient actively assists in the treatment and d) the patient relaxing, allowing the practitioner to move and balance the body tissues. When the proper diagnosis is made and coupled with the appropriate technique, manipulation has no contraindications and can be applied to all tissues of the body, including muscles, tendons, ligaments, joints, fascia and viscera. Pre-treatment assessment should be performed as part of each manipulative treatment visit to ensure that the correct diagnosis and correct treatment is employed.

Contraindications to HVLA manipulation include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritides, aortic aneurysm, and signs of progressive neurologic deficits.

- Time to produce effect: 4 to 6 treatments.
- Frequency: 1 to 2 times per week for the first 2 weeks as indicated by the severity of the condition. Treatment may continue at 1 treatment per week for the next 6 weeks.
- Optimum duration: 8 weeks.
- Maximum duration: 8 weeks. At week 8, patients should be re-evaluated. Care beyond 8 weeks may be indicated for certain chronic pain patients in whom manipulation is helpful in improving function, decreasing pain and improving quality of life. In these cases,

treatment may be continued at one treatment every other week until the patient has reached MMI and maintenance treatments have been determined. Extended durations of care beyond what is considered “maximum” may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities. Such care should be re-evaluated and documented on a monthly basis.

F.14.d Manipulation under General Anesthesia (MUA)

Manipulation under General Anesthesia (MUA) refers to manual manipulation of the lumbar spine in combination with the use of a general anesthetic or conscious sedation. It is intended to improve the success of manipulation when pain, muscle spasm, guarding, and fibrosis appear to be limiting its application in patients otherwise suitable for their use. There have been no high quality studies to justify its benefits given the risks of general anesthetic and conscious sedation. **It is not recommended.**

F.14.e Manipulation under Joint Anesthesia (MUJA)

Manipulation Under Joint Anesthesia (MUJA) refers to manipulation of the lumbar spine in combination with a fluoroscopically guided injection of anesthetic with or without corticosteroid agents into the facet joint at the level being manipulated. There are no controlled clinical trials to support its use. **It is not recommended.**

F.14.f Massage - Manual or Mechanical

Massage - Manual or Mechanical: Massage is manipulation of soft tissue with broad ranging relaxation and circulatory benefits. This may include stimulation of acupuncture points and acupuncture channels (acupressure), application of suction cups and techniques that include pressing, lifting, rubbing, pinching of soft tissues by or with the practitioner’s hands. Indications include edema (peripheral or hard and non-pliable edema), muscle spasm, adhesions, the need to improve peripheral circulation and range of motion, or to increase muscle relaxation and flexibility prior to exercise. There is good evidence that massage therapy in combination with exercise reduces pain and improves function short-term for patients with subacute low back pain.

- Time to produce effect: Immediate
- Frequency: 1 to 2 times per week
- Optimum duration: 6 weeks
- Maximum duration: 2 months

F.14.g Mobilization (Joint)

Mobilization is a generally well-accepted treatment. Mobilization is passive movement involving oscillatory motions to the vertebral segment(s). The passive mobility is performed in a graded manner (I, II, III, IV, or V), which depicts the speed and depth of joint motion during the maneuver. It may include skilled manual joint tissue stretching. Indications include the need to

improve joint play, segmental alignment, improve intracapsular arthrokinematics, or reduce pain associated with tissue impingement. For Level V mobilization, contraindications include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritides, aortic aneurysm, and signs of progressive neurologic deficits.

- Time to produce effect: 6 to 9 treatments
- Frequency: 3 times per week
- Optimum duration: 4 to 6 weeks
- Maximum duration: 6 weeks

F.14.h Mobilization (Soft Tissue)

Mobilization is a generally well-accepted treatment. Mobilization of soft tissue is the skilled application of muscle energy, strain/counter strain, myofascial release, manual trigger point release, and manual therapy techniques designed to improve or normalize movement patterns through the reduction of soft tissue pain and restrictions. These can be interactive with the patient participating or can be with the patient relaxing and letting the practitioner move the body tissues. Indications include muscle spasm around a joint, trigger points, adhesions, and neural compression. Mobilization should be accompanied by active therapy.

- Time to produce effect: 4 to 9 treatments
- Frequency: Up to 3 times per week
- Optimum duration: 4 to 6 weeks
- Maximum duration: 6 weeks

F.14.i. Percutaneous Electrical Nerve Stimulation (PENS)

In Percutaneous Electrical Nerve Stimulation (PENS), needles are used to deliver low-voltage electrical current under the skin. Theoretically this therapy prevents pain signals traveling through small nerve fibers from reaching the brain, similar to the theory of TENS. There is good evidence that PENS produces improvement of pain and function compared to placebo; however, there is no evidence that the effect is prolonged after the initial 3 week treatment episode. There are no well done studies that show PENS performs better than TENS for chronic pain patients. PENS is more invasive, requires a trained health care provider and has no clear long term effect; **therefore it is not generally recommended.**

- Time to Produce Effect: 1 to 4 treatments
- Frequency: 2 to 3 times per week
- Optimum 9 sessions

- Maximum Duration: 12 sessions per year

F.14.j Superficial Heat and Cold Therapy (Including Infrared Therapy)

Superficial heat and cold is a generally accepted treatment. Superficial heat and cold are thermal agents applied in various manners that lower or raise the body tissue temperature for the reduction of pain, inflammation, and/or effusion resulting from injury or induced by exercise. Includes application of heat just above the surface of the skin at acupuncture points. Indications include acute pain, edema and hemorrhage, need to increase pain threshold, reduce muscle spasm and promote stretching/flexibility. Cold and heat packs can be used at home as an extension of therapy in the clinic setting.

- Time to produce effect: Immediate
- Frequency: 2 to 5 times per week
- Optimum duration: 3 weeks as primary or intermittently as an adjunct to other therapeutic procedures up to 2 months
- Maximum duration: 2 months

F.14.k Traction - Manual

Manual traction is an accepted treatment and an integral part of manual manipulation or joint mobilization. Indications include decreased joint space, muscle spasm around joints, and the need for increased synovial nutrition and response. Manual traction is contraindicated in patients with tumor, infection, fracture, or fracture dislocation.

- Time to produce effect: 1 to 3 sessions
- Frequency: 2 to 3 times per week
- Optimum/maximum duration: 1 month

F.14.l Traction - Mechanical

Mechanical traction is indicated for decreased joint space, muscle spasm around joints, and the need for increased synovial nutrition and response. Traction modalities are contraindicated in patients with tumor, infections, fracture, or fracture dislocation. Non-oscillating inversion traction methods are contraindicated in patients with glaucoma or hypertension. There is some evidence that mechanical traction, using specific, instrumented axial distraction technique, is not more effective than active graded therapy without mechanical traction. Therefore, mechanical traction is not recommended for chronic axial spine pain.

- Time to produce effect: 1 to 3 sessions up to 30 minutes. If response is negative after 3 treatments, discontinue this modality.
- Frequency: 2 to 3 times per week

- Optimum/maximum duration: 1 month

F.14.m Ultrasound

Ultrasound (including phonophoresis) is an accepted treatment which uses sonic generators to deliver acoustic energy for therapeutic thermal and/or nonthermal soft tissue effects. Indications include scar tissue, adhesions, collagen fiber and muscle spasm, and the need to extend muscle tissue or accelerate the soft tissue healing. Ultrasound with electrical stimulation is concurrent delivery of electrical energy that involves dispersive electrode placement. Indications include muscle spasm, scar tissue, pain modulation and muscle facilitation.

Phonophoresis is the transfer of medication to the target tissue to control inflammation and pain through the use of sonic generators.. These topical medications include, but are not limited to, steroidal anti-inflammatory and anesthetics.

- Time to produce effect: 6 to 15 treatments
- Frequency: 3 times per week
- Optimum duration: 4 to 8 weeks
- Maximum duration: 2 months

F.14.n Vertebral Axial Decompression (VAX-D)/DRX, 9000

Vertebral Axial Decompression consists of motorized traction devices which purport to produce non-surgical disc decompression by creating negative intradiscal pressure in the disc space include devices with the trade names of VAX-D and DRX 9000. There are no good studies to support their use. They are not recommended.

G. Therapeutic Procedures - Operative

When considering operative intervention in chronic pain 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 of 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:

1. Return-to-work or maintaining work status.
2. Fewer restrictions at work or performing activities of daily living.
3. Decrease in usage of medications prescribed for work-related history.
4. Measurable functional gains, such as increased range of motion or 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.

G.1 Neurostimulation

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.

There is some evidence that SCS is superior to reoperation in setting of persistent radicular pain after lumbosacral spine surgery, and there is some evidence that SCS is superior to conventional medical management in the same setting. Success was defined as achieving 50% or more pain relief. Some functional gains have been demonstrated. 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 several studies have 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 in the management of chronic intractable pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

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) or failed back surgery with persistent radicular neuropathic pain.

While there is no evidence demonstrating effectiveness for use of SCS with CRPS II, it is generally accepted that SCS can be used for patients who have this condition. There is no evidence that supports its use for spinal axial pain. 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.

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 lost of paresthesia (12%).

Surgical Indications – Patients with established CRPS I or II or a failed spinal surgery with persistent functionally limiting radicular pain greater than axial pain who have failed conservative therapy including active and /or passive therapy, pre-stimulator trial psychiatric evaluation and treatment, medication management, and therapeutic injections. SCS is not recommended for patients with the major limiting factor of persistent axial spine pain. SCS may be indicated in a subset of patients who have a clear neuropathic radicular pain (radiculitis). The extremity pain should account for at least 50% or greater of the overall back and leg pain

experienced by the patient. 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 may regress over time. There appears to be a likely benefit of up to three years. Patients must meet the following criteria to be considered for neurostimulation:

1. SCS may be indicated in a subset of patients who have a clear neuropathic radicular pain (radiculitis), are not candidates for surgical intervention on the spine, have burning pain in a distribution amenable to stimulation coverage, and have pain at night not relieved by position. The extremity pain should account for at least 50% or greater of the overall leg and back pain experienced by the patient. In cases of complex regional pain syndrome, please refer to the CRPS guidelines.
2. 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 cord stimulator trial, the evaluation should find the following:
 - No indication of falsifying information, or of invalid response on testing,
 - No primary psychiatric risk factors or “red flags” (e.g., psychosis, active suicidality, severe depression, or addiction). (Notes that tolerance and dependence to opioid analgesics are not addictive behaviors and do not preclude implantation.)
 - A level of secondary risk factors or “yellow flags” (e.g., moderate depression, job dissatisfaction, dysfunctional pain conditions) judged to be below the threshold for compromising the patient's ability to benefit from neurostimulation.
 - The patient is cognitively capable of understanding and operating the neurostimulation control device.
 - The patient is cognitively capable of understanding and appreciating the risks and benefits of the procedure.
 - The patient has demonstrated a history of motivation in and adherence to prescribed treatments.
 - Statement of likelihood of patient being responsive to this therapy.

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 screening trial is scheduled. Significant personality disorders must be taken into account when considering a patient for spinal cord stimulation and other major procedures.

3. All reasonable surgical and non-surgical treatment has been exhausted.
4. The topography of pain and its underlying pathophysiology are amenable to stimulation coverage (the entire painful extremity area has been covered).

5. 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 radicular or CRPS 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.

Contraindications — Unsuccessful SCS test –inability to obtain objective, documented, functional improvement or reduction of pain; those with cardiac pacemakers who should be evaluated on an individual basis as some may qualify for surgery; patients 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.

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 on 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 screen exam.

Post-Operative Considerations – MRI is contraindicated after placement of neurostimulators except for cranial imaging with some models.

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.

G.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 in the patient meets both of the following criteria: (a) experiences a 50% decrease in pain, which may be confirmed by Visual Analog 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.

G.3 Intrathecal Drug Delivery

Intrathecal drug delivery is not generally recommended and 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. Specific brands of 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.

Description - This mode of therapy delivers small doses of medications directly into the cerebrospinal fluid.

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 (i.e. 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 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.

Indications – Clinical studies are conflicting, regarding long-term, effective pain relief in patients with non-malignant pain. The Department 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:

1. A diagnosis of a specific physical condition known to be chronically painful has been made on the basis of objective findings; and
2. 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
3. Pre-trial psychiatric or psychological evaluation has been performed (see G.1 Neurostimulation) 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 spinal cord stimulation and other major procedures; and
4. There is no evidence of current addictive behavior. (Tolerance and dependence to opioid analgesics are not addictive behaviors and do not preclude implantation.); and
5. 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.

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.

G.4 Neuroablation with Rhizotomy as the Exception

Neuroablation or neuro-destructive procedures are not commonly used in the management of non-malignant pain. These techniques require specific expertise to perform, have erratic results, and high rates of complication. Therefore, the Department does not recommend the use of neuroablative procedures except rhizotomy for injured workers with chronic pain.

G.5 Dorsal Nerve Root Resection

This procedure is not recommended. There exists the possibility of complications including unintended extensive nerve damage causing significant motor or sensibility changes from larger than anticipated lesioning of the ganglia at the dorsal ganglia level. For radiofrequency ablation, refer to Section F.5.b Therapeutic Procedures—Non-operative, Dorsal Root Ganglion Radiofrequency Ablation.

H. 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 CPD 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 CPD 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:

1. 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;
2. Modalities will emphasize self-management and self-applied treatment;
3. Management of pain or injury exacerbations will emphasize initiation of active therapy techniques and may occasionally require anesthetic injection blocks.
4. Dependence on treatment provided by practitioners other than the authorized treating physician will be minimized;
5. Periodic reassessment of the patient's condition will occur as appropriate.
6. 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.

H.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.

H.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. 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. Prior to purchasing a membership, a therapist and/or exercise specialist who has treated the patient may visit the facility with the patient to assure proper use of the equipment.

- 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.

H.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.

H.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) in-patient 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 Section F.2 Biofeedback, Section E.2 Personality/Psychological/Psychosocial Evaluation Pain Management or Section F.10 Personality/Psychological/Psychosocial Intervention.

- Maintenance duration: 6 to 10 visits during the first year and 4 to 6 visits a year thereafter. In cases of significant exacerbation, refer to Section F.10 Personality/Psychological/Psychosocial Intervention.

H.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.

H.6 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:

1. 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.
2. 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 medications are generally not recommended.
3. All patients on chronic opioid medication dosages need to sign an appropriate opioid contract with their physician for prescribing the opioids.
4. 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.

5. 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.

H.7 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 during the first year and then decreased to 5 visits a year thereafter.

H.8 Injection Therapy

Trigger Point Injections - These injections may occasionally be necessary to maintain function in those with myofascial problems.

- Maintenance duration: Not more than 4 injections per session not to exceed 3 to 6 sessions per 12-month period.

Epidural and Selective Nerve Root Injections - Patients who have experienced functional benefits from these injections in the past may require injection for exacerbations of the condition.

- Maintenance duration: 2 to 4 injections per 12-month period. For chronic radiculopathy, injections may be repeated only when a functional documented response lasts for 3 months. Patients should be reassessed after each injection session for an 80% improvement in pain (as measured by accepted pain scales) and evidence of functional improvement. A positive result would include a return to baseline function, return to increased work duties, and measurable improvement in physical activity goals including return to baseline after an exacerbation. Injections may only be repeated when these functional and time goals are met. Repeated injections with steroids should be done with caution especially in patients who have received other steroid injections or oral steroid therapy as higher yearly total doses of steroids may be associated with an increase of osteoarthritis.

Zygapopyseal (Facet) Injections

- Maintenance duration: 2 injections per year and limited to 3 joint levels either unilaterally or bilaterally. Injections may be repeated only when a functional documented response lasts for 3 months. Patients should be reassessed after each injection session for an 80% improvement in pain (as measured by accepted scales) and evidence of functional improvement. A positive result would include a return to base line function, return to increased work duties, and a measurable improvement in physical activity goals including return to baseline after an exacerbation. Injections may only be repeated when these functional and time goals are met. Repeated injections with steroids should be done with caution especially in patients who have received other steroid injections or oral steroid therapy as higher yearly total doses of steroids may be associated with an increase in osteoarthritis.

Sacro-iliac Joint

- Maintenance duration: 2 per year injections may be repeated only is when a functional documented response lasts for 3 months. Patients should be reassessed after each injection session for an 80% improvement in pain (as measured by accepted pain scales) and evidence of functional improvement. A positive result would include a return to base line function, return to increased work duties, and a measurable improvement in physical activity goals including return to baseline after an exacerbation. Injections may only be repeated when these functional and time goals are met. Repeated injections with steroids should be done with caution especially in patients who have received other steroid injections or oral steroid therapy as higher yearly doses of steroids may be associated with an increase in osteoarthritis.

Radiofrequency Medical Branch Neurotomy/Facet Rhizotomy

- Maintenance duration: 1 time per year up to 12 total—not exceeding 3 levels. The patient must meet the criteria as described in Section F.5.b. The initial indications including repeat blocks and limitations apply. The long-term effects of repeat rhizotomies, especially on younger patients, are unknown. There is a possibility that repeated denervation could result in premature degenerative changes. In addition, the patient should always reconsider all of the possible permanent complications before consenting to a repeat procedure. There are no studies addressing the total number of RF neurotomies that should be done for a patient. Patient should receive at least 6 to 18 months minimum improvement in order to qualify for repeat procedures.
- Optimum/Maximum Duration: Twice in the first year after the initial rhizotomy and once a year after up to 12 total.

H.9 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.

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