DEPARTMENT OF LABOR

Division of Industrial Affairs

The Office of Workers' Compensation

Health Care Practice Guidelines

PART B Chronic Pain Treatment Guidelines

1.0 Introduction

1.1 Pursuant to 19 **Del.C.** §2322C, health care practice guidelines have been adopted and recommended by the Workers' Compensation Oversight Panel to guide utilization of health care treatments in workers' compensation including – care provided for the treatment of employees by or under the supervision of a licensed health care provider, prescription drug utilization, inpatient hospitalization and length of stay, diagnostic testing, physical therapy, chiropractic care and palliative care. The health care practice guidelines apply to all treatments provided after the effective date of the regulation adopted by the Department of Labor, May 23, 2008, and regardless of the date of injury.

1.2 The guidelines are, to the extent permitted by the most current medical science or applicable science, based on well-documented scientific research concerning efficacious treatment for injuries and occupational disease. To the extent that well-documented scientific research regarding the above is not available at the time of adoption of the guidelines or is not available at the time of any revision to the guidelines, the guidelines have been and will be based upon the best available information concerning national consensus regarding best health care practices in the relevant health care community.

1.3 The guidelines, to the extent practical and consistent with the Act, address treatment of those physical conditions which occur with the greatest frequency, or which require the most expensive treatments, for work-related injuries based upon currently available Delaware data.

1.4 Services rendered by any health care provider certified pursuant to 19 **Del.C.** §2322D(a) to provide treatment or services for injured employees shall be presumed, in the absence of contrary evidence, to be reasonable and necessary if such treatment and/or services conform to the most current version of the Delaware health care practice guidelines.

1.5 Services rendered outside the Guidelines and/or variation in treatment recommendations from the Guidelines may represent acceptable medical care, be considered reasonable and necessary treatment and, therefore, determined to be compensable, absent evidence to the contrary, and may be payable in accordance with the Fee Schedule and Statute, accordingly.

1.6 Services provided by any health care provider that is not certified pursuant to 19 **Del.C.** §2322D(a) shall not be presumed reasonable and necessary unless such services are pre-authorized by the employer or insurance carrier, subject to the exception set forth in 19 **Del.C.** §2322D(b).

1.7 Treatment of conditions unrelated to the injuries sustained in an industrial accident may be denied as unauthorized if the treatment is directed toward the non-industrial condition unless the treatment of the unrelated injury is rendered necessary as a result of the industrial accident.

1.8 The Workers' Compensation Oversight Panel and Department of Labor recognized that acceptable medical practice may include deviations from these Guidelines, as individual cases dictate. Therefore, these Guidelines are not relevant as evidence of a provider's legal standard of professional care.

1.9 In accordance with the requirements of the Act, the development of the health care guidelines has been directed by a predominantly medical or other health professional panel, with recommendations then made to the Workers' Compensation Oversight Panel.

2.0 General Guideline Principles

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

2.1 Application of the guidelines. The Guidelines provide procedures to implement medical treatment Guidelines and to foster communication to resolve disputes among the provider, payer, and patient.

2.2 Education. Education of the patient should be a consideration in the treatment of chronic pain and disability. No treatment plan is complete without addressing issues of individual education as a means of facilitating self-management of symptoms and prevention.

2.3 Informed Decision Making. Providers should implement informed decision making as a crucial element of a successful treatment plan. Patients, with the assistance of their health care practitioner, should identify their personal and professional functional goals of treatment at the first visit. Progress towards the individual's identified functional goals should be addressed by all members of the health care team at subsequent visits and throughout the established treatment plan. Nurse care managers, physical therapists, and other members of the health care team play an integral role in informed decision making and achievement of functional goals. Patient education and informed decision making should facilitate self-management of symptoms and prevention of further injury.

2.4 Treatment Parameter Duration. Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document.

2.5 Active Interventions. Patient responsibility, such as therapeutic exercise and/or functional treatment, is 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.

2.6 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.

2.7 Positive Patient Response. Positive results are defined primarily as functional gains that can be objectively measured. Objective functional gains include, but are not limited to, positional tolerances, range of motion (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.

2.8 Re-evaluation of Treatment every 10 to 12 Treatments. With respect to Therapy (Active or Passive), if a given treatment or modality is not producing positive results within 10 to 12 treatments, the treatment should be either modified or discontinued. Before discontinuing the treatment, the provider should have a detailed discussion with the patient to determine the reason for failure to produce positive results. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

2.9 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 identification of pathologic conditions.

2.10 Six-month Time Frame. The prognosis drops precipitously for returning an injured worker to work once the injured worker has been temporarily totally disabled for more than 6 months. The emphasis within these Guidelines is to move patients along a continuum of care and return to work within a 6-month time frame, whenever possible. It is important to note that time frames may be less pertinent for injuries that do not involve work-time loss or not occupationally related.

2.11 Return to Work

2.11.1 Early return to work should be a prime goal in treating occupational injuries give the poor return to work prognosis for an injured worker who has been out of work more than 6 months. The patient should be educated regarding the benefits of return to work, work restrictions and follow-up if problems arise.

2.11.2 Employers should be encouraged to offer transitional work. This may consist of temporary work in a less demanding position, return to the regular job with restrictions, or gradual return to the regular job.

2.11.3 Due to the large spectrum of injuries of varying severity and varying physical demands in the workplace, it is not possible to make specific return to work guidelines for each injury.

2.12 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 Office of Workers' Compensation 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.

2.13 Guideline Recommendations and Inclusion of Medical Evidence. All recommendations are based on available evidence and/or consensus judgment. When possible, Guideline recommendations will note the level of evidence supporting the treatment recommendation. It is generally recognized that early reports of a positive treatment effect are frequently weakened or overturned by subsequent research. When interpreting medical evidence statements in the Guidelines, the following apply:

2.13.1 "Consensus" means the judgment of experienced professionals based on general medical principals.

2.13.2 Consensus recommendations are designated in the Guidelines as "generally well-accepted," "generally accepted," "acceptable/accepted," or "well-established."

2.13.3 "Some evidence" means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective. The Department recognizes that further research is likely to have an impact on the intervention's effect.

2.13.4 "Good evidence" 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. The Department recognizes that further research may have an impact on the intervention's effect.

2.13.5 "Strong evidence" 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. The Department recognizes that further research is unlikely to have an important impact on the intervention's effect.

All recommendations are based on available evidence and/or consensus recommendations of the standard of care within Delaware. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the Guideline as being "not recommended."

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3.0 Overview of Chronic Pain Management

3.1 It is estimated by the Institute of Medicine that approximately 100 million adults suffer from chronic pain in the United States. The World Health Organization's survey found that 37% of adults in 10 developed countries have chronic pain conditions. This overview covers the biopsychosocial nature of chronic pain and a comprehensive plan of care including functional assessment and goal setting, psychological assessment, medication management, sleep considerations, and active therapy.

3.2 Chronic pain may develop from persistent acute pain due to neuroplastic changes occurring in the central nervous system.

3.2.1 All chronic pain appears to involve a central sensitization which changes the perception of pain. Thus, treatment patters are aimed at a number of mechanisms contributing to chronic pain.

3.2.2 Chronic pain is recognized as a biopsychosocial disease process.

3.2.2.1 Each treatment plan should be individualized with a patient-centered approach addressing the many available treatment combinations. Therefore, all areas of the chronic pain Guideline should be considered when developing a treatment plan.

3.2.2.2 This may include a psychological evaluation; an active therapy plan; medications specific to the pain process for that patient; continuing functional assessment; complementary medication alternatives, when appropriate; and continued return to work/regular daily activity.

3.3 Once a patient has been identified as a chronic pain patient, usually 3 months after an injury when pain persists or when pain persists beyond a reasonable post-operative period, the physician should perform a complete re-evaluation. This will assist both the patient and the provider in developing an appropriate treatment plan.

3.3.1 Although it is unusual to identify an unknown pathology at this point in the treatment, it is recommended that the provider acknowledge the full complement of patient symptoms and concerns.

3.3.2 Repeating or ordering new imaging may be necessary; however, it is not usually recommended as the findings may add to the patient's confusion regarding the work-related injury.

3.4 It is essential that the patient and provider understand the type of pain the patient is experiencing and how the pain affects day-to-day activities. Identifying the presence of neuropathic pain, as well as any sources of nociceptive pain, will assist the patient and provider when choosing medication and other forms of treatment recommended in the Guideline.

3.4.1 During the chronic pain assessment, it is suggested that all physicians review with the patient their usual activities over several different typical 24-hour periods. This will assist both parties in understanding what functions are not able to be performed by the patient, how significantly sleep is impacted, and whether pain is affecting social and family relationships.

3.4.2 This information is also essential for establishing agreed upon functional goals.

3.5 Chronic pain patients may require psychological evaluations. Patients may merely need assistance with coping mechanisms, and/or anxiety or depression may be caused or exacerbated by chronic pain. Treatment in this area is essential for the chronic pain patient. A limited number of cognitive behavioral sessions are frequently effective for these conditions.

3.6 Review of the current prescribed and over-the-counter medications is an important part of this initial chronic pain evaluation.

3.6.1 If the patient has been chronically on opioids, it is very likely that the full required opioid trial and review has not been performed.

3.6.2 Thus, the physician will need to ensure that the proper steps have been taken if opioids are to be continued. It is also reasonable to taper opioids in order to determine the patient's baseline and how other medications are actually affecting the pain.

3.7 The following is a general summary of the required elements. A number of other Guidelines, including the Center for Disease Control and Prevention (CDC) have confirmed these steps.

3.7.1 An opioid trial shall be performed before chronic opioids are determined to be useful for patients. About 50% of patients will not be able to tolerate the side effects and/or not show a sufficient increase in function with opioid use. Patients should be aware that this is trial and like any other medication trial, it will not be continued unless there is sufficient benefit. The average benefit is about a 30% decrease in pain. Thus, all other required treatment must be continued during the time period of the chronic opioid trial.

3.7.2 Long-acting opioids should never be used for acute pain, post-operative pain, or before an opioid trial has been completed. There is no evidence they are more beneficial than short acting opioids, and the trial should begin with short acting opioids.

3.7.3 A risk assessment tool, such as the Opioid Risk Tool (ORT) should be completed to assure the provider that there are no prior elements suggesting substance abuse or, when such elements are present, the physician may choose to refer to a provider with more expertise in substance abuse.

3.7.4 Urine drug testing should be done prior to the trial.

3.7.5 Check the Prescription Monitoring Program (PMP).

3.7.6 The psychological evaluation should be considered.

3.7.7 A functional history should be taken, and functions goals should be set. This needs to be followed throughout all chronic pain treatment to determine if the patient is increasing or decreasing in function.

3.7.8 A provider physician agreement must be completed. This is extremely helpful as it reviews for the patient the expectations regarding the patient's behavior as well as the expectations regarding when a physician would choose to tape or remove the patient from opioids and what other treatment is expected to continue during an opioid trial.

3.7.8.1 If the opioid trial is successful, the physician should continue to monitor with random drug testing and PMP checks. In addition, the Current Opioid Misuse Measure (COMM) is a tool that can be used for patients on opioids to screen for possible abuse. It should be noted that current estimates suggest approximately 14 to 19 percent of chronic opioid users may become addicted to opioids.

3.7.8.2 The patient will need to be monitored for side effects. Constipation is anticipated. There may also be problems with sexual dysfunction. Opioids may increase or cause sleep apnea problems, and this should be monitored. At all visits, the functional status of the patient

should be recorded. This can be accomplished with reliable, patient-reported functional status tools. Function is preferably validated by physical exam or by other objective measures from the provider.

3.7.8.3 Lack of sleep is a significant problem for patients with uncontrolled chronic pain. Taking a good history in this area and promoting an appropriate sleep regime is essential for patients, if they are to establish a productive lifestyle.

3.7.8.4 Active therapy is one of the most important components. Regular exercise is shown to decrease depression as well as decrease chronic pain. Helping the patient choose appropriate physical activities and cognitive activities will be important for recovery.

3.7.8.5 Although treatment chronic pain patients is challenging due to the many disciplines and treatment patterns available, the rewards are great when a patient with chronic pain is able to resume work and engage in satisfying life activities.

4.0 Introduction to Chronic Pain

4.1 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:

4.1.1 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.

4.1.2 Neuropathic including that originating from brain, peripheral nerves or both; and

4.1.3 Psychogenic that originates in mood, characterological, social, or psychophysiological processes.

4.2 Mechanisms Involved in Chronic Pain

4.2.1 Recent advances in the neurosciences reveal additional mechanisms involved in chronic pain.

4.2.1.1 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.

4.2.1.2 Current research indicates that chronic pain involves additional mechanisms that cause:

4.2.1.2.1 Neural remodeling at the level of the spinal cord and higher levels of the central nervous system;

4.2.1.2.2 Changes in membrane responsiveness and connectivity leading to activation of larger pain pathways; and

4.2.1.2.3 Recruitment of distinct neurotransmitters.

4.2.1.3 Changes in gene function and expression may occur, with lasting functional consequences.

4.2.1.3.1 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.

4.2.1.3.2 The chronic pain experience clearly represents both psychologic and complex physiologic mechanisms, many of which are just beginning to be understood.

4.2.2 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)."

4.2.2.1 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.

4.2.2.2 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.

4.2.3 The term “chronic pain syndrome” has been incorrectly 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 cases to have meaning due to the many different physical and psychosocial issues associated with it. The IASP offers a taxonomy of pain, which underscores the wide variety of pathological conditions associated with chronic pain. The 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. Practitioners should use the nationally accepted terminology indicated in the most current ICD system. Chronic pain can be diagnosed as “Pain disorder with related psychological factors” when the associated body part code is also provided. Alternately, chronic pain can also be diagnosed as “Psychological factors affecting physical conditions,” and this code should also be accompanied by the associated body part.

4.2.4 Injured patients generally initiate treatment with complaints of pain, which is generally attributable to a specific injurious event, but occasionally to an ostensible injury. Thus, the physician should not automatically assume that complaints of acute pain are directly attributable to pathophysiology at the tissue level. Pain is known to be associated with sensory, affective, cognitive, social, and other processes. The pain sensory system itself is organized into two parts, often called first and second pain. A-∂ nerve fibers conduct first pain via the neospinothalamic tract to the somatosensory cortex and provide information about pain location and quality. In contrast, unmyelinated C fibers conduct second pain via the paleospinothalamic tranct and provide information about pain intensity. Second pain is more closely associated with emotion and memory neural systems that it is with sensory systems.

4.2.5 As a patient’s condition transitions through the acute, subacute, and chronic phases, the central nervous system (CNS) is reorganized. The temporal summation of second pain produces a sensitization or “windup” of the spinal cord, and the connections between the brain regions involved in pain perception, emotion, arousal, and judgment are changed by persistent

pain. The temporal submission of second pain produces a sensitization or “windup” of the spinal cord, and the connections between the brain regions involved in pain perception, emotion, arousal, and judgment are changed by persistent pain. These changes cause the CNS’s “pain neuromatrix” to become sensitized to pain. This CNS reorganization is also associated with changes in the volume of brain areas, decreased grey matter in the prefrontal cortex, and the brain appearing to age more rapidly. As pain continues over time, the CNS remodels itself so that pain becomes less closely associated with sension, and more closely associated with arousal, emotion, memory, and beliefs. Because of these CNS processes, all clinicians should be aware that as the patient enters the subacute phase, it becomes increasingly important to consider the psychosocial context of the disorder being treated, including the patient’s social circumstances arousal level, emotional state, and beliefs about the disorder. However, behavioral complications and physiological changes associated with chronicity and central sensitization may also be present in the acute phase, and within hours of the initial injury. It is the intent of many of the treatments in this Guideline to assist in remodeling these CNS changes.

4.2.6 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.

4.2.7 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, in conjunction with other health care specialists.

4.2.8 Most acute and some chronic pain problems are adequately addressed in other Office of Workers' Compensation 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.

5.0 Definitions

The following words and terms, when used in this regulation, have the following meaning:

“**Aftersensation**” means the abnormal persistence of a sensory perception, provoked by a stimulus even though the stimulus has ceased.

“**Allodynia**” means pain due to a non-noxious stimulus that does not normally provoke pain. Types of allodynia are:

“**Dynamic mechanical allodynia**” means pain obtained by moving the stimulus such as a brush or cotton tip across the abnormal hypersensitive area.

“**Mechanical allodynia**” means the abnormal perception of pain from usually non-painful mechanical stimulation.

“**Static mechanical allodynia**” means pain obtained by applying a single stimulus such as light pressure to a defined area.

“**Thermal allodynia**” means the abnormal sensation of pain from usually non-painful thermal stimulation such as cold or warmth.

“**Analgesia**” means absence of pain in response to stimulation that would normally be painful.

“**Biopsychosocial**” means the multiple facets of any clinical situation; namely, the

biological, psychological, and social situation of the patient.

"**Central pain**" means pain initiated or caused by a primary lesion or dysfunction in the central nervous system.

"**Central sensitization**" means 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 a "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.

"**Dysesthesia**" means the abnormal sensation described by the patient as unpleasant. As with paresthesia, dysesthesia may be spontaneous or evoked by maneuvers on physical examination.

"**Hyperesthesia**" means the exaggerated pain response from a usually painful stimulation.

"**Hyperesthesia (positive sensory phenomena)**" means a phenomena that includes allodynia, hyperalgesia, and hyperpathia. Hyperesthesia is elicited by light touch, pin prick, cold, warm, vibration, joint position sensation or two-point discrimination, which is perceived as increased or more.

"**Hyperpathia**" means an abnormally painful and exaggerated reaction to stimulus, especially to a repetitive stimulus.

"**Hypoalgesia**" means diminished pain perception in response to a normally painful stimulus.

"**Hypoesthesia** (negative sensory phenomena) means a stimulus such as light touch, pin prick, cold, point position sensation, two-point discrimination, or sensory neglect which is perceived as decreased.

"**Malingering**" means the intentional feigning of illness or disability in order to escape work or gain compensation.

"**Myofascial pain**" means regional pain characterized by tender points in taut bands of muscle that produce pain in a characteristic reference zone.

"**Myofascial trigger point**" means 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.

"**Neuralgia**" means pain in the distribution of a nerve or nerves.

"**Neuritis**" means the inflammation of a nerve or nerves.

"**Neurogenic pain**" means the pain initiated or caused by a primary lesion, dysfunction, or transitory perturbation in the peripheral or central nervous system.

"**Neuropathic pain**" means pain due to an injured or dysfunctional central or peripheral nervous system.

"**Neuropathy**" means a disturbance of function or pathological change in a nerve: in one nerve, mononeuropathy; in several nerves, mononeuropathy multiplex; diffuse 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.

"**Nociceptor**" means a receptor preferentially sensitive to a noxious stimulus or to a stimulus which would become noxious if prolonged.

"**Pain behavior**" means 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.

"**Pain threshold**" means the smallest stimulus perceived by a subject as painful.

"**Paresthesia**" means 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.

"**Peripheral neurogenic pain**" means a pain initiated or caused by a primary lesion or dysfunction or transitory perturbation in the peripheral nervous system.

"**Somatic dysfunction**" means an impaired or altered function of related components of the somatic (body framework) system which includes skeletal, arthrodial, and myofascial structures.

"**Summation**" means an 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.

"**Sympathetically Maintained Pain**" or "**SMP**" means a pain that is maintained by sympathetic efferent innervations or by circulating catecholamines.

"**Tender points**" means 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).

6.0 Initial Evaluation and Diagnostic Procedures

6.1 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.

6.2 History (Hx) and Evaluation

6.2.1 History (Hx)

6.2.1.1 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.

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

6.2.2.1 Site of pain. Localization and distribution of the pain help determine the type of pain the patient has (i.e., central versus peripheral).

6.2.2.2 Pain diagram drawings to document the distribution of pain.

6.2.2.3 Visual Analog Scale (VAS). Current pain, highest pain level, and usually pain level may be recorded. Include a discussion of the range of pain during the day and how activities, use of modalities, and other actions affect the intensity of pain.

6.2.2.4 Duration. Including intermittent pain, activity related pain.

6.2.2.5 Place of onset. Circumstances during which the pain began (e.g., an accident, an illness, a stressful incident, or spontaneous onset).

6.2.2.6 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 often described as burning.

6.2.2.7 List of activities. Activities which aggravate or exacerbate, ameliorate, decrease, or have no effect on the level of pain.

6.2.2.8 Associated symptoms. Does the patient have numbness or paresthesia, dysesthesia, weakness, bowel or bladder dysfunction, altered temperature, increased sweating, cyanosis, or edema? Is there local tenderness, allodynia, hyperesthesia, or hyperalgesia? Does the patient have constitutional symptoms such as fevers, chills, night sweats, unexpected weight loss, or pain that awakes them from a deep sleep at night?

6.2.3 Medical Management History

6.2.3.1 Diagnostic tests. Relevant previous medical records and tests should be reviewed.

6.2.3.2 Prior treatment. Chronological review of medical records including previous medical evaluations and response to treatment intervensions. In other words, what has been tried and which treatments have helped?

6.2.3.3 Prior surgery. If the patient has had prior surgery specifically for the pain, ~~he/she~~ they may be less likely to have a positive outcome.

6.2.3.4 Medications. History of and current use of medications, including opioids, over-the-counter medications, cannabis products, 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 Delaware Prescription Monitoring Program (PDMP).

6.2.3.5 Review of systems check list. Determine if there is any interplay between the pain complaint and other medical conditions.

6.2.3.6 Psychosocial functioning. Determine if any of the following are present: current symptoms of depression or anxiety; evidence of stressors in the workplace or at home; and past history of psychological problems. 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, patients diagnosed with chronic pain may be referred for a full psychosocial evaluation.

6.2.3.7 Pre-existing conditions. Treatment of these conditions is appropriate when the pre-existing condition affects recovery from chronic pain.

6.2.3.8 Family history pertaining to similar disorders.

6.2.4 Substance Use/Abuse

6.2.4.1 Alcohol use.

6.2.4.2 Smoking history and use of nicotine replacements.

6.2.4.3 History of current and prior prescription and recreational drug use or abuse.

6.2.4.4. The use of caffeine or caffeine containing beverages.

6.2.4.5 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.

6.2.5 Physical Examination

6.2.5.1 Neurologic evaluation may include cranial nerves survey, muscle tone and strength, atrophy, detailed sensory examination (see ii-below), motor evaluation (station, gain, 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, signs suggestive of a sensory ataxia (positive Romberg, impaired proprioception, etc.), and provocative neurological maneuvers as pertaining to the patient's diagnosis.

6.2.5.2 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. Ideally, the examination should determine if the following sensory signs are present and consistent on repeated examination.

6.2.5.2.1 Hyperalgesia.

6.2.5.2.2 Hyperpathia.

6.2.5.2.3 Paresthesia.

6.2.5.2.4 Dysesthesia.

6.2.5.2.5 Mechanical Allodynia – static versus dynamic.

6.2.5.2.6 Thermal Allodynia.

6.2.5.2.7 Hypoesthesia.

6.2.5.2.8 Hyperesthesia.

6.2.5.2.9 Summation.

6.2.6 Personality/Psychological/Psychosocial Evaluations for Pain Management

6.2.6.1 These 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.

6.2.6.2 Psychosocial evaluations should determine if further psychosocial or behavioral 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 require consideration of variations of 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.

6.2.6.3 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.

6.2.6.4 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. All patients who are diagnosed as having chronic pain may 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 amendable 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. It is recognized that there is limited access in Delaware to professionals that provide the services noted above and that the inability to get an evaluation will not preclude continuation of treatment under these Guidelines.

6.2.6.5 Qualifications

6.2.6.5.1 A psychologist with a PhD, PsyD, or 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 treatment chronic pain disorders and/or working with patients with physical impairments.

6.2.6.5.2 Psychometric tests should be administered by psychologists with a PhD, PsyD, or EdD or health professionals working under the supervision of a doctorate level psychologist. Physicians with appropriate training may also administer such testing, but interpretation of the tests should be done by properly credentialed mental health professionals.

6.3 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.

6.3.1 Radiographic Imaging, MRI, CT, bone scan, radiography, and other special imaging studies may provide useful information for many musculoskeletal disorders causing chronic pain.

6.3.2 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.

6.3.3 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.

6.4 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

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

6.4.2 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;

6.4.3 Thyroid, glucose and other tests to detect endocrine disorders;

6.4.4 Serum calcium, phosphorous, uric acid, alkaline phosphatase, and acid phosphatase can detect metabolic bone disease;

6.4.5 Urinalysis to detect bacteria (usually with culture and sensitivity), calcium, phosphorus, hydroxyproline, or hematuria;

6.4.6 Liver and kidney function may be performed for baseline testing and monitoring of medications; and

6.4.7 Toxicology Screen and/or Blood Alcohol Level if suspected drug or alcohol abuse.

6.5 Injections-Diagnostic

6.5.1 Spinal diagnostic injections

6.5.1.1 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). 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.

6.5.1.1. 1 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.

6.5.1.1.2 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 conditions. Regarding diagnostic 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. 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 should be identified as to specific body part (e.g., low back, neck, leg, or arm pain).

6.5.1.2 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 anesthesiology, radiology, surgery, or physiatry. The practitioner who performs spinal injections 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. Practitioners performing spinal injections for low back and cervical pain must also be knowledgeable in radiation safety.

6.5.1.3 Specific diagnostic injections. In general, relief should last for at least the duration of the local anesthetic used and/or should significantly relieve pain and result in functional improvement. The following injections are used primarily for diagnosis:

6.5.1.3.1 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). To be a positive diagnostic block, the patient should report a reduction of pain of 50% or greater relief from baseline for the length of time appropriate for the local anesthetic used. It is suggested that this be reported on a form.

6.5.1.3.1.1 A separate block on a different date should be performed to confirm the level of involvement.

6.5.1.3.1.2 Frequency and maximum duration. May be repeated once for comparative blocks. Limited to 4 levels.

6.5.1.4 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.

6.5.1.4.1 A positive diagnostic block should result in a 50% reduction in nerve-root generated pain appropriate for the anesthetic used as measured by accepted pain scales (such as a VAS).

6.5.1.4.2 Frequency and maximum duration. Once per suspected level. Limited to three levels, may be repeated for confirmation.

6.5.1.5 Zygapophyseal (facet) blocks. Facet blocks are generally used diagnostically to direct functional rehabilitation programs. A positive diagnostic block should result in a positive diagnostic functional benefit and/or a 50% 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.

Frequency and maximum duration. Once per suspected level, limited to three levels, may be repeated for confirmation.

6.5.1.6 Atlanto-Axial and Atlanto-Occipital injections. The injections are generally accepted for diagnosis and treatment but do not lend themselves to denervation techniques owing to variable neuroanatomy.

Frequency and maximum duration. Once per side.

6.5.1.7 Sacroiliac joint injection. This injection is a generally accepted injection of local anesthetic in an intra-articular fashion into the sacroiliac joint under fluoroscopic guidance.

6.5.1.7.1 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 at least 50% pain relief.

6.5.1.7.2 Frequency and maximum duration. 1 may be repeated for confirmation.

7.0 Therapeutic Procedures – Non-Operative

7.1 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.

7.2 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.

7.3 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 Return-to-Work in this section for detailed information.

7.4 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:

7.4.1 Return-to-work or maintaining work status.

7.4.2 Fewer restrictions at work or performing activities of daily living.

7.4.3 Decrease in usage of medications.

7.4.4 Measurable functional gains, such as increased range of motion or documented increase in strength.

7.5 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.

7.6 Psychological or psychosocial screening should be performed on all chronic pain patients.

The following procedures are listed in alphabetical order.

7.7 Acupuncture is an accepted and widely used procedure for the relief of pain and inflammation. 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. While it is commonly used when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten the return of functional activity. Acupuncture should be performed by MD, DO, DC with appropriate training; or a licensed acupuncturist.

7.7.1 Acupuncture is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated, and retained for a period of time. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range of motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm.

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

7.7.2 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.

7.7.3 Total time frames for acupuncture and acupuncture with electrical stimulation 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.

7.7.3.1 Time to produce effect: 3 to 6 treatments.

7.7.3.2 Frequency: 1 to 3 times per week.

7.7.3.3 Maximum course duration: 14 treatments (one course).

7.7.3.4 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. An additional course of treatment beyond 14 treatments may 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.

7.7.4 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 Active Therapy (Therapeutic Exercise) and Passive Therapy sections (Massage and Superficial Heat and Cold Therapy) for a description of these adjunctive acupuncture modalities and time frames.

7.8 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. Stress-related psycho physiological reactions may arise as a reaction to organic pain and in some cases may cause pain. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorily, or tactilely with coaching by a biofeedback specialist.

7.8.1 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, narcotic 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.

7.8.2 Recognized types of biofeedback include:

7.8.2.1 Electroymyogram or EMG is used for self-management of pain and stress reactions involving muscle tension.

7.8.2.2 Skin temperature is used for self-management of pain and stress reactions, especially vascular headaches.

7.8.2.3 Respiration Feedback or RFB is used for self-management of pain and stress reactions via breathing control.

7.8.2.4 Respiratory Sinus Arrhythmia or RSA is used for self-management of pain and stress reactions via synchronous control of heart rate and respiration.

Respiratory sinus arrhythmia is a benign phenomenon which consists of a small rise in heart rate during inhalation, and a corresponding decrease during exhalation. This phenomenon has been observed in meditators and athletes and is thought to be a psycho physiological indicator of health.

7.8.2.5 Heart Rate Variability or HRV is used for self-management of stress via managing cardiac reactivity.

7.8.2.6 Electrodermal Response or EDR is used for self-management of stress involving palmar sweating or galvanic skin response.

7.8.2.7 Electroencephalograph or EEG or QEEG is used for self-management of various psychological states by controlling brainwaves.

7.8.3 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. During 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 using 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 non-licensed health care providers of biofeedback for chronic pain patients must be BCIA certified and shall have their biofeedback treatment plan approved by the authorized treating psychologist or psychiatrist. Biofeedback treatment must be done in conjunction with the patient's psychosocial intervention. Biofeedback may also be provided by licensed health care providers, who follow a set treatment and educational protocol. Such treatment may utilize standardized material, ~~or~~ relaxation tapes, or smart phone apps.

7.8.3.1 Time to produce effect: 3 to 4 sessions.

7.8.3.2 Frequency: 1 to 2 times per week.

7.8.3.3 Optimum duration: 6 to 8 sessions.

7.8.3.4 Maximum duration: 10 to 12 sessions.

7.8.3.5 Treatment beyond 12 sessions must be documented with respect to need, expectation, and ability to facilitate positive symptomatic or functional gains.

7.9 Complementary Alternative Medicine or 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:

7.9.1 Alternative medical systems 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.

7.9.2 Mind-body interventions include practices such as hypnosis, meditation, bioenergetics, and prayer.

7.9.3 Biological-based practices 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.

7.9.4 Body-based therapy includes the practices of Yoga and Rolfing bodywork.

7.9.5 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.

7.9.6 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.

7.9.6.1 Frequency: Per CAM therapy selected.

7.9.6.2 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.

7.10 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.

7.10.1 Sleep apnea may also occur as a primary diagnosis or be caused or exacerbated by opioid and hypnotic use. This should be investigated diagnostically.

7.10.2 A recent systematic review explored the relationship between sleep and pain. It noted that studies of healthy individuals and those in pain from medical conditions both showed decreased pain thresholds after sleep deprivation. In this report some studies focusing on sleep continuity disruption showed a disruption of the natural pain inhibitory function. Sleep continuity disruption may be one of the most common sleep problems associated with pain. Thus, clinicians should strongly focus on assuring functional sleep for patients.

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

reduce dysfunctional beliefs and attitudes about sleep. There is some evidence that behavioral modification, such as patient education and group or individual counseling, can be effective in reversing the effects of insomnia. Cognitive and behavioral modifications are easily implemented and can include:

7.10.3.1 Maintaining a regular sleep schedule, retiring and rising at approximately the same time on weekdays and weekends.

7.10.3.2 Avoiding daytime napping.

7.10.3.3 Avoiding caffeinated beverages after lunchtime.

7.10.3.4 Making the bedroom quiet and comfortable, eliminating disruptive lights, sounds, television sets, and keeping a bedroom temperature of about 65°F.

7.10.3.5 Avoiding alcohol or nicotine within two hours of bedtime.

7.10.3.6 Avoiding large meals within two hours of bedtime.

7.10.3.7 Avoiding exposure to TV screens or computers within 2 hours of bedtime.

7.10.3.8 Exercising vigorously during the day, but not within two hours of bedtime, since this may raise core temperature and activate the nervous system.

7.10.3.9 Associating the bed with sleep and sexual activity only, using other parts of the home for television, reading and talking on the telephone.

7.10.3.10 Leaving the bedroom when unable to sleep for more than 20 minutes, returning to the bedroom when ready to sleep again.

7.10.3.11 Reducing time in bed to estimated typical sleeping time.

7.10.3.12 Engaging in relaxing activities until drowsy.

These modifications should be undertaken before sleeping medication is prescribed for long term use.

7.10.3.13 Behavioral modifications should be trialed before the use of hypnotics. Reinforcing these behaviors may also decrease hypnotic use and overall medication costs. Some patients may use other mediations to assist in sleep, such as trazadone, amitriptyline, doxepin, or lose doses of melatonin. There is some evidence that group cognitive behavioral therapy reduces the severity and day time consequences of insomnia for at least six months. 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. There is some evidence that a dietary supplement containing melatonin, magnesium, and zinc, conveyed in pear pulp, taken 1 hour before bedtime, results in significantly better quality of sleep and quality of life than a placebo treatment in long-term care facility residents aged 70 and older with primary insomnia.

7.10.3.14 Many medications used in chronic pain can affect the sleep cycle. There is some evidence that the following medications exert different effects with respect to sleep variables. Total sleep time and REM sleep duration are likely to be greater with pregabalin than with duloxetine or amitriptyline. However, pregabalin is likely to lead to dizziness and fatigue more frequently than the other drugs, and oxygen desaturation during sleep also appears to be greater with pregabalin.

7.10.3.15 Insomnia requires difficulty initiating or maintaining sleep, waking up early, or insufficient restorative sleep despite adequate opportunity for sleep, as well as daytime symptoms of sleep deprivation. In general, recommendations for treatment of insomnia include Cognitive Behavioral Therapy.

7.11 Education/Informed/Shared Decision Making. Informed decision making is the hallmark of a successful treatment plan. In most cases, the continuum of treatment from the least invasive to the most invasive (e.g., surgery) should be discussed. The intention is to find the treatment along this continuum which most completely addresses the

condition. Patients should identify their personal values and functional goals of treatment at the first visit. It is recommended that specific individual goals are articulated at the beginning of treatment as this is likely to lead to increased patient satisfaction above that achieved from improvement in pain or other physical function. Progress toward the individual functional goals identified should be addressed at follow-up visits and throughout treatment by other members of the health care team as well as an authorized physician.

7.12 Injections: Therapeutic. When considering the use of injections in chronic pain management, the treating physician must carefully consider the inherent risks and benefits. Any continued use of injections 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.
- Decrease in usage of medications.

Measurable functional gains, such as increased range of motion for documented increase in strength. Reduction of reported pain scores.

7.12.1 Spinal therapeutic injections. As a general 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 typically may be used after initial conservative treatments, such as physical and occupational therapy, medication, manual therapy, exercise, acupuncture, etc., have been undertaken. Special considerations for all spinal injections (excluding trigger point, Botox and occipital or peripheral nerve blocks) multi-planar fluoroscopy, during procedures are 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 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. Practitioners who perform spinal injections must also be knowledgeable of radiation safety.

7.12.1.1 Epidural Steroid Spinal Injections

7.12.1.1.1 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. For ESI in the low back, the transforaminal approach is the preferred method for unilateral, single-level pathology and for post-surgical patients. Also, for the low back, there is good evidence that the transforaminal approach can deliver medication to the target tissue with few complications and can be used to identify the specific site of pathology.

7.12.1.1.2 Needle Placement: Multi-planar fluoroscopic imaging is required for all transforaminal epidural steroid injections. Contrast epidurograms allow one to verify the flow of medication into the epidural space. Permanent images are required to verify needle placement. Indications – 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). Although there is no evidence regarding the effectiveness of ESI for non-radicular pain, it is a generally accepted intervention.

7.12.1.1.3 Frequency: Up to 3 treatments (a treatment may be a 1- or 2- level injection) over a period of 6 months, depending upon each patient's response.

7.12.1.1.4 Maximum: Two sessions (consisting of up to 3 injections each) may be done in 1 year based upon the patient's response.

7.12.1.2 Zygapophyseal (Facet) Injection

7.12.1.2.1 Description: A generally accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid. There is conflicting evidence to support a long-term therapeutic effect using facet injections.

7.12.1.2.2 Indications patients with pain suspected to be of facet origin: Patients with recurrent pain should be evaluated, to determine the need for a rhizotomy.

Facet injections may be repeated if they result in documented functional benefit and/or at least an 50% initial improvement in pain as measured by accepted pain scales (such as VAS).

7.12.1.2.3 Maximum duration: 4 per level per year. Prior authorization must be obtained for injections beyond three levels.

7.12.1.3 Sacro-iliac Joint Injection

7.12.1.3.1 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.

7.12.1.3.2 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. These injections may be repeated if they result in increased documented functional benefit and/or at least an 50% initial improvement in pain scales as measured by accepted pain scales (such as VAS).

7.12.1.3.3 Maximum duration: 3 injections per year.

7.12.1.4 Trigger point injections and dry needling

7.12.1.4.1 Description: Trigger point injection can consist of injection 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. Medication is injected in the area of maximum tenderness. Injection efficacy can be enhanced if injections are immediately followed by myofascial therapeutic interventions, such as vapo-coolant spray and stretch, ischemic pressure massage (myotherapy), specific soft tissue mobilization and physical modalities.

7.12.1.4.2 Effectiveness: The effectiveness of trigger point injection or dry needling is uncertain, in part due to the difficulty of demonstrating advantages of active medication over injection of saline. Needling alone may be responsible for some of the therapeutic response.

7.12.1.4.3 Indications: Trigger point injections and dry needling 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 and dry needling should be utilized primarily for the purpose of facilitating functional progress. Trigger point and dry needling injections are indicated in those patients where well-circumscribed trigger points have been consistently observed. Generally, these injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a 4-week time frame.

7.12.1.4.4 Frequency: Weekly. Suggest no more than 4 injection sites per session per week to avoid significant post-injection soreness.

7.12.1.4.5 Optimum duration: 4 sessions.

7.12.1.4.6 Maximum duration: 8 weeks. Some patients may require 2 to 4 repetitions of trigger point injection series over a 1- to 2-year period.

7.12.1.5 Botulinum Toxin (Botox) Injection

7.12.1.5.1 Description: Botulinum toxin injection is used to temporarily weaken or paralyze muscles. It 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, and there is good evidence of its efficacy in improving function in cervical dystonia (torticollis). 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.

7.12.1.5.2 Botox injections are used to improve range of motion and reduce painful muscle spasm. The injections may be useful in musculoskeletal conditions associated with muscle spasm or headaches. There should be evidence of limited range of motion prior to the injection. The injections also may be useful in central neurologic conditions that produce spasticity or dystonia (e.g., brain injury, spinal cord injury, or stroke). Use is recommended according to current FDA guidelines.

7.12.1.5.3 Frequency: No less than 3 months between re-administration.

7.12.1.5.4 Optimum duration: 3 to 4 months.

7.12.1.5.5 Maximum duration: Currently unknown. Repeat injections should be based upon functional improvement and therefore used sparingly to avoid development of antibodies that might render future injections ineffective.

7.13 Medications

7.13.1 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 and the Delaware Prescription Monitoring Program (PMP) to determine if the patient is receiving their prescribed regimen. Appropriate application of pharmacological agents depends on the patient's age, 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, 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. Besides taking medications, continuing participation in exercise programs and using self-management techniques such as biofeedback, cognitive behavioral therapy, and other individuals physical and psychological practices are required elements for successful chronic pain management. Management must begin with establishing goals and expectations, including shared decision making about risks and benefits of medications. Medication reconciliation is the process of comparing the medications that the patient is currently taking with those for which the patient has orders. This needs to include drug name, dosage, frequency, and route. The reconciliation can assist in avoiding medication errors such as omissions,

duplications, dosing errors, or drug interactions. The results can also be used to assist discussion with the patient regarding prescribing or changing medications and the likelihood of side effects, drug interactions, and achieving expected goals. At a minimum, medication reconciliation should be performed for all patients upon the initial visit and whenever refilling or prescribing new medications.

7.13.2 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 originally licensed for indications other than analgesia but are effective in the control of many types of chronic pain.

7.13.3 It is generally wise to begin management with lower cost of non-opioid 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 monitor for any drug interactions.

7.13.4 All medications should be given an appropriate trial in order to test for therapeutic effect. Trials of medication requiring specific therapeutic drug levels may take several months to achieve, depending upon the half-life of the drug. 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.

7.13.5 The use of sedatives and hypnotics is not generally recommended for chronic pain patients. 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 where these drugs were used acutely or sub-acutely.

7.13.6 Pharmaceutical neuropathic pain studies are limited. Diabetic peripheral neuropathy (DPN) and post-herpetic neuralgia (PHN) are the two most frequently studied noncancer neuropathic pain conditions in randomized clinical trials of drug treatment. Some studies enroll only DPN or PHN patients, while other studies may enroll both kinds of patients. There appear to be consistent differences between DPN and PHN with respect to placebo responses, with DPN showing greater placebo response than PHC. Thus, there is an increased likelihood of a "positive" trial result for clinical trials of drug treatment for PHN than for DPN.

7.13.7 Although many studies focus on mean change in pain, this may not be the most reliable result. It does not necessarily allow for subgroups that may have improved significantly. Furthermore, the DPN and PHN studies do not represent the type of neurologic pain usually seen in workers' compensation.

7.13.8 For these reasons, few pharmaceutical agents listed in this Guidelines are supported by high levels of evidence, but the paucity of evidence statements should not be construed as meaning that medication is not to be encouraged in managing chronic pain patients.

It is advisable to begin with the lowest effective dose proven to be useful for neuropathic pain in the literature. If the patient is tolerating the medication and clinical benefit is appreciated, maximize the dose for that medication or add another second line medication with another mechanism of action. If a medication is not effective, taper off the medication and start another agent.

7.13.9 Maintain goal dosing for up to 8 weeks before determining its effectiveness. Many patients will utilize several medications from different classes to achieve maximum benefit.

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

7.13.10 For the clinician to interpret the following material, it should be noted that: drug profiles listed are not complete; dosing of drugs will depend upon the specific drug, especially for off-label use; and not all drugs within each class are listed, and other drugs within the class may be appropriate. Clinicians should refer to informational texts or consult a pharmacist before prescribing unfamiliar medications or when there is a concern for drug interactions. The following drug classes are listed in alphabetical order, not in order of suggested use. The following list is not all inclusive. It is acknowledged that medications not on this list may be appropriate choices for the care of injured workers.

7.13.11 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 analgesics, but a trial of their use may be warranted in many cases of refractory pain.

7.13.11.1 Clonidine (Catapres)

7.13.11.1.1 Description: Central alpha 2 agonist.

7.13.11.1.2 Indications: Sympathetically mediated pain, treatment of withdrawal from opioids. As of the time of this Guideline writing, formulations of clonidine have been FDA approved for hypertension.

7.13.11.1.3 Major contraindications: Severe coronary insufficiency, renal impairment.

7.13.11.1.4 Dosing and time to therapeutic effect: Increase dosage weekly to therapeutic effect.

7.13.11.1.5 Major side effects: Sedation, hypotension, sexual dysfunction, thrombocytopenia, weight gain, agitation, rebound hypertension with cessation.

7.13.11.1.6 Drug interactions: Beta adrenergic, tricyclic antidepressants.

7.13.11.1.7 Recommended laboratory monitoring: Renal function, blood pressure.

7.13.11.2 Tizanidine (Zanaflex)

7.13.11.2.1 Description: Alpha 2 adrenergic agonist.

7.13.11.2.2 Indications: Spasticity, musculoskeletal disorders.

7.13.11.2.3 Dosing and time to therapeutic effect: As needed (PRN) or titrate to effective dose.

7.13.11.2.4 Recommended laboratory monitoring: Hepatic and renal function.

7.13.12 Anticonvulsants. Although the mechanism of action of anticonvulsant drugs in neuropathic pain states remains to be fully defined, they 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 oxcarbazepine, by contrast, are relatively non-significant enzyme inducers, creating fewer drug interactions. Gabapentin and pregabalin are commonly prescribed for neuropathic pain. There is an association between older

anticonvulsants including gabapentin and nontraumatic fractures for patients older than 50; this should be taken into account when prescribing these medications. Gabapentin and pregabalin have indirect (not GABA A or GABA B receptor mediated) GABA-mimetic qualities rather than receptor mediated actions. This can potentially result in euphoria, relaxation, and sedation. It is likely that they also affect the dopaminergic "reward" system related to addictive disorders. Misuse of these medications usually involves doses 3-20 times that of the usual therapeutic dose. The medication is commonly used with alcohol or other drugs of abuse. Providers should be aware of the possibility and preferably screen patients for abuse before prescribing these medications. Withdrawal symptoms, such as insomnia, nausea, headache, or diarrhea, are likely when high doses of pregabalin have been used. Tolerance can also develop.

7.13.12.1 Gabapentin (Fanatrex, Gabarone, Gralise, Horizant, Neurontin)

7.13.12.1.1 Description: Structurally related to gamma-aminobutyric acid (GABA) but does not interact with GABA receptors. Gabapentin affects the alpha-2-delta-1 ligand of voltage gated calcium channels, thus inhibiting neurotransmitter containing intra-cellular vesicles from fusing with the pre-synaptic membranes and reducing primary afferent neuronal release of neurotransmitters (glutamate, CGRP, and substance P). It may also modulate transient receptor potential channels, NMDA receptors, protein kinase C and inflammatory cytokines, as well as possibly stimulating descending norepinephrine medicated pain inhibition.

7.13.12.1.2 Indications: At the time of this Guideline writing, formulations of gabapentin have been FDA approved for post-herpetic neuralgia and partial onset seizures. There is strong evidence that gabapentin is more effective than placebo in the relief of painful diabetic neuropathy and postherpetic neuralgia. 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 (Aventyl, Pamelor) and gabapentin are equally effective for pain relief of postherpetic neuralgia. There is some evidence that the combination of gabapentin and morphine may allow lower doses with greater analgesic effect than the drugs given separately. 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. If medically appropriate, patients may receive a trial of tricyclics before use of gabapentin.

7.13.12.1.3 Relative contraindications: Renal insufficiency. Dosage may be adjusted to accommodate renal dysfunction.

7.13.12.1.4 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. It is taken 3 to 4 times per day, and the target dose is 1800 mg.

7.13.12.1.5 Recommended laboratory monitoring: Renal function.

7.13.12.2 Pregabalin (Lyrica)

7.13.12.2.1 Description: Structural derivative of the inhibitory neurotransmitter gamma aminobutyric acid which inhibits calcium influx at the alpha-2-subunit of voltage-gated calcium channels of neurons. By inhibiting calcium influx, there is inhibition of release for excitatory neurotransmitters.

7.13.12.2.2 Indications: As of the time of this Guideline writing, pregabalin is FDA approved for the treatment of neuropathic pain, postherpetic neuralgia,

fibromyalgia, diabetic peripheral neuropathy, and partial-onset seizure in adults with epilepsy. There is an adequate meta-analysis supporting strong evidence that in the setting of painful diabetic neuropathy, pregabalin as a stand-alone treatment is more effective than placebo in producing a 50% pain reduction but this goal is realized in only 36% of patients treated with pregabalin compared with 24% of patients treated with placebo. There is an absence of published evidence regarding its effectiveness in improving physical function in this condition. There is also some evidence that pregabalin may be effective in treatment neuropathic pain due to spinal cord injury.

7.13.12.2.2.1 When pregabalin is compared with other first line medications for the treatment of neuropathic pain and diabetic peripheral neuropathy such as amitriptyline and duloxetine, there is good evidence that it is not superior to these medications. Additionally, amitriptyline was found more effective compared to pregabalin for reducing pain scores and disability. Side effects were similar for the 2 medications. Therefore, amitriptyline is recommended as a first line drug for patients without contraindications, followed by duloxetine or pregabalin. This is based on improved effectiveness in treatment neuropathic pain and a favorable side effect profile compared to pregabalin. Pregabailn may be added to amitriptyline therapy.

7.13.12.2.2.2 Pregabalin seems to be not effective and/or not well tolerated in a large percentage of patients. There is evidence in several of the studies using run-in phases, enrichment, and partial enrichment techniques to strengthen the results. This analysis technique excludes placebo responders, non-responders, and adverse events prior to the treatment part of the study. This was done in the large meta-analysis, and one study had 60% of participants excluded in the run-in phase. Duloxetine, pregabalin, and amitriptyline are approximately of equal benefit with respect to pain relief in the setting of diabetic peripheral neuropathy. There is some evidence that they exert different effects with respect to sleep variables. Total sleep time and REM sleep duration are likely to be greater with pregabalin that with duloxetine or amitriptyline. However, pregabalin is likely to lead to dizziness and fatigue more frequently than the other drugs, and oxygen desaturation during sleep also appears to be greater with pregabalin.

7.13.12.2.2.3 Relative contraindications: Avoid use with hypersensitivity to pregabalin or other similar class of drugs, avoid abrupt withdrawal, avoid use with a CNS depressant or alcohol, and exercise with caution when using:

7.13.12.2.2.3.1 In the elderly;

7.13.12.2.2.3.2 With renal impairment;

7.13.12.2.2.3.3 With CHF class III/IV;

7.13.12.2.2.3.4 With a history of angioedema; or

7.13.12.2.2.3.5 With depression.

7.13.12.2.2.4 Dosing and time to therapeutic effect: Pregabalin comes in dosages ranging from 25 mg to 300 mg in 25 mg and 50 mg increments. For neuropathic pain, start at 75 mg twice daily for one week and then increase to 150 mg twice daily for 2 to 3 weeks if needed. with a possible final increase to 300 mg twice daily with a max dose of 600 mg/day. The full benefit may be achieved as quickly as 1 weeks, but it may take 6-8 weeks. To discontinue, taper the dose down for at least 1 week.

7.13.12.2.2.5 Major side effects: Dizziness (≤ 45%), somnolence (≤ 36%), peripheral edema (≤ 16%), weight gain (≤ 16%), xerostomia (≤ 15%), headache (≤ 14%), fatigue (≤ 11%), tremor (≤ 11%), blurred vision/diplopia (≤ 12%), constipation (≤ 10%), confusion (≤ 7%), euphoria (≤ 7%), impaired

coordination (≤ 6%), thrombocytopenia (≥ 1%). Patients should be monitored for hypersensitivity reactions, angioedema, suicidality, withdrawal symptoms, and seizures during abrupt discontinuation. In regard to euphoria, pregabalin has higher rates compared to gabapentin in patients with history of substance misuse. Thus, prescribers should be aware that there is potential for misuse.

7.13.12.2.2.6 Drug interactions: Avoid use with antiepileptic agents and any CNS depression mediations. Specifically avoid use with carbinoxamine, doxylamine, and gingko. Monitor closely when pregabalin is used with opioids.

7.13.12.2.2.7 Laboratory monitoring: Creatinine at baseline.

7.13.12.3 Other Anticonvulsants with Limited Third Line Use. It is recommended that a physician experienced in pain management be involved in the care when these medications are used.

7.13.12.3.1 Topiramte (Topamax, Topiragen) - sulfamate substitute monosaccharide. FDA approved for epilepsy or prophylaxis for migraines. Topiramate is without evidence of efficacy in diabetic neuropathic pain, the only neuropathic condition in which it has been adequately tested. The data we have includes the likelihood of major bias due to last observation carried forward imputation, where adverse event withdrawals are much higher with active treatment than placebo control. Despite the strong potential for bias, no difference in efficacy between topiramate and placebo was apparent. There is good evidence that Topiramate demonstrates minimal effect on chronic lumbar radiculopathy or other neuropathic pain. If it is utilized, this would be done as a third- or fourth-line medication in appropriate patients.

7.13.12.3.2 Lamotrigine (Lamictal). 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 insufficient evidence that Lamotrigine is effective in treating neuropathic pain and fibromyalgia at doses of about 200 to 400 mg daily. Given the availability of more effective treatments including antiepileptics and antidepressant medicines, Lamotrigine does not have a significant place in therapy based on the available evidence. The adverse effect profile of Lamotrigine is also of concern. If it is utilized, this would be done as a third- or fourth-line medication in appropriate patients.

7.13.12.3.3 Carbamazepine. This drug 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. 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 likely effective in some people with chronic neuropathic pain but with caveats. No trial was longer than 4 weeks, had good reporting quality, nor used outcomes equivalent to substantial clinical benefit. In these circumstances, caution is needed in interpretation, and meaningful comparison with other interventions is not possible. Carbamazepine is generally not recommended; however, it may be used as a third- or fourth-line medication. It may be useful for trigeminal neuralgia.

7.13.13 Antidepressants. Antidepressants are classified into several 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.

7.13.13.1 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.

7.13.13.2 First line drugs for neuropathic pain are the tricyclics with the newer formations having better side effect profiles. SNRIs are considered second line drugs due to their costs and the number needed to treat for a response.

7.13.13.3 Duloxetine may be considered for first line use in a patient who is a candidate for pharmacologic treatment of both chronic pain and depression. 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.

7.13.13.4 Tricyclics (e.g., amitriptyline [Elavil], nortriptyline [Pamelor, Aventyl], doxepin [Sinequan, Adapin])

7.13.13.4.1 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. There is some evidence that in the setting of chronic low back pain with or without radiculopathy, amitriptyline is more effective than pregabalin at reducing pain and disability after 14 weeks of treatment. There is some evidence that in the setting of neuropathic pain, a combination of morphine plus nortriptyline produces better pain relief than either monotherapy alone, but morphine monotherapy is not superior to nortriptyline monotherapy, and it is possible that it is less effective than nortriptyline. There is insufficient low-quality evidence supporting the use of desipramine to treat neuropathic pain. Effective medicines with much greater supportive evidence are available. There may be a role for desipramine in patients who have not obtained pain relief from other treatments. There is no good evidence of a lack of effect; therefore, amitriptyline should continue to be used as part of the treatment of neuropathic pain. Only a minority of people will achieve satisfactory pain relief. Limited information suggests that failure with one antidepressant does not mean failure with all. There is insufficient evidence to support the use of nortriptyline as a first line treatment. However, nortriptyline has a lower incidence of anticholinergic side effects than amitriptyline. It may be considered for patients who are intolerant to the anticholinergic effects of amitriptyline. Effective medicine with greater supportive evidence are available, such as duloxetine and pregabalin. There is some evidence that a combination of some gabapentin and nortriptyline provides more effective pain relief than monotherapy with either drug, without increasing side effects of either drug.

7.13.13.4.2 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 first line drug treatment for depression.

7.13.13.4.3 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 years of age or older, especially if higher doses are used. Caution should be utilized in prescribing TCAs. They are not recommended for use in elderly patients 65 years of age or older, particularly if they are at fall risk.

7.13.13.4.4 Dosing and time to therapeutic effect: Varies by specific tricyclic. Low dosages are commonly used for chronic pain and/or insomnia. Lower doses decrease side effects and cardiovascular risks.

7.13.13.4.5 Major side effects: Side effects vary according to the medication used; however, the side effect profile for all these medications is generally higher in all areas except GI distress, which is more common among the SSRIs and SNRIs. Anticholinergic side effects include dry mouth, sedation, orthostatic hypotension, cardia arrhythmia, urinary retention, and weight gain. Dry mouth leads to dental and periodontal conditions (e.g., increased cavities). Patients should also be monitored for suicidal ideation and drug abuse. Anticholinergic side effects are more common with tertiary amines (amitriptyline, imipramine, doxepin) than with secondary amines (nortriptyline and desipramine).

7.13.13.4.6 Drug interactions: Tramadol (may cause seizures, both also increase serotonin/norepinephrine, so serotonin syndrome is a concern), clonidine, cimetidine (Tagamet), sympathomimetrics, valproic acide (Depakene, Depakote, Epilim, Stavzor), warfarin (Coumadine, Jantoven, Marfarin), carbamazepine, bupropion (Aplezin, Budeprion, Buproban, Forfivo, Wellbutrin, Zyban), anticholinergics, quinolones.

7.13.13.4.7 Recommended laboratory monitoring: Renal and hepatic function. EKG for those on high dosages or with cardiac risk.

7.13.13.5 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.

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

7.13.13.6.1 Description: Venlafaxine (Effexor), desvenlafaxine (Pristiq), duloxetine, and milnacipran (Savella). There is strong evidence that duloxetine monotherapy is more effective than placebo in relieving the pain of diabetic peripheral neuropathy; however, monotherapy leads to a 50% pain reduction in only half of patients who receive a therapeutic dose. AHRQ supports the use of duloxetine for chronic low back pain.

7.13.13.6.1.1 There is good evidence that in patients with painful diabetic neuropathy who have not had good responses to monotherapy with 60 mg of duloxetine or 300 mg of pregabalin, a clinically important benefit can be achieved by either of two strategies: doubling the dose of either drug or combining both drugs at the same dose. It is likely that the strategy of combining the two drugs at doses of 60 and 300 mg respectively is more beneficial overall. There was no evidence to support the use of milnacipran to treat neuropathic pain conditions, although it is generally used for fibromyalgia. It is not generally recommended but may be used if patients cannot tolerate other medications.

7.13.13.6.1.2 There is insufficient evidence to support the use of venlafaxine in neuropathic pain. However, it may be useful for some patients who fail initial recommended treatments. Venlafaxine is generally reasonably well tolerated, but it can precipitate fatigue, somnolence, nausea, and dizziness in a minority of people. The sustained release formulations are generally more tolerable as inter-dose withdrawal symptoms can be avoided. They should be trialed if the patient cannot tolerate the immediate release formulation.

7.13.13.6.2 Indications: At the time of writing this Guideline, duloxetine has been FDA approved for treatment of diabetic neuropathic pain and chronic musculoskeletal pain. Therefore, best evidence supports the use of duloxetine alone or with pregabalin if patients do not have sufficient relief from a tricyclic or cannot take a tricyclic.

7.13.13.6.3 Relative contraindications: Seizures, eating disorders.

7.13.13.6.4 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 with 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.

7.13.13.6.5 Drug interactions: Drug specific.

7.13.13.6.6 Laboratory monitoring: Drug specific. Hepatic and renal monitoring, venlafaxine may cause cholesterol or triglyceride increases.

7.13.13.7 Atypical Antidepressants/Other Agents. Such drugs may be used for depression; however, are not appropriate for neuropathic pain.

7.13.14 Hypnotics and sedatives. Sedative and hypnotic drugs decrease activity, induce drowsiness, and may cause moderate agitation in some individuals. Many drugs produce these effects incidental to their usual intended effects, similar to the side effects of many antihistamines and antidepressants. Due to the addition potential, withdrawal symptoms, and sedating side effects, benzodiazepines and other similar drugs found in this class, are not generally recommended to be initiated or continued if previously prescribed for another condition. There is an increased likelihood of death when opioids and benzodiazepines are used together; therefore, it is recommended that no more than 30 morphine milligram equivalents (MMEs) should be used when hypnotics or sedatives are prescribed. If a patient has been regularly taking these medications prior to the injury, they should be assessed by a psychiatrist to determine the need for continued treatment. 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. Nocturnal oximetry or other sleep studies may be appropriate to identify hypoxia. Most insomnia in chronic pain patients should be managed primarily through behavioral interventions. Medications are a rare secondary measure.

7.13.14.1 Zaleplon (Sonata) Escopiclone (Lunesta, Lunestar), Zolpidem (Ambien, Edluar, Intermezzo, Zolpimist).

7.13.14.1.1 Description: A nonbenzodiazepine hypnotic.

7.13.14.1.2 Indications: Insomnia.

7.13.14.1.3 Dosing and time to therapeutic effect: Time of onset is 30 to 60 minutes. Due to rapid elimination, may be taken as little as 4 hours before awakening.

7.13.14.1.4 Drug interactions: Increases sedative effect of another central nervous system (CNS) depressant drugs.

7.13.14.1.5 Recommended laboratory monitoring: Hepatic function.

7.13.14.2 Benzodiazepine-based hypnotics include temazepam (Restoril, Temazepam, Gelthix), trazolam (Halcion), and flurazepam (Dalmane). None are 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. These medications are not recommended for use in the working populations except in rare circumstances.

7.13.15 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.

7.13.15.1 Baclofen (intrathecal)

7.13.15.1.1 Description: May be effective due to stimulation of Gamma Aminobutyric Acid (GABA) receptors.

7.13.15.1.2 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.

7.13.15.1.3 Side effects: Exacerbation of psychotic disorders, may precipitate seizures in epileptics, dry mouth, and sexual dysfunction.

7.13.15.1.4 Recommended laboratory monitoring: Renal and hepatic function.

7.13.15.1.5 Caution: Abrupt discontinuation of baclofen can precipitate a withdrawal syndrome and has been seen with both low and high doses. The most common side effects of baclofen withdrawal include pruritis, tremor, and mood disturbance. In extreme circumstances, seizures, muscle rigidity (resembling neuroleptic malignant syndrome), and even death can occur.

7.13.15.2 Cyclobenzaprine (Flexeril)

7.13.15.2.1 Description: Structurally related to tricyclics.

7.13.15.2.2 Indications: Acute 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.

7.13.15.2.3 Major contraindications: Cardiac dysrhythmias.

7.13.15.2.4 Dosing and time to therapeutic effect: Variable, onset of action is 1 hour.

7.13.15.2.5 Major side effects: Sedation, anticholinergic, blurred vision. Patients should also be monitored for suicidal ideation and drug abuse.

7.13.15.2.6 Drug interactions: Contraindicated for use with MAO inhibitors; interacts with tramadol, duloxetine, escitalopram, and fluoxetine. Likely interactions with other SSRIs and SNRIs. Drug interactions are similar to those for tricyclics.

7.13.15.2.7 Recommended laboratory monitoring: Hepatic and renal function.

7.13.15.3 Carisoprodol (Soma) Carisoprodol (Soma, Soprodal, Vanadom) This medication should not be used in chronic pain patients due to its addictive nature secondary to the active metabolite meprobamate.

7.13.15.4 Metazalone (Skelaxin)

7.13.15.4.1 Description: Central acting muscle relaxant.

7.13.15.4.2 Indications: Acute 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.

7.13.15.4.3 Major contraindications: Significantly impaired renal or hepatic disease, pregnancy, and disposition to drug induced hemolytic anemia.

7.13.15.4.4 Dosing and time to therapeutic effect: 800 mg, 3 to 4 times per day, onset of action 1 hour.

7.13.15.4.5 Major side effects: Sedation, hematologic abnormalities.

7.13.15.4.6 Drug interactions: Other sedating drugs (e.g., opioids, benzodiazepines).

7.13.15.4.7 Recommended laboratory monitoring: Hepatic function.

7.13.15.5 Methocarbamol

7.13.15.5.1 Description: Central action muscle relaxant.

7.13.15.5.2 Indications: Muscle spasm.

7.13.15.5.3 Major contraindications: Hypersensitivity, possible renal compromise.

7.13.15.5.4 Dosing and time to therapeutic effect: 1500 mg 4 times per day. Longer dosing 4000 to 4500 mg per day.

7.13.15.5.5 Major side effects: Decreased cognition, light headedness, GI effects among others.

7.1315.5.6 Drug interactions: Alcohol and other CNS depressants.

7.13.15.6 Tizanidine (Zanaflex)

7.13.15.6.1 Description: Alpha 2 adrenergic agonist.

7.13.15.6.2 Indications: True centrally mediated spasticity, musculoskeletal disorders. As of the time of this Guideline writing, formulations of tizanidine have been FDA approved for the management of spasticity in spinal cord injury and multiple sclerosis.

7.13.15.6.3 Major contraindications: Concurrent use with ciprofloxacin (Cipro, Proquin) or fluvoxamine (Luvox); or hepatic disease.

7.13.15.6.4 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).

7.13.15.6.5 Major side effects: Hypotension, sedation, heptotoxicty, hallucinations and psychosis, dry mouth.

7.13.15.6.6 Drug interactions: Alcohol can increase sedation, and concurrent use with ciprofloxacin or fluvoxamine is 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.

7.13.15.6.7 Laboratory monitoring: Hepatic function, blood pressure.

7.13.16 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.

7.13.16.1 Deaths in the United States from opioids have escalated in the last 15 years. The CDC states the following in their 2016 Guidelines for prescribing opioids: Opioid pain medication use presents serious risk, including overdose and opioid use disorder. From 1999 to 2014, more than 165,000 persons died from overdose related to opioid pain medication in the United States. In the past decade, while the death rates for the top leading causes of death such as heart disease and cancer have decreased substantially, the death rate associated with opioid pain medication has increased markedly. Sales of opioid pain medication have increased in parallel with opioid-related overdose deaths. The Drug Abuse Warning Network estimated that >420,000 emergency department visits were related to the misuse or abuse of narcotic pain relievers in 2011, the most recent year for which data are available. Opioid poisoning has also been identified in work-related populations.

7.13.16.2 Effectiveness and Side Effects. Opioids include some of the oldest and most effective drugs used in the control of severe pain. The discovery of opioids 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 a ntinociceptive 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.

7.13.16.2.1 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. There is strong evidence that in the setting of chronic nonspecific low back pain, the short and intermediate term reduction in pain intensity of opioids, compared with placebo, falls short of a clinically important level of effectiveness. There is an absence of evidence that opioids have any beneficial effects on function or reduction of disability in the setting of chronic nonspecific low back pain. AHRQ found that opioids are effective for treating chronic low back pain. However, the reported noted no evidence regarding the long-term effectiveness or safety of chronic opioids. There is good evidence that opioids are more efficient than placebo in reducing neuropathic pain by clinically significant amounts. There is lack of evidence that opioids improve function and quality of life more effectively than placebo. There is good evidence that opioids produce significantly more adverse effects that placebo such as constipation, drowsiness, dizziness, nausea, and vomiting. There is a lack of evidence that they are superior to gabapentin or nortriptyline for neuropathic pain and reduction.

7.13.16.2.2 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. There is strong evidence that adverse events such as constipation, dizziness, and drowsiness are more frequent with opioids than with placebo. Common side effects are drowsiness, constipation, nausea, and possible testosterone decrease with longer term use.

7.13.16.2.3 There is some evidence that in the setting of chronic low back pain with disc pathology, a high degree of anxiety or depressive symptomatology is associated with relatively less pain relief despite higher opioid dosage than when these symptoms are absent. A study comparing Arkansas Medicaid and a national commercial insurance population found that the tope 5% of opioid users accounted for 48-70% of total opioid use. Utilization was increased among those with mental health and substance use disorders and those with multiple pain conditions. Psychological issues should always be screened for and treated in chronic pain patients. Therefore, for the majority of chronic pain patients, chronic opioids are unlikely to provide meaningful increase in function of daily activities. However, a subpopulation of patients may benefit from chronic opioids when properly prescribed and all requirements from medical management are followed.

7.13.16.3 Hyperalgesia. Administration of opioid analgesics leads not only to analgesia leads not only to analgesia but may also lead to a paradoxical sensitization to noxious stimuli. Opioid induced hyperalgesia has been demonstrated in animals and humans using electrical or mechanical pain stimuli. This increased sensitivity to mildly painful stimuli does not occur in all patients and appears to be less likely in those with cancer, clear inflammatory pathology, or clear neuropathic pain. When hyperalgesia is suspected, opioid tapering is appropriate.

7.13.16.4 Opioid Induced Constipation (OIC). Some level of constipation is likely ubiquitous among chronic opioid users. An observational study of chronic opioid users who also used some type of laxative at least 4 times per week noted that approximately 50% of the patients were dissatisfied and they continue to report stool symptoms. Seventy-one percent used a combination of natural and dietary treatment, 64.3% used over the-counter laxatives, and 30% used prescription laxatives. Other studies report similar percentages. There are insufficient quality studies to recommend one specific type of laxative over others.

7.13.16.4.1 The easiest method for identifying constipation, which is also recommended by a consensus, multidisciplinary group, is the Bowel Function Index. It assesses the patient's impression over the last 7 days for ease of defecation, feeling of incomplete bowel evacuation, and personal judgment re-constipation.

7.13.16.4.2 Stepwise treatment for OIC is recommended, and all patients on chronic opioids should receive information on treatment for constipation. Dietary changes increasing soluble fibers are less likely to decrease OIC and may cause further problems if GI motility is decreased. Stool softeners may be tried, but stimulant and osmotic laxatives are likely to be more successful. Osmotic laxatives include lactulose and polyethylene glycol. Stimulants include bisacodyl, sennosides, and sodium picosulfate, although there may be some concern regarding use of stimulants on a regular basis.

7.13.16.4.3 Opioid rotation or change in opioids may be helpful for some patients. It is possible that sustained release opioid products cause more constipation than short acting agents due to their prolonged effect on the bowel opioid receptors. Tapentadol is a u-opioid agonist and norepinephrine

reuptake inhibitor. It is expected to cause less bowel impairment than oxycodone or other traditional opioids. Tapentadol may be the preferred opioid choice for patients with OIC.

7.13.16.4.4 Other prescription medications may be used if constipation cannot adequately be controlled with the previous measures. Naloxegol is a pegylated naloxone molecule that does not pass the blood brain barrier and thus can be given with opioid therapy. There is good evidence that it can alleviate OIC and that 12.5 mg starting dose has an acceptable side effect profile.

7.13.16.4.4.1 Methylnaltrexone does not cross the blood brain barrier and can be given subcutaneously or orally. It is specifically recommended for opioid induced constipation for patients with chronic non-cancer pain.

7.13.16.4.4.2 Misoprostol is a synthetic prostaglandin E1 agonist and has the side effect of diarrhea in some patients. It also has been tried for opioid induced constipation, although it is not FDA approved for this use.

7.13.16.4.4.2.1 Lubiprostone is a prostaglandin E1 approved for use in opioid constipation.

7.13.16.4.4.2.2 Most patients will require some therapeutic control for their constipation. The stepwise treatment discussed should be followed initially. If that has failed and the patient continues to have recurrent problems with experiencing severe straining, hard or lumpy stool with incomplete evacuation, or infrequent stools for 25% of the time despite the more conservative measures, it may be appropriate to use a pharmaceutical agent.

7.13.16.1.5 Physiologic Responses to Opioids. Physiologic responses to opioids 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.

7.13.16.1.6 Adverse Events. 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 risk for out of hospital deaths not involving suicide was also high. The prevalence of drug abuse in the population of patients undergoing pain management varies according to region and other issues. One study

indicated that 1/4 of patients being monitored for chronic opioid use have abused drugs occasionally, and 1/2 of those have frequent episodes of drug abuse. Eighty percent of patients admitted to a large addiction program reported that their first use of opioids was from prescribed medication. There is good evidence that in generally healthy patients with chronic musculoskeletal pain, treatment with long-acting opioids, compared to treatments with anticonvulsants or antidepressants, is associated with an increased risk of death of approximately 69%, most of which arises from non-overdose causes principally cardiovascular in nature. The excess cardiovascular mortality principally occurs in the first 180 days from starting opioid treatment. There is some evidence that compared to an opioid dose under 20 MME per day, a dose of 20-50 mg nearly doubles the risk of death, a dose of 50 to 100 mg may increase the risk more than fourfold, and a dose greater than 100 mg per day may increase the risk as much as sevenfold. However, the absolute risk of fatal overdose in chronic pain patients is fairly low and may be as low as 0.04%. There is good evidence that prescription opioids in excess of 200 MME average daily doses are associated with a nearly tripling of the risk of opioid-related death, compared to average daily doses of 20 MME. Average daily doses of 100-200 mg and doses of 50-99 mg per day may be associated with a doubling of mortality risk, but these risk estimates need to be replicated with larger studies.

7.13.16.1.7 Doses of opioids in excess of 120 MME 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. 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. The CDC recommends limiting to 90 MME per day to avoid increasing risk of overdose.

7.13.16.1.7.1 In summary, there is strong evidence that any dose above 50 MME per day is associated with a higher risk of death and 100 mg or greater appears to significantly increase the risk.

7.13.16.1.7.2 Workers who eventually are diagnosed with opioid abuse after an injury are also more likely to have higher claims cost. A retrospective observational cohort study of workers' compensation and short-term disability cases found that those with at least one diagnosis of opioid abuse cost significantly more in days lost from work for both groups and in overall healthcare costs for the short-term disability groups. About 0.5% of eligible workers were diagnosed with opioid abuse.

7.13.16.1.8 Dependence versus Addiction. 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 two distinct phenomena: dependence and addiction.

7.13.16.1.8.1 Dependence is a physiological tolerance and 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. Dependence is a physiological phenomenon, which is expected with the continued administration of opioids, and need not deter physicians from their appropriate

use. Before increasing the opioid dose, the physician should review other possible causes of the decline in analgesic effect. Increasing the dose may not result in improved function or decreased pain. Remember that it is recommended for total morphine milligram equivalents (MME) per day to remain at 50 or below. 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, hyperalgesia, or abusive use of the medication.

7.13.16.1.8.2 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.

7.13.16.3 Choice of Opioids. No long-term studies establish the efficacy of opioids over one year of use or superior performance by one type. There is no evidence that one long-acting opioid is more effective than another, or more effective than other types of medications, in improving function or pain. There is some evidence that long-acting oxycodone (Dazidox, Endocodone, ETH-oxydose, Oxycontin, Oxyfast, OxyIR, Percolone, Roxicodone) and oxymorphone have equal analgesic effects and side effects, although the milligram dose of oxymorphone (Opana) is ½ that of oxycodone.

7.13.16.3.1 There is no evidence that long-acting opioids are superior to short-acting opioids for improving function or pain or causing less addiction. A number of studies have been done assessing relief of pain in cancer patients. A recent systematic review concludes that oxycodone does not result in better pain relief than other strong opioids including morphine and oxymorphone. It also found no difference between controlled release and immediate release oxycodone. There is some evidence that extended-release hydrocodone has a small and clinically unimportant advantage over placebo for relief of chronic low back pain among patients who are able to tolerate the drug and that 40% of patients who being taking the drug do not attain a dose which provides pain relief without unacceptable adverse effects. Hydrocodone ER does not appear to improve function in comparison with placebo. A Cochrane review of oxycodone in cancer pain also found no evidence in favor of the longer acting opioid. There does not appear to be any significant difference in efficacy between once daily hydromorphone and sustained release oxycodone. Nausea and constipation are common for both medications between 26-32%. There is some evidence that in the setting of neuropathic pain, a combination of morphine plus nortriptyline produces better pain relief than either monotherapy alone, but morphine monotherapy is not superior to nortriptyline monotherapy, and it is possible that it is actually less effective than nortriptyline.

7.13.16.3.2 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. The 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. Clinical considerations should determine the need for long-acting opioids given their lack of evidence noted above.

7.13.16.3.3 Addiction and abuse potential 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. One systematic study of prescribed opioids estimated rates of drug misuse were estimated at 21-29% and addiction at 8-12%. There is good evidence that in the setting of new onset chronic non-cancer pain, there is a clinically important relationship between opioid prescription and subsequent opioid use disorder. Compared to no opioid use, short-term opioid use approximately triples the risk of opioid use disorder in the next 18 months Use of opioids for over 90 days is associated with very pronounced increased risks of the subsequent development of an opioid use disorder, which may be as much as one hundredfold when doses greater than 120 MME are taken for more than 90 days. The absolute risk of these disorders is very uncertain but is likely to be greater than 6.1% for long duration treatment with a high opioid dose.

7.13.16.3.4 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 prescription is lower than the corresponding rates for extended-release oxycodone, hydromorphone (Dilaudid, Palladone), and methadone. Extended-release oxycodone appears to be the most commonly abused opioid, both in the general population and in the abuse rate per 1000 prescriptions. Tramadol, by contrast, appears to have a lower abuse rate than for other opioids. Newer drug formulations such as 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.

7.13.16.4 Types of opioids are:

7.13.16.4.1 Buprenorphine (various formulations) is prescribed as an intravenous injection, transdermal patch, buccal film, or sublingual tablet due to lack of bioavailability of oral agents. Depending upon the formulation, buprenorphine may be indicated for the treatment of pain or for the treatment of opioid dependence (addiction).

7.13.16.4.1.1 Buprenorphine for opioid dependence (addiction). When using Buprenorphine for opioid dependence (addiction), the FDA has approved a number of buccal films including those with naloxone and a sublingual tablet to treat opioid dependence (addiction).

7.13.16.4.1.2 Buprenorphine for pain. When using Buprenorphine for pain, the FDA has approved specific forms of an intravenous and subcutaneous injectable, transdermal patch, and a buprenorphine buccal film to treat pain. However, by law, the transdermal patch and the injectable forms cannot be used to treat opioid dependence (addiction), even by DATA-2000 waivered physicians authorized to prescribe buprenorphine for addiction. Transdermal forms may cause significant skin reaction. Buprenorphine 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.

7.13.16.4.1.3 There is insufficient evidence to support or refute the suggestion that buprenorphine has any efficacy in any neuropathic pain condition. There is good evidence transdermal buprenorphine is noninferior to oral tramadol in the treatment of moderate to severe musculoskeletal pain arising from conditions like osteoarthritis and low back pain. The population of patients for whom it is more appropriate than tramadol is not established but would need to be determined on an individual patient basis if there are clear reasons not to use oral tramadol. In a well-done study, 63% of those on buccal buprenorphine achieved a 30% or more decrease in pain at 12 weeks compared to a 47% placebo response. Approximately 40% of the initial groups eligible for the study dropped out during the initial phase when all patients received the drug to test for incompatibility.

7.13.16.4.1.4 There is strong evidence that in patients being treated with opioid agonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidence by positive urines, are equivalent between methadone and buprenorphine. There is strong evidence that buprenorphine is superior to placebo with respect to retention in treatment, and good evidence that buprenorphine is superior to placebo with respect to positive urine testing for opiates.

7.13.16.4.1.5 There is an adequate meta-analysis supporting good evidence that transdermal fentanyl and transdermal buprenorphine are similar with respect to analgesia and sleep quality, and they are similar with respect to some common adverse effects such as constipation and discontinuation due to lack of effect. However, buprenorphine probably causes significantly less nausea than fentanyl, and it probably carries a lower risk of treatment discontinuation due to adverse events. It is also likely that both transdermal medications cause less constipation then oral morphine. Overall, due to cost and lack of superiority, buprenorphine is not a front-line opioid choice. However, it may be used in those with a history of addiction or at high risk for addiction who otherwise qualify for chronic opioid use. It is also appropriate to consider buprenorphine products for tapering strategies and those on high dose morphine 90 MME.

7.13.16.4.2 Codeine with Acetaminophen. Some patients cannot genetically metabolize codeine and therefore have no response. Codeine is not generally used on a daily basis for chronic pain. Acetaminophen dose per day should be limited to 2 grams.

7.13.16.4.3 Fentanyl (Actiq, Duragesic, Fentora, Sublimaze) is not 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 trans buccally in this population. If it is being considered for a very specific patient population, it requires support from a pain specialist.

7.13.16.4.4 Meperidine (Demerol) is not recommended 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.

7.13.16.4.5 Methadone requires special precautions given its unpredictably long half-life and non-linear conversion from other opioids such as morphine. It may also cause cardiac arrhythmias due to QT prolongation and has been linked with a greater number of deaths due to its prolonged half-

life. No conclusions can be made regarding differences in efficacy or safety between methadone and placebo, other opioids, or other treatments. There is strong evidence that in patients being treated with opioid agonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidenced by positive urines, are equivalent between methadone and buprenorphine. Methadone should only be prescribed by those with experience in managing their medication. Conversion from another opioid to methadone (or the other way around) can be very challenging, and dosing titration must be done very slowly (no more than every 7 days). Unlike many other opioids, it should not be used on an "as needed" basis, as decreased respiratory drive may occur before the full analgesic effect of methadone is appreciated. If methadone is being considered, genetic screening is appropriate. CYP2B6 polymorphism appears to metabolize methadone more slowly than the usual population and may cause more frequent deaths.

7.13.16.4.6 Morphine may be used in the non-cancer pain population. A study in chronic low back pain suggested that individuals with a greater amount of endogenous opioids will have a lower pain relief response to morphine.

7.13.16.4.7 Oxycodone and Hydromorphone. There is no evidence that oxycodone (as oxycodone CR) is of value in treating people with painful diabetic neuropathy, postherpetic neuralgia, or other neuropathic conditions. There was insufficient evidence to support or refute the suggestion that hydromorphone has any efficacy in any neuropathic pain condition. Oxycodone was not associated with greater pain relief in cancer patients when compared to morphine or oxymorphone.

7.13.16.4.8 Propoxyphene (Darvon, Davon-N, PP-Cap) has been withdrawn from the market due to cardiac effects including arrhythmias.

7.13.16.4.9 Tapentadol (Nucynta) is a 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. 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. However, a high-quality systematic review found inadequate evidence to support tapentadol to treat chronic pain. Tapentadol is not recommended as a first line opioid for chronic, subacute, or acute pain due to the cost and lack of superiority over other analgesics. There is some evidence that tapentadol cause less constipation than oxycodone. Therefore, it may be appropriate for patients who cannot tolerate other opioids due to GI side effects.

7.13.16.4.10 Tramdol (Rybix, Ryzolt, Ultram)

7.13.16.4.10.1 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. There are side effects similar to opioid side effects and may limit its use. They include nausea, sedation, and dry mouth.

7.13.16.4.10.2 Indications: Mild to moderate pain relief. As of the time of this Guidelines writing, formulations of tramadol have 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. Unlike other pure opioids agonists, there is a ceiling dose to tramadol due to its serotonin activity (usually 300-400 mg per day). There is some evidence that it alleviates neuropathic pain following spinal cord injury. There is inadequate evidence that extended-release tramadol/acetaminophen in a fixed-dose combination of 75 mg/650 mg is more effective than placebo in relieving chronic low back pain; it is not more effective in improving function compared to placebo. There is some evidence that tramadol yields a short-term analgesic response of little clinical importance relative to placebo in post-herpetic neuralgia which has been symptomatic for approximately 6 months. 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 or other medications.

7.13.16.4.10.3 Contraindications: Use cautiously in patients who have a history of seizures, who are taking medication that may lower the seizure threshold or taking medications that impact serotonin reuptake and could increase the risk for serotonin syndrome, such as monoamine oxidase inhibitors (MAO) inhibitors, SSRIs, TCAs, and alcohol. Use with caution in patients taking other potential QT prolonging agents. 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.

7.13.16.4.10.4 Side effects: May cause impaired alertness or nausea. This medication has physically addictive properties, and withdrawal may follow abrupt discontinuation.

7.13.16.4.10.5 Drug interactions: Opioids, sedating medications, any drug that affects serotonin and/or norepinephrine (e.g., SNRIs, SSRIs, MAOs, and TCAs).

7.13.16.4.10.6 Laboratory monitoring: Renal and hepatic function.

7.13.16.5 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 does per day should not exceed 4 grams per any 24 hour period and is preferably limited to 2 grams per day to avoid possible liver damage.

7.13.16.5.1 Indications: 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 contract, 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.

7.13.16.5.2 In most cases, analgesic treatment should begin with acetaminophen, aspiring, 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 Section G.10, Medications).

7.13.16.5.3 There is good evidence from a prospective cohort study that in the setting of common low back injuries, when baseline pain and injury severity are taken into account, a prescription for more than 7 days of opioids in the first 6 weeks is associated with an approximate doubling of disability one year after the injury.

7.13.16.6 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. Refer to subsection 7.11.6.11, High Risk Behavior, below.

7.13.16.7 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, and Delaware's Uniform Controlled Substance Act Regulations. As per the regulations, in addition to the requirements for acute pain treatment, the practitioner must adhere to the following additional requirements for Chronic Pain patients:

7.13.16.7.1 Query the PMP at least every 6 months, more frequently if clinically indicated, or whenever the patient is also being prescribed a benzodiazepine;

7.13.16.7.2 Query the PMP whenever the patient is assessed to potentially be at risk for substance abuse or misuse or demonstrates such things as loss of prescription(s), requests for early refills or similar behavior;

7.13.16.7.3 Administer fluid drug screens at least once every six months;

7.13.16.7.4 Obtain a signed Treatment Agreement;

7.13.16.7.5 Conduct a Risk Assessment;

7.13.16.7.6 Document in the patient's medical record alternative treatment options that have been tried by the patient, including non-

pharmacological treatments and their adequacy with respect to providing sufficient management of pain;

7.13.16.7.7 Make efforts to address psychiatric and medical comorbidities concurrently, rather than sequentially, when concurrent treatment is clinically feasible; and

7.13.16.7.8 At the practitioner's discretion, seek a case review and consult with, or otherwise refer the patient to, a state licensed physician who holds a subspecialty board certification in addiction psychiatry from the American Board of Psychiatry and Neurology or an addiction certification from the American Board of Addiction Medicine or an addiction specialist if any of the following occur:

7.13.16.8 General Indications. There must be a clear understanding that opioids are to be used for a limited term as a trial. The patient should have a thorough understanding of all 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 shared decision-making agreement signed by the patient must clarify under what term the opioids will be tapered.

7.13.16.8.1 Risk factors to consider are: 7.13.16.8.1.1 History of severe post-operative pain;

7.13.16.8.1.2 Opioid analgesic tolerance (daily use for months);

7.13.16.8.1.3 Current mixed opioid agonist/antagonist treatment (e.g., buprenorphine, naltrexone);

7.13.16.8.1.4 Chronic pain (either related or unrelated to the surgical site);

7.11.6.8.1.5 Psychological comorbidities (e.g., depression, anxiety, catastrophizing);

7.13.16.8.1.6 History of substance use disorder;

7.13.16.8.1.7 History of "all over body pain";

7.13.16.8.1.8 History of significant opioid sensitivities (e.g., nausea, sedation);

7.13.16.8.1.9 History of intrathecal pump use or nerve stimulator implanted for pain control.

7.13.16.8.2 Employment requirements are outlined. The patient's employment requirements should also be discussed as well as the need to drive. It is generally not recommended to allow workers in safety sensitive positions to take opioids. Opioid naïve patients or those changing doses are likely to have decreased driving ability. Some patients on chronic opioids may have nominal interference with driving ability; however, effects are specific to individuals. Providers may choose to order certified driver rehabilitation assessment.

7.13.16.8.3 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. Review of the Delaware Prescription Monitoring Program (PMP).

7.13.16.8.4 Informed, written, witnessed consent by the patient includes the aspects noted above. Patients should also be counseled on safe storage and disposal of opioids.

7.13.16.8.5 The trial, with a short-acting agent, 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 measurable, achievable, and relevant prior to opioid trial or adjustment to measure changes in activity/function. Measurement of functional goals may include patient completed validated functional tools.

7.13.16.9 In some cases, ongoing, long-term management may be appropriate for chronic use provided:

7.13.16.9.1 The patient has been on a stable dose of such opioid for over a 2-year period prior to 2022.

7.13.16.9.2 The total dose level of all medication does not exceed 90 MME per day.

7.13.16.9.3 Prescriptions from a single practitioner.

7.13.16.9.4 Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects; full review of at least every 3 months.

7.13.16.9.5 Ongoing effort to gain improvement of social and physical function as a result of pain relief.

7.13.16.9.6 Review of the Delaware Prescription Drug Monitoring Program (PMP).

7.13.16.9.7 Shared decision-making agreement detailing the following:

7.13.16.9.7.1 Side effects anticipated from the medication;

7.13.16.9.7.2 Requirement to continue active therapy; and

7.13.16.9.7.3 Need to achieve functional goals including return to work for most cases;

7.13.16.9.7.4 Reasons for termination of opioid management, referral to addiction treatment, or for tapering opioids (tapering is usually for use longer than 30 days). Examples to be included in the contract include:

7.13.16.9.7.1 Diversion of medication;

7.13.16.9.7.2 Lack of functional effect at higher doses;

7.13.16.9.7.3 Non-compliance with other drug use;

7.13.16.9.7.4 Drug screening showing use of drugs outside of the prescribed treatment or evidence of non-compliant use of prescribed medication;

7.13.16.9.7.5 Requests for prescriptions outside of the defined time frames;

7.13.16.9.7.6 Lack of adherence identified by pill count, excessive sedation, or lack of functional gains;

7.13.16.9.7.7 Excessive dose escalation with no decrease in use of short term medications;

7.13.16.9.7.8 Apparent hyperalgesia;

7.13.16.9.7.9 Shows signs of substance use disorder (including work or family problems related to opioid use, difficulty controlling use, craving);

7.13.16.9.7.10 Experiences overdose or other serious adverse event; and

7.13.16.9.7.11 Shows warning signs for overdose risk such as confusion, sedation, or slurred speech.

7.13.16.9.8 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 8 to 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.

7.13.16.9.8.1 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. Clinicians should determine before drug screening how they will use knowledge of marijuana use. It is appropriate to screen for alcohol and marijuana use and have a contractual policy regarding both alcohol and marijuana use during chronic opioid management. Alcohol use in combination with opioids is likely to contribute to death. From a safety standpoint, it is more important to screen for alcohol use than marijuana use as alcohol is more likely to contribute to unintended overdose.

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

7.13.16.9.8.3 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.

7.13.16.9.9 Chronic use limited to 2 oral opioids.

7.13.16.9.10 Transdermal medication use, other than buprenorphine, is generally not recommended.

7.13.16.9.11 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 2-3 grams/day for long-term use in healthy patients. A safer chronic dose may be 1800 mg/day.

7.13.16.9.12 Continuing review of overall therapy plan regarding non-opioid means of pain control and functional and status.

7.13.16.9.13 Tapering of opioids may be necessary for many reasons including the development of hyperalgesia, decreased effects from an opioid, lack of compliance with the opioid contract, or intolerance of side effects. Some patients appear to experience allodynia or hyperalgesia on chronic opioids. This premise is supported by a study of normal volunteers who received opioid infusions and demonstrate an increase in secondary hyperalgesia. Options for treating hyperalgesia 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. Tapering may also be appropriate by patient choice to accommodate "fit-for-duty" demands, prior to major surgery to assist with post-operative pain control, to alleviate the effects of chronic use including hypogonadism, medication side effects, or in the instance of a breach of drug agreement, overdose, other drug use aberrancies, or lack of functional benefit. It is also appropriate for any tapering criteria listed in subsection 7.13.20 Opioid Addiction. Generally tapering can be accomplished by decreasing the dose of 10% per week. This will generally take 6 to 12 weeks and may need to be done one drug class at a time. Behavioral support is required during this service. Tapering may occur prior to MMI or in some cases during maintenance treatment.

7.13.16.9.14 Medication assisted treatment with buprenorphine or methadone may be considered for opioid abuse disorder, in addition to behavioral therapy.

7.13.16.9.15 Inpatient treatment may be required for addiction or opioid tapering in complex cases.

7.13.16.10 Relative Contraindications. Extreme caution should be used in prescribing controlled substances for workers with one or more "relative contraindications." Consultation with a pain or addiction specialist may be useful in these cases.

7.13.16.10.1 History of alcohol or other substance abuse, or a history of chronic, benzodiazepine use. Sleep apnea: If patient has symptoms of sleep apnea, diagnostic tests should be pursued prior to chronic opioid use.

7.13.16.10.2 Off work for more than 6 months with minimal improvement in function from other active therapy.

7.13.16.10.3 Severe personality disorder or other known severe psychiatric disease per psychiatrist or psychologist.

7.13.16.10.4 Monitoring of behavior for signs of possible substance abuse indicating an increased risk for addiction and possible need for consultation with an addiction specialist.

7.13.16.11 High Risk Behavior. The following are high risk warning signs for possible drug abuse or addiction. Patients with these findings may need a consultation by a physician experienced in pain management and/or addiction. Behaviors in the left-hand column are warning signs, not automatic grounds for dismissal, and should be followed up by a reevaluation with the provider. Repeated behaviors in the left-hand column may be more indicative of addiction. Behaviors in the right-hand column should be followed by a substance abuse evaluation.

Less suggestive for addiction but are increased in depressed patients	More suggestive of addiction and are more prevalent in patients with substance use disorder
• Frequent requests for early refills: claiming lost or stolen prescriptions • Opioids used more frequently, or at higher doses than prescribed • Using opioids to treat non-pain symptoms • Borrowing or hoarding opioids • Using alcohol or tobacco to relieve pain • Requesting more or specific opioids • Recurring emergency room visits for pain • Concerns expressed by family members • Unexpected drug rest results • Inconsistencies in the patient's history	• Buying opioids on the street; stealing; or selling drugs • Multiple prescribers (doctor shopping) • Trading sex for opioids • Using Illicit drugs, +urine drug tests for illicit drugs • Forging prescriptions • Aggressive demands for opioids • Injecting oral/topical opioids • Signs of intoxication (ETOH odor, sedation, slurred speech, motor instability, etc.)

7.13.16.11.1 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. Trans buccal administration should be avoided other than for buprenorphine. A daily dosage above 50 MME may be appropriate for certain patients. However, when the patient's dosage exceeds 50 MME per day or the patient is sedentary with minimal function, consideration should be given to lowering the dosage. Some patients may require dosages above 90 MME per day. However, if the patient reaches a dosage above 90 MME per day, it is appropriate to taper or refer to a pain or addiction specialist. The provider should also adhere to all requirements in this Guideline and closely monitor the patient as this is considered a high-risk dosage. In some cases, buprenorphine may be a preferred medication for pain control in those patients. Consultation may be necessary.

7.13.16.11.2 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.

7.13.16.11.3 Naloxone may be prescribed when any risk factors are present. The correct use of Naloxone should be discussed with the patient and family.

7.13.16.11.4 Benzodiazepines should not be prescribed when opioids are used except in rare circumstances. Refer to subsection 7.13.4. Hypnotics and Sedatives, for more information.

7.13.16.11.5 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.

7.13.16.11.6 Drug Interactions. Patients receiving opioid agonists should not be given a mixed-agonist-antagonist such as pentazocine (Talacen, Talwin) 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 (Anx, Atarax, Hypam, Rezine, Vistaril) should be avoided except when during tapering of opioids. Alcohol should not be used.

7.13.16.11.7 Recommended Laboratory Monitoring. Primary laboratory monitoring is recommended for acetaminophen/aspiring/NSAIDs combinations (renal and liver function, blood dyscrasia), although combination opioids are not recommended for long-term use. Morphine and other medication may require renal testing and other screening.

7.13.16.11.8 Sleep Apnea Testing. Both obstructive and central sleep apnea are 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 02-saturation device may be useful for monitoring respiratory depression secondary to opioids, although there are no studies on this topic.

7.13.16.11.9 Regular consultation of the Delaware Prescription Monitoring Program (PMP). Physicians should review their patients 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.

7.13.16.11.10 Addiction. If addiction occurs, patients will require treatment. After detoxification, they may need long-term treatment with naltrexone (Depade, ReVia), an antagonist which can be administered in a long-acting form or buprenorphine which requires education per the Drug Enforcement Agency (DEA).

7.13.16.11.11 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.

7.13.16.12 Post-operative Pain Management. Proper post-operative pain management may avoid overuse and misuse of opioids. A recent practice Guideline strongly recommends a multi-modal approach to post-operative pain. Suggestions include use of TENS, cognitive behavioral therapy, use of oral medication over parenteral medication and patient controlled analgesia when parenteral medication is used, use of NSAIDS (for appropriate procedures) or acetaminophen, gabapentin or pregabalin may also be used, and peripheral regional anesthesia when appropriate. Ketamine is also suggested for major surgeries, patients with high opioid tolerance for those who have difficulty tolerating opioids. However, ketamine does have side effects such as hallucination and nightmares. It is not recommended as a first line medication for most patients.

Generally, post-operative pain management is under the supervision of the surgeon and hospitalist with the goal of returning to the pre-operative level of pharmaceutical management.

7.13.16.13 Pre-operative psychological preparation or neuroscience education may improve post-operative pain management. Pre-operative cognitive-behavioral therapy or other psychological intervention likely improves in-hospital mobilization and analgesic use for lumbar spinal fusion patients and for other surgical patients. One randomized study compared patients who receive one session of pre-operative pain neuroscience education from physical therapist prior to lumbar discectomy and those who did not. There was no change in the primary outcomes from surgery. However significant changes occurred in secondary outcomes which included preparation for surgery, surgery meeting their expectations, and a 45% decrease in health expenditure for the follow up year. Thus, pre-operative pain neuroscience education may prove a useful addition for any patient prior to surgical decisions. Refer to subsection 7.18, Therapy-Active, for a description of Pain Neuroscience Education. Optimal surgical outcomes are more likely when the patient commits to a post-operative active therapy program.

7.13.16.14 Surgical procedures may be necessary for patients already taking chronic opioids, and they may encounter difficulty with pain control post-operatively. These patients will usually require higher doses of opioids during their post-operative phase and may benefit the most from multimodal therapy or ketamine.

7.13.16.15 Topical Drug Delivery. It is strongly advised that physicians consult a pain specialist or addiction specialist when caring for post-operative patients with a history of substance abuse or previous addiction.

7.13.17 Nonsteroidal Anti-Inflammatory Drugs. 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 FDA advises that many 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 prostaglandin analog misoprostol along with these NSAIDs may reduce the risk of duodenal and gastric ulceration in patients at higher risk for this adverse event (e.g., age > 60, concurrent antiplatelet or corticosteroid therapy). They do not impact possible cardiovascular complications. Due to the cross-reactivity between aspirin and NSAIDs, NSAIDs should not be used in aspirin-sensitive patients, and they 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. Patients with renal or hepatic disease may need increased dosing intervals with chronic use. Chronic use of NSAIDs is generally not recommended due to increased risk of cardiovascular events and GI bleeding.

7.13.17.1 Topical NSAIDs may be more appropriate for some patients as there is some evidence that topical NSAIDs are associated with fewer systemic adverse events than oral NSAIDs.

7.13.17.2 NSAIDs may be associated with non-unions. Thus, their use with fractures is questionable.

7.13.17.3 Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent on the patient's age and general health status and should be within parameters listed for each specific medication. Complete Blood Count (CBC) and liver and renal function should be monitored at least every 6 months in patients on chronic NSAIDs and initially when indicated.

7.13.17.4 There is no evidence to support or refute the use of oral NSAIDs to treat neuropathic conditions.

7.13.17.5 Non-selective Nonsteroidal Anti-Inflammatory Drugs Includes NSAIDs and acetylsalicylic acid. 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 or symptoms of serious GI 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.

7.13.17.6 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.

7.13.17.7 There is good evidence that celecoxib (Celebrex) in a dose of 200 mg per day, administered over a long period, does not have a worse cardiovascular risk profile than naproxen at a dose of up to 1000 mg per day or ibuprofen at a dose of up to 2400 mg per day. There is good evidence that celecoxib has a more favorable safety profile than ibuprofen or naproxen with respect to serious GI adverse events, and it has a more favorable safety profile than ibuprofen with respect to renal adverse events. There is an absence of evidence concerning the relative safety of celecoxib at doses greater than 200 mg per day. COX-2 inhibitors should not be first line for low-risk patients who will be using an NSAID short-term. COX-2 inhibitors are indicated in select patients who do not tolerate traditional NSAIDs. 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 years of age, take corticosteroids or anti-coagulants, or have a longer duration of therapy. Celecoxib is contraindicated in sulfonamide allergic patients.

7.13.18 Topical Drug Delivery

7.13.18.1 Description: Topical medications may be an alternative treatment for localized musculoskeletal disorders and is an acceptable form of treatment in selected cases.

7.13.18.2 Indication: Neuropathic pain for many agents; episodic use of NSAIDs and salicylates for joint pain or musculoskeletal disorders. All topical agents should be used with strict instructions for application as well as maximum number of applications per day to obtain the desired benefit and avoid potential toxicity.

7.13.18.3 Dosing and time to therapeutic effect: It is necessary that all topical agents be used with strict instructions for application as well as maximum number of applications per day to obtain the desired benefit and avoid potential toxicity. For most patients, the effects of long-term use are unknown. Thus, episodic use may be preferred for some agents.

7.13.18.4 Side effects: Localized skin reactions may occur, depending on the medication agent used.

7.13.18.5 Topical Agents

7.13.18.5.1 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 strong evidence that a single application of 8% capsaicin is more effective than a control preparation of 0.04% capsaicin for up to 12 weeks. However, there may be a need for frequent application, and it is not known whether subsequent applications of capsaicin are likely to be as effective as the first application. There is some evidence that in patients who are being treated with capsaicin 8% patches, 2 methods of pre-treatment are equally effective in controlling application pain and in enabling patients to tolerate the patch: topical 4% lidocaine cream applied to the area for 1 hour before

placement of the capsaicin patch and 50 mg oral tramadol taken 30 minutes before patch placement.

7.13.18.5.2 Clonidine. There is good evidence that topical clonidine gel 0.1% is likely to alleviate pain from diabetic peripheral neuropathy in patients who display a nociceptive response to the application of 0.1% capsaicin applied to the pretibial area. It is likely that patients who do not display a pain response to pretibial capsaicin are not likely to have a clinically meaningful analgesic response to clonidine gel. It is unknown if this screening test applies to other types of neuropathic pain. Clonidine gel may be used for neuropathic pain.

7.13.18.5.3 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 or 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. Despite the lack of evidence, it is physiologically possible that topical tricyclics and a higher dose of ketamine could have some effect on neuropathic pain. Other less expensive topicals and compounds, including over the counter, should be trialed before more expensive compounds are ordered. The use of topical tricyclics or ketamine should be limited to patients with neuritic or sympathetically mediated pain with documented supporting objective findings such as allodynia or hyperalgesia. Continued use of these agents beyond the initial prescription requires documentation of effectiveness, including functional improvement, or decreased use of other medications, particularly decreased use of opioids or other habituating medications.

7.13.18.5.4 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 and there is variability and systemic absorption among individuals. There is good evidence that lidocaine 5% plasters, applied for up to 12 hours to the lower extremities of patients with post-herpetic neuralgia and diabetic painful neuropathy, is non-inferior to pregabalin for the same indications. The topical lidocaine is associated with significantly fewer drug-related adverse events over 4 weeks of observation. 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 3 patches may be used simultaneously for 12 hours per day. It should be applied only to intact skin. Metered dose 8% pump sprays have also been used and usually require a 3 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.

7.13.18.5.5 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 COS inhibition. There is insufficient evidence to support the use of topical rubefacients containing salicylates for acute injuries or chronic conditions. They seem to be relatively well tolerated in the short-term, based on limited data. The amount and quality of the available data mean that uncertainty remains about the effects of salicylate-containing rubefacients.

7.13.18.5.6 There is good evidence that diclofenac gel (Voltaren, Solaraze) reduces pain and improves functions in mild-to-moderate hand osteoarthritis. There is good evidence that topical diclofenac and ketoprofen are more effective than placebo preparations for purposes of relieving pain attributable to knee osteoarthritis. There is good evidence that topical NSAIDs probably reduce the risk of GI adverse effects by approximately 1/3 compared to oral NSAIDs. Topical diclofenac does not appear to affect the anti-platelet properties of aspirin unlike the oral version. The topical solution of 2% sodium diclofenac applied thrice a day is equal to 1.5% 4 times per day. 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 (refer to the Cumulative Trauma Conditions Medical Treatment Guideline). It is likely that other NSAIDs would also be effective topically. Thus, topical NSAIDs are permitted when patients show functional improvement.

7.13.18.5.7 Other than local skin reactions, the side effects of therapy are minimal, although not non-existent. The usual contraindications to use of these compounds needs to be considered. Local skin reactions are rare and systemic effects are 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. This allows the topical use of these medications when systemic administration is relatively contraindicated, such as the case in patients with hypertension, cardiac failure, or renal insufficiency (refer to the Cumulative Trauma Conditions Medical Treatment Guideline). Both topical salicylates and NSAIDs are appropriate for many chronic pain patients. However, to receive refills, patients should demonstrate increased functions, decreased pain, or decreased need for oral medications.

7.13.18.5.8 Other Compounded Topical Agents. At the time of writing this Guideline, 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 who have allergies or side effects from other more commonly used oral agents. A compounded topical agent must be pre-authorized.

7.13.18.6 Smoking Cessation Medications and Treatment. Tobacco dependence is chronic and may require repeated attempts to quit. All smoking cessation programs should be accompanied by behavioral support which may include practical counseling sessions and social support, which usually includes telephone follow-up. A variety of medications have been used

including Bupropion SR, nicotine patches, gum, inhaler, lozenges or nasal spray, and varenicline. When nicotine supplements are used, cotinine testing will be positive. Urine anabasine or exhaled carbon monoxide 5 ppm or less may be used to check tobacco abstinence.

7.13.18.6.1 There is some evidence that among adults motivated to quit smoking, 12 weeks of open-table treatment including counseling and one of the following: nicotine patch, varenicline, or combination nicotine replacement therapy (nicotine patch and nicotine lozenge) are equally effective in assisting motivated smokers to quit smoking over a period of one year.

7.13.18.6.2 There is some evidence that among adults motivated to quit smoking, abrupt smoking cessation is the more effective method that lads to lasting abstinence over a period of 4 weeks to 6 months compared to gradual cessation, even for smokers who initially prefer to quit by gradual reduction.

7.13.19 Other Agents

7.13.19.1 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.

7.13.19.2 Oral Herbals. There is insufficient evidence due to low quality studies that an oral herbal medication, Compound Qishe Tablet, reduced pain more than placebo. There is also insufficient evidence that Jingfukang and a topical herbal medicine, Compound Extractum Nucis Vomicae, reduced pain more than Diclofenace Diethylamine Emulgel. Further research is very likely to change both the effect size and our confidence in the results. Currently, no oral herbals are recommended.

7.13.19.3 Vitamin D. A large beneficial effect of Vitamin D across different chronic painful conditions is unlikely. Therefore, it is not recommended.

7.13.19.4 Alpha-Lipoic Acid. An adequate meta-analysis shows that there is some evidence that alpha-lipoic acid at a dose of 600 mg per day may reduce the symptoms of painful diabetic neuropathy in the short term of 3 to 5 weeks. The effect of the intravenous route appears to be greater than that of the oral route, but the oral route may have a clinically relevant effect. Doses of 1200 or 1800 mg have not been shown to have additional therapeutic benefit. This medication may be used for neuropathic pain.

7.13.20 Opioid Addiction Treatment. The DSM-V renames opioid addiction as substance use disorder (SUD) and classifies opioid use disorder according to categories defined as mild (2-3 features of stated criteria), moderate (4-5 features of stated criteria), or severe (6-7 features of stated criteria). Terms used are stated and described as:

7.13.20.1 Opioid physical dependence: Opioid withdrawal symptoms (withdrawals) which occur as a result of abrupt discontinuation of an opioid in an individual who became habituated to the medication or through

administration of an antagonist. Opioid physical dependency is not in and of itself consistent with the diagnosis of addiction/substance use disorder.

7.13.20.2 Tolerance: A physiologic state caused by the regular use of an opioid in which increasing doses are needed to maintain the same affect. In patients with “analgesic tolerance,” increased doses of the opioid may be needed to maintain pain relief.

7.13.20.3 Opioid Misuse: The utilization of opioid medications outside of the prescribing instructions for which it was originally prescribed. Misuse may be as innocuous as taking slightly more or less medications than prescribed to crushing or snorting an opioid.

7.13.20.4 Opioid Abuse: The use of any substance for a non-therapeutic purpose or the use of a medication for purposes other than those for which the agent is prescribed. Abuse includes intentional use for altering a state of consciousness. Abuse frequently affects the individual’s ability to fulfill normal societal roles, resulting in difficulty with employment, or legal, or interpersonal problems.

7.13.20.5 Pseudo-addiction: Addiction-like behaviors consistent with overutilization of medications outside of the prescribing provider’s instructions and recommendations for the express purpose of improved pain management. This occurs when a patient believes there is insufficient pain relief. Once pain is adequately managed with a higher dose of medications than initially prescribed or with improved therapy, the behaviors consistent with addition are discontinued.

7.13.20.6 Addiction: A primary chronic neurobiological disease influenced by genetic, psychosocial or environmental factors. It is characterized by impaired control over drug use, compulsive drug use, and continued drug use despite harm and because of craving.

7.13.20.7 Substance use disorder/addiction in the workers’ compensation system can be encountered in three ways. First, the individual has an active substance use disorder at the time of injury. The party responsible for treatment of the substance use disorder may be outside of the workers’ compensation system. However, if there is no other paying party and the treatment is necessary to recover from the current workers’ compensation injury, treatment may be covered by the workers’ compensation payor. The second possibility is that a patient with a substance use disorder, who is currently in recovery at the time of the workers’ compensation injury, relapses because of the medications which are prescribed by the treating provider. This patient may become re-addicted and will manifest substance use disorder characteristics and symptoms consistent with the diagnosis. The third possibility is an individual with no history of substance use disorder who is injured because of an occupational accident. This particular individual becomes “addicted” to the medications as a result of the medications being prescribed. This is most likely to occur with the use of opioids but could possibly occur with use of other medications such as benzodiazepines or specific muscle relaxants such as carisoprodol.

7.13.20.8 If the treating provider is suspicious of a patient exhibiting opioid misuse, abuse, or addiction, the patient should preferably be evaluated by a specialist in the field of addiction medicine. It would be the responsibility

of the specialist to identify the medication misuse, abuse, addiction, or pseudo-addiction and to determine what additional treatment, if any, needs to be implemented.

7.13.20.9 During the initial injury evaluation, an authorized treating provider should obtain an addiction history as part of a complete history and physical. If it is determined at the time of the initial evaluation by the treating provider that there is the pre-existing condition of active SUD or history of opioid addiction/SUD, then it is prudent to consider an evaluation with an addiction medicine physician prior to issuing opioid treatments if possible. The addiction medication specialist will be able to counsel the patient, accordingly, determine medication needs, and determine the appropriate follow-up to hopefully avoid aggravation or relapse of substance abuse disorders which will complicate the recovery process. Many patients exhibits opioid misuse, opioid abuse, and pseudo-addictive behaviors. These issues can be managed once the problem is identified, and a discussion is carried out with the patient regarding these abnormal behaviors.

7.13.20.10 Once the diagnosis of SUD is confirmed, an addiction medicine specialist familiar with addiction treatment should assist in co-management the patient's care and the problematic drug prescriptions. This co-management technique is critical for the injured worker with a SUD diagnosis during the initial injury phrase, recovery, and stabilization phase until he has reached MMI. If it is determined during the active treatment and recovery phase that there is no longer a need for opioids then the addiction medicine specialist will be in charge of the transition from use of opioids to safe taper/discontinuation of the opioids while monitoring for relapse of addiction.

7.13.20.11 Co-management is equally important for managing the chronic pain patient that has a concomitant opioid addiction/SUD with a legitimate need for analgesic medications. The addiction medicine specialist in all likelihood will monitor the patient more closely including judicious prescribing, PDMP reviews, urine drug testing, drug counts, and clarifying functional improvement as a result of the medications prescribed and frequent follow-ups which may initially seem excessive.

7.13.20.12 All abstinence addiction treatment begins with a discontinuation of the addicting substance; this is referred to as the detox phase of the treatment and can be performed in a number of ways. However, detoxification alone is not considered adequate addiction treatment. Detoxification is simply a method of discontinuing the medications in an effort to stabilize the patient prior to more extensive treatment.

7.13.20.12.1 Phase 1. The methods of detoxification can include:

7.13.20.12.1.1 Abrupt discontinuation. Not recommended due to high rate of relapse due to craving and withdrawal symptoms;

7.13.20.12.1.2 Slow but progressive taper - 10% of total dosage per week as an outpatient treatment;

7.13.20.12.1.3 Conversion to a different medication opioid (buprenorphine/naloxone) to enable a more stable and comfortable taper occasionally done as an outpatient but more commonly done as part of a more comprehensive treatment program; and

7.13.20.12.1.4 Rapid detox under anesthesia. Not recommended due to relatively high incidence of complications and high expense. The methodology chosen for Phase 1 detoxification is left up to the specialist and is simply the initial phase of stabilization prior to considering the need for a Phase 2 of addiction treatment program.

7.13.20.12.2 Phase 2. Once a patient is safely through the detoxification phase and the condition is stabilized regardless of the method chosen, then successful addiction treatment begins generally utilizing a number of techniques to prevent the return to active substance use and addiction. This phase of treatment generally involves teaching the patient to develop control over the compulsions, psychosocial factors, and associated mental health issues which are critical to maintain abstinence. This phase of treatment is generally managed in a 30-90-day non-hospital residential treatment program. The treatment prescribed in a residential treatment program generally includes individual and group therapy with certified addiction counselors and psychologists. Phase 2 of treatment may or may not be combined with opioid substitution therapy with medications such as buprenorphine/naloxone (partial agonist of the opioid receptor), methadone, or naltrexone. Injectable depot naltrexone may be used.

7.13.20.12.2.1 Buprenorphine/naloxone therapy utilizes a sublingual partial opioid receptor agonist which binds to the opioid receptor, reducing craving and resulting in analgesia when necessary. Due to its high affinity to the opioid receptor, it blocks the effect of non-approved additional opioid use. The buprenorphine is administered either sublingually or, when FDA approved, as a subcutaneous implant. Naloxone was added to the sublingual drug formulation to discourage using this medication intravenously. With intravenous administration of buprenorphine/naloxone, the naloxone becomes absorbed neutralizing the effects of opioids. Buprenorphine/naloxone can be an excellent option in patients requiring analgesic medications with a prior history of opioid addiction because buprenorphine results in less sedation and euphoria than the other standard schedule II opioid medications. Prescribing Suboxone film (buprenorphine/naloxone) for addiction purposes can only be done by a physician and requires special training and certification. Once special training is completed, an application is filed with the DEA to obtain a special DEA license referred to as an X-DEA number. This X-DEA number needs to accompany all prescription for Suboxone when delivered to the pharmacy and identifies the prescription is being issued specifically for the treatment of addiction/SUD.

7.13.20.12.2.2 Methadone may be an option if the patient is admitted to a federally licensed methadone treatment facility where a daily dose of medication is administered, and the patient continues to utilize therapeutic treatments/cognitive behavioral therapies as noted above. There is strong evidence that in patients being treated with opioid antagonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidence by positive urines, are equivalent between methadone and buprenorphine. The methodology and rationale for methadone treatment is to saturate the opioid receptors with methadone (a slow onset and prolonged duration opioid),

reducing the opioid craving. The majority of the opioid receptors are bound by the methadone leaving very few unbound opioid receptors available in the event additional opioids are utilized in an attempt to achieve the euphoric effect. When the patient is stabilized on a methadone dose determined by the federally licensed methadone clinic and their associated physicians, the patient's drug-seeking, craving, legal issues, and attempts to utilize non-approved medications is reduced. Patients will frequently return to more productive lives free of the compulsions, cravings, and legal issues and are usually able to maintain jobs and improve family dynamics.

7.13.20.12.2.3 Other medications which may be useful and can be utilized during the Phase 2 and 3 treatment include opioid receptor antagonists such as naltrexone (ReVia, Vivitrol) which produces no euphoria. The purpose of naltrexone therapy is to add an additional layer of protection and treatment for the patients by allowing them to receive a daily oral dose of naltrexone (ReVia) or monthly injection of naltrexone (Vivitrol). Administration of naltrexone will bind with very high affinity to the opioid receptor resulting in the opioid receptors being non-responsive to other opioid utilization thereby preventing any euphoric response or reinforcement with unsanctioned opioid use. This treatment method can be problematic in an individual receiving intramuscular naltrexone therapy especially if that individual requires surgery and post-operative pain management because the analgesics needed for post-operative pain management will be significantly less effective because of the prolonged opioid antagonist properties of the naltrexone.

7.13.20.12.2.4 In summary, medication assisted treatment for patients addicted to opioids is the treatment recommended by most experts. A Canadian evidence-based guideline recommends long-term treatment with buprenorphine/naloxone, or methadone for some patients, based on the high relapse rate without medication assistance. The likelihood of relapse in the workers' compensation population for individuals who have become addicted through prescription drug use is unknown. Buprenorphine implants are likely equally effective as sublingual buprenorphine for preventing for illicit opioid use. Implants are significantly more costly. Naltrexone treatment, an opioid agonist, has also been used to maintain abstinence. It can be provided in monthly injections or orally 3 times per week. Choice of these medications should be made by the addiction specialist.

7.13.20.12.3 Phase 3. Aftercare begins after discharge from the non-hospital residential treatment program and is designed for long-term management of addiction. This phase is potentially the time when relapse is most likely to occur if the patient has not developed significant skills necessary to deal with compulsions, cravings, and associated psychosocial factors contributing to SUD. Long term strategies include:

7.13.20.12.3.1 Intense outpatient programs (IOP);

7.13.20.12.3.2 Group therapy/meetings such as Narcotics Anonymous; and

7.13.20.12.3.3 Residential communities (RC) which are groups of patients living together in a community for up to 6 months for the express purpose of maintaining abstinence from their drug of choice but at the same time transitioning and learning how to live in the general community.

Residential communities are extremely useful to give patients an opportunity to be reintroduced to employment and psychosocial interactions with family and friends while maintaining contact with the community supporting their addiction recovery. In addition, Phase 3 medication treatment may include utilization of opioid substitution therapy (buprenorphine/naloxone) or opioid receptor antagonist therapy as noted above. It must be noted that relapse is common despite the utilization of intense cognitive behavioral therapy, addiction treatment strategies, and long-term Phase 3 treatment and medication. Risk monitoring should be continued, including checking for behavioral aberrancies, checking the PMP, and drug testing. Additional treatment or readmission for repeat treatment is not uncommon.

7.13.20.13 Opioid/Chemical Treatment Program Requirements

7.13.20.13.1 Chemical dependency for workers' compensation issues will usually be related to opioids, anxiolytics, or hypnotics as prescribed for the original workers' compensation injury. Chemical dependency should be treated with specific programs providing medical and psychological assessment, treatment planning, and individual as well as group counseling and education. Established functional goals which are measurable, achievable, and time specific are required.

7.13.20.13.2 Inpatient or outpatient programs may be used, depending upon the level of intensity of services required. Formal inpatient 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 or alcohol) and those with complex medical conditions or psychiatric issues related to drug misuse. A medical physician with appropriate training and 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. The initial medical exam should include appropriate laboratory testing such as liver function, screening for sexual diseases, etc.

7.13.20.13.3 Addiction specialists, alcohol and drug counselors, psychologists, psychiatrists, 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. Peer support specialists should receive competency-based training. A designated individual is assigned to each worker to assist in coordinating care. There should be good communication between the program and other external services, external health care providers, Al-Anon, Alcoholics Anonymous (AA), and pain medicine providers. Drug screening should be performed as appropriate for the individual, at least weekly during the initial detoxification and intensive treatment phases. At least 8 random drug screens per year should be completed for those on medication assisted treatment and drug diversion control methods should be in place.

7.13.20.13.4 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.

7.13.20.13.5 Transition and discharge should be carefully planned with full communication to outside resources.

7.13.20.13.6 Duration of inpatient programs are usually 4 weeks while outpatient programs may take 12 weeks.

7.13.20.13.7 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.

7.13.20.13.8 Both ultra-rapid and rapid detoxification are not recommended due to possible respiratory depression and death and the lack of evidence for long range treatment.

7.13.20.13.9 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% day or per week. Tapering programs under the supervision of physicians with pain expertise may proceed more aggressively. 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.

7.13.20.13.10 Time Frames for Opioid/Chemical Treatment Programs

7.13.20.13.10.1 Time to produce effect: 10 to 12 treatments.

7.13.20.13.10.2 Frequency of full-time programs: No less than 5 hours/day, 5 days/week; part time programs: 4 hours/day for 2-3 days per week.

7.13.20.13.10.3 Optimum duration: 2 to 12 weeks at least 2-3 times a week. With follow-up visits weekly or every other week during the first 1 to 2 months after the initial program is completed.

7.13.20.13.10.4 Maximum duration: 4 months for full time programs and up to 6 months for part-time programs. Periodic review and monitoring thereafter for 1-year, additional follow-up based upon the documented maintenance of functional gains.

7.14 Orthotics/Prosthestics/Equipment

7.14.1 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.

7.14.2 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.

7.14.3 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.

7.14.4 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, or post spinal fusion surgery. 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.

7.14.4.1 Orthotic/prosthetic training is the skilled instruction (preferably by qualified providers) in the proper use of orthotic devices and/or prosthetic limbs.

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

7.15 Personality/Psychological/Psychosocial Intervention

7.15.1 Introduction. Psychosocial treatment is a generally accepted, well-established therapeutic and diagnostic procedure with selected use in acute pain problems, but with more widespread use in sub-acute and chronic pain populations. Psychosocial treatment may be important component in the total management of a patient with chronic pain and should be implemented as soon as the problem is identified.

7.15.1.1 Studies have noted that there is not a direct connection between impairment and disability nor is there a direct connection between lumbar imaging and pain. It appears that the lack of connections is likely accounted for by differences among individuals in level of depression, coping strategies, or other psychological distress.

7.15.1.2 There is some evidence that in the setting of chronic low back pain when disc pathology is present, a high degree of anxiety or depressive symptomatology is associated with relatively less pain relief in spite of higher opioid dosage than when these symptoms are absent. Therefore, psychological issues should always be screen for and treated in chronic pain patients.

7.15.2 Psychological treatments for pain can be conceptualized as having a neuropsychological basis. These treatments for pain have been shown to decrease physiological reactivity to stress, alter patterns of brain activation as demonstrated by functional MRI (fMRI), alter the volume of grey matter and other structures in the brain, and alter blood flow patterns in the brain. The most researched psychological treatment is Cognitive Behavioral Therapy (CBT) which is summarized in this section.

7.15.3 Once 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.

7.15.4 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.

7.15.5 A psychologist with a Ph.D., PsyD, EdD credentials, or a Psychiatric MD/DO may perform psychosocial treatments. Other licensed mental health providers working in consultation with a Ph.D., PsyD, EdD, or Psychiatric MD/DO, and with experience in treating chronic pain disorders in injured workers may also perform treatment.

7.15.6 Psychosocial interventions include psychotherapeutic treatments for behavioral health conditions, as well as behavioral medicine treatments. These interventions may similarly be beneficial 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 (CBT), relaxation training, mindfulness training, and sleep hygiene psychoeducation.

7.15.6.1 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 post-traumatic stress disorder (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 it 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.

7.15.6.2 CBT must be distinguished from neuropsychological therapies used to teach compensatory strategies to brain injured patients, which are also called “cognitive therapy.” Many other clinical providers also provide a spectrum of cognitive interventions including motivational interviewing, pain neuroscience education, and other interventions aimed at patient education and change in behavior.

7.15.6.3 It should be noted 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 cognitive ability and 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 is 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 who 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.

7.15.6.3.1 CBT is often combined with active therapy in an interdisciplinary program, whether formal or informal. It must be coordinated with a

psychologist or psychiatrist. CBT can be done in a small group or individually, and the usual number of treatments varies between 8 and 16 sessions.

7.15.6.3.2 Before CBT or other psychological treatments are performed, the patient must have a full psychological evaluation. The CBT program must be done under the supervision of a psychologist with a PhD, PsyD, or EdD or a psychiatric MD/DO.

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

7.15.7 Hypnosis. The term hypnosis can encompass a number of therapy types including relaxation, imagery, focused attention, interpersonal processing, and suggestion. Hypnosis has been used in depression and for distress related to medical procedures. A number of studies support the use of hypnosis for chronic pain management. At least one pilot study suggested that hypnotic cognitive therapy assist recovery in chronic pain. Other imaging studies support the concept that hypnosis can actively affect cortical areas associated with pain. Thus, this therapy may be used at the discretion of the psychologist. A more recent meta-analysis was completed which purported to show evidence for hypnosis. However, the heterogeneity of the studies included prevents this study from meeting our standards for evidence.

7.15.8 For all psychological/psychiatric interventions, an assessment and treatment plan must be provided to the treating physician prior to initiating treatment. The treatment plan must include specific, measurable, achievable, and realistic behavioral goals, with specific interventions and time frames to achieve those goals. The report should also address pertinent issues such as pre-existing, exacerbated or aggravated, and/or causative issues, as well as a realistic functional prognosis.

Time Frames for Cognitive Behavioral Therapy (CBT) or Similar Treatment	
Time to Produce Effect	12-16 hours of treatment (1-hour individual sessions or alternately 1- to 2-hour group sessions).

Time Frames for Cognitive Behavioral Therapy (CBT) or Similar Treatment	
Frequency	1 to 2 times weekly for the first 2 weeks, decreasing to 1 time per week thereafter.
Maximum Duration	24 1-hour sessions.
Note	Before CBT or other psychological/psychiatric interventions are done, the patient must have a full psychological evaluation. The CBT program must be done under the supervision of a psychologist with a PhD, PsyD, or EdD, or a Psychiatric MD/DO.
Time Frames for Other Psychological/Psychiatric Interventions	

Time to Produce Effect	6 to 8 weeks.
Frequency	1 to 2 times weekly for the first 2 to 4 weeks (excluding hospitalization, if required), decreasing to 1 time per week for the second month. Thereafter, 2 to 4 times monthly with the exception of exacerbations, which may require increased frequency of visits. Not to include visits for medication management.
Optimum Duration	2 to 6 months.
Maximum Duration	Commonly 6 months for most cases. Extensions under conditions as noted below. (Not to include visits for medication management). For select patients (e.g., ongoing medical procedures or complications, medication dependence, diagnostic uncertainty, delays in care due to patient or systemic variables), less intensive but longer supervised psychological/psychiatric treatment may be required. If counseling beyond 6 months is indicated, the nature of the psychosocial risks being managed, or functional progress must be documented. Progress notes for each appointment should include goal setting, with specific, measurable, achievable, and realistic goals, and a timetable with an expected end point. In complex cases, goal setting may include maintaining psychological equilibrium while undergoing invasive procedures.

7.16 Restriction of Activities. Continuation of normal daily activities is the goal 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.

7.17 Rehabilitation. It is understood Individuals with Chronic Pain may require additional visits due to acute exacerbations. The practitioner is required to document the rationale for care and may be subject to Utilization Review. All visit limits pertain to an annual amount. It is also understood that practitioners should only provide treatment that is consistent with impairments and dysfunctions identified by a comprehensive physical assessment.

7.18 Therapy – Active. Therapies are based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and alleviating discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task, and thus assists in developing skills promoting independence to allow self-care after discharge. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual, and/or tactile instructions. 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.

7.18.1 Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices. Interventions are selected based on the complexity of the presenting dysfunction with ongoing examination, evaluation and modification of the plan of care as improvement or lack thereof occurs. Change and/or discontinuation of an intervention should occur if there is attainment of expected goals/outcome, lack of

progress, lack of tolerance and/or lack of motivation. Passive interventions/modalities may only be used as adjuncts to the active program.

7.18.2 Activities of Daily Living. Supervised instruction, active-assisted training, and/or adaptation of activities or equipment to improve a person's capacity in normal daily living activities such as ~~self-are~~ selfcare, work re-integration training, homemaking, and driving.

7.18.3 Functional activities are the use of therapeutic activity to enhance mobility, body mechanics, employability, coordination, and sensory motor integration.

7.18.4 Nerve gliding exercises consist of a series of flexion and extension movements of the hand, wrist, elbow, shoulder, and neck that produce tension and longitudinal movement along the length of the median and other nerves of the upper extremity. These exercises are based on the principle that the tissues of the peripheral nervous system are designed for movement, and that tension and glide (excursion) of nerves may have an effect on neurophysiology through alterations in vascular and axoplasmic flow. Biomechanical principles have been more thoroughly studied than clinical outcomes.

7.18.5 Neuromuscular re-education is the skilled application of exercise with manual, mechanical, or electrical facilitation to enhance strength, movement patterns, neuromuscular response, proprioception, kinesthetic sense, coordination education of movement, balance, and posture. Indications include the need to promote neuromuscular responses through carefully timed proprioceptive stimuli, to elicit and improve motor activity in patterns similar to normal neurologically developed sequences and improve neuromotor response with independent control.

Maximum number of visits 24

7.18.6 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, increased range of motion, and are used to promote normal movement patterns. Can also include complementary/alternative exercise movement therapy.

7.18.6.1 Time to produce effect: 2 to 6 treatments.

7.18.6.2 Frequency: 3 to 5 times per week.

7.18.6.3 Optimum duration: 4 to 8 weeks.

7.18.5.4 Maximum duration: 24 visits, and maximum of 24 in combination with functional activities.

7.19 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 2.5, General Guideline Principles, Active Interventions. Passive therapies may be used intermittently as a provider deems appropriate or regularly if there are specific goals with objectively measured functional improvements during treatment.

7.19.1 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 comorbidities may also extend durations of care. Specific goals with objectively measured functional improvement during treatment must be cited to justify extended durations of care. It is recommended that, if no functional gain is observed after the number of treatments under “time to produce effect” have been completed, alternative treatment interventions, further diagnostic studies, or further consultations should be pursued.

The following passive therapies are:

7.19.2 Electrical stimulation (unattended and attended) is an accepted treatment. Once applied, unattended electrical stimulation requires minimal on-site supervision by the provider. Indications include pain, inflammation, muscle spasm, atrophy, decreased circulation, and the need for osteogenic stimulation. A home unit should be purchased if treatment is effective and frequent use is recommended.

7.19.2.1 Time to produce effect: 2 to 4 treatments.

7.19.2.2 Maximum duration: 14 visits.

7.19.3 Iontophoresis is an accepted treatment which consists of the transfer of medication, including steroidal anti-inflammatories and anesthetics, through the use of electrical stimulation. Indications include pain (Lidocaine), inflammation (hydrocortisone, salicylate), edema (mecholyl, hyaluronidase, salicylate), ischemia (magnesium, mecholyl, iodine), muscle spasm (magnesium, calcium), calcific deposits (acetate), scars, and keloids (sodium chloride, iodine, acetate). There is no proven benefit for this therapy in the low back.

7.19.3.1 Time to produce effect: 1 to 4 treatments.

7.19.3.2 Frequency: 3 times per week with at least 48 hours between treatments.

7.18.3.3 Maximum duration: 8 visits per body region.

7.19.4 Manipulation is generally accepted, well-established and widely used therapeutic intervention for low back pain. 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.

7.19.4.1 High velocity, low amplitude (HVLA) technique, chiropractic manipulation, osteopathic manipulation, muscle energy techniques, counter strain, and non-force techniques are all types of manipulative treatment. This may be applied by osteopathic physicians (D.O.), chiropractors (D.C.), properly trained physical therapists (P.T.), or properly trained medical physicians. Under these different types of manipulation exist many subsets of different techniques that can be described as:

7.19.4.1.1 Direct is a forceful engagement of a restrictive/pathologic barrier;

7.19.4.1.2 Indirect is a gentle/non-forceful disengagement of a restrictive/pathologic barrier;

7.19.4.1.3 The patient actively assists in the treatment; and

7.19.4.1.4 The patient relaxing, allowing the practitioner to move 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. Pre-treatment assessment should be performed as part of each manipulative

treatment visit to ensure that the correct diagnosis and correct treatment is employed.

7.19.4.2 High velocity, low amplitude (HVLA) manipulation is performed by taking a joint to its end range of motion and moving the articulation into the zone of accessory joint movement, well within the limits of anatomical integrity. There is good scientific evidence to suggest that HVLA manipulation can be helpful for patients with acute low back pain problems without radiculopathy when used within the first 4 to 6 weeks of symptoms. Although the evidence for sub-acute and chronic low back pain and low back pain with radiculopathy is less convincing, it is a generally accepted and well-established intervention for these conditions. Indications for manipulation include joint pain, decreased joint motion, and joint adhesions. Contraindications to HVLA manipulation include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritides, aortic aneurysm, and signs of progressive neurologic deficits.

7.19.4.3 Time to produce effect for all types of manipulative treatment: 1 to 6 treatments.

7.19.4.4 Frequency: Up to 3 times per week for the first 4 weeks as indicated by the severity of involvement and the desired effect, then up to 2 treatments per week for the next 4 weeks. For further treatments, twice per week or less to maintain function.

7.19.4.5 Maximum duration: 26 visits.

7.19.4.6 The combination of 97140 plus either CMT or OMT code is equal to one visit when performed on the same day. Any combination of manual therapeutic intervention exceeding 26 visits (not units) need to go to UR.

7.19.5 Massage – Manual or Mechanical. Massage is manipulation of soft tissue with broad ranging relaxation and circulatory benefits. This may include 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.

7.19.5.1 In sub-acute low back pain populations there is good evidence that massage can increase function when combined with exercise and patient education. Some studies have demonstrated a decrease in provider visits and pain medication use with combined therapy. One study indicated improved results with acupressure massage. It is recommended that all massage be performed by trained, experienced therapists and be accompanied by an active exercise program and patient education. In contrast to the sub-acute population, massage is a generally accepted treatment for the acute low back pain population, although no studies have demonstrated its efficacy for this set of patients.

7.19.5.2 Time to produce effect: Immediate.

7.19.5.3 Frequency: 1 to 3 times per week.

7.19.5.4 Maximum duration: 12 visits (CPT codes 97124 and 97140 cannot exceed 26 visits in combination).

7.19.6 Mobilization (joint) 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. For further discussion on Level V joint mobilization please see section on HVLA manipulation [Refer to Section 7.14. 4.1]. 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. Mobilization should be accompanied by active therapy. 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.

7.19.6.1 Time to produce effect for all types of manipulative treatment: 1 to 6 treatments.

7.19.6.2 Frequency: Up to 3 times per week for the first 4 weeks as indicated by the severity of involvement and the desired effect, then up to 2 treatments per week for the next 4 weeks. For further treatments, twice per week or less to maintain function.

7.19.6.3 Maximum duration: 26 visits. CPT codes 97124 and 97140 cannot exceed 48 visits in combination.

7.19.7 Mobilization (soft tissue) 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.

Maximum duration: 26 visits CPT codes 97124 and 97140 cannot exceed 48 visits in combination.

7.19.8 Short-wave diathermy and infrared therapy are accepted treatments which involve the use of equipment that exposes soft tissue to a magnetic or electrical field. Indications include enhanced collagen extensibility before stretching, reduced muscle guarding, reduced inflammatory response, and enhanced re-absorption of hemorrhage/hematoma or edema. They are accepted modalities as adjuncts to acupuncture or situations where other forms of contact superficial heat are contraindicated.

Infrared therapy is an accepted treatment which involves electromagnetic radiation including wavelengths between the 780um to 100um used for patients requiring the application of superficial heat in conjunction with other procedures or modalities, to reduce or decrease pain/produce analgesia, reduce stiffness/tension, myalgia, spasm, or swelling. It is an accepted modality to be used only in conjunction with acupuncture.

7.19.9 Superficial heat and cold therapy (excluding infrared therapy) 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.

7.19.9.1 Time to produce effect: Immediate.

7.19.9.2 Frequency: 2 to 5 times per week.

7.19.9.3 Maximum duration: 12 visits, with a maximum of 1 unit per day.

7.19.10 Traction Mechanical. 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. Motorized traction devices are included (i.e. VAX-D, DRX9000, etc.)

7.19.10.1 Time to produce effect: 1 to 3 sessions up to 30 minutes. If response is negative after 3 treatments, discontinue this modality.

7.19.10.2 Frequency: 2 to 3 times per week. A home traction unit can be purchased if therapy proves effective.

7.19.10.3 Maximum duration: 16 visits.

7.19.11 Transcutaneous Electrical Nerve Stimulation (TENS) is a generally accepted treatment. TENS should include at least one instructional session for proper application and use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width and amplitude modulation. Consistent, measurable functional improvement should be documented prior to the purchase of a home unit.

7.19.11.1 Time to produce effect: Immediate.

7.19.11.2 Frequency: Variable Duration: 3 visits.

7.19.12 Ultrasound (including phonophoresis) is an accepted treatment. Ultrasound uses sonic generators to deliver acoustic energy for therapeutic thermal and/or non-thermal 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.

7.19.12.1 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. Phonopheresis is not recommended for low back pain.

7.19.12.2 Time to produce effect: 6 to 15 treatments.

7.19.12.3 Frequency: 3 times per week.

7.19.12.4 Maximum duration: 18 visits.

7.20 Therapy – Active. The following active therapies are widely used and accepted methods of care for a variety of work-related injuries. They are 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. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy requires supervision from a provider such as verbal, visual, and/or tactile instruction(s). At times, the 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.

7.20.1 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:

7.20.2 Activities of Daily Living (ADL) are well-established interventions which involve 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.

7.20.2.1 Time to produce effect: 4 to 5 treatments.

7.20.2.2 Maximum duration: 10 visits.

7.20.3 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 includes the implementation of active therapeutic procedures in a swimming or therapeutic pool. The water provides a buoyancy force that lessens the amount of force gravity applies to the body. The decreased gravity effect allows the patient to have a mechanical advantage and more likely have a successful trial of therapeutic exercise. The therapy may be indicated for individuals who:

7.20.3.1 Cannot tolerate active land-based or full-weight bearing therapeutic procedures require increased support in the presence of proprioceptive deficit;

7.20.3.2 Are at risk of compression fracture due to decreased bone density; have symptoms that are exacerbated in a dry environment;

7.20.3.3 Would have a higher probability of meeting active therapeutic goals than in a land-based environment.

7.20.3.4 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.

7.20.3.5 Time to produce effect: 4 to 5 treatments.

7.20.3.6 Frequency: 3 to 5 times per week.

7.20.3.7 Maximum duration: 16 visits.

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

7.20.4 Functional activities are well-established interventions which involve the use of therapeutic activity to enhance mobility, body mechanics, employability, coordination, balance, and sensory motor integration.

7.20.4.1 Time to produce effect: 4 to 5 treatments.

7.20.4.2 Frequency: 3 to 5 times per week.

7.20.4.3 Maximum duration: 26 visits.

7.20.4.4 Total number of visits 97110 and 97530 should not exceed 40 visits without pre-authorization.

7.20.5 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. It may be indicated for impaired muscle function to radiculopathy. (Foot drop)

7.20.5.1 Time to produce effect: 2 to 6 treatments.

7.20.5.2 Frequency: 3 times per week.

7.20.5.3 Maximum duration: 14 visits inclusive of electrical stimulation codes. If beneficial, provide with home unit.

7.20.6 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.

7.20.6.1 Time to produce effect: 2 to 6 treatments.

7.20.6.2 Frequency: 3-5 times per week.

7.20.6.3 Maximum duration: 24 visits.

7.20.7 Therapeutic exercise is a generally well-accepted treatment. Therapeutic exercise, with or without mechanical assistance or resistance, may include isoinertial, isotonic, isometric and isokinetic types of exercises.

7.20.7.1 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, increased range of motion.

7.20.7.2 Therapeutic exercises are used to promote normal movement patterns and can also include complementary/alternative exercise movement therapy (with oversight of a physician or appropriate healthcare professional).

7.20.8 Spinal 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.

7.20.8.1 Time to produce effect: 2 to 6 treatments.

7.20.8.2 Frequency: 3 to 5 times per week.

7.20.8.3 Maximum duration: 26 visits.

7.20.8.4 Total number of visits of 97110 & 97530 may not exceed 40 visits without pre-authorization.

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8.0 Therapeutic Procedures - Operative

8.1. 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. 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

8.1.1 Return-to-work or maintaining work status.

8.1.2 Fewer restrictions at work or performing activities of daily living.

8.1.3 Decrease in usage of medications.

8.1.4 Measurable functional gains, such as increased range of motion or documented increase in strength.

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

8.2 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. Similarly, patients with uncontrolled diabetes are at increased risk of post-operative infection and poor wound healing. It is recommended that routine lab work prior to any surgical intervention including hemoglobin A1c. If it higher than the recommended range, the surgery should be postponed until optimization of blood sugars has been achieved.

8.3 Prior to surgical intervention, the patient and treatment 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.

8.2 Neurostimulation

8.2.1 Description. Neurostimulation 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 (IPG). There is some evidence that spinal cord stimulators (SCS) are superior to reoperation in the 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.

8.2.1.1 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.

8.2.1.2 A recent randomized trial found that patients with spinal cord stimulators for CRPS preferred different types and levels of stimulation for pain relief. No difference was found between 40,500 and 1200 Hz levels or burst stimulation.

8.2.2 SCS can be used for patients who have CRPS II. Spinal cord stimulation for spinal axial pain has traditionally not been very successful. It is possible that future technological advances such as high frequency and burst stimulation may demonstrate better results for axial spine pain. Currently, traditional spinal cord stimulators are not recommended for axial spine 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.

8.2.3 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 of the trunk and/or limbs, including unilateral and bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

8.2.4 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 experienced in neurostimulation implantation and participate in ongoing injection training workshops, such as those sponsored by the Internal Society for Injection Studies or as sponsored by implant manufacturers. Permanent electrical lead and IPG placement should be performed by surgeons (orthopedic or neurosurgery) with fellowship training in spine based surgical interventions or other physicians who have completed an Accreditation Council for Graduate Medical Education (ACGME) accredited pain medicine fellowship and have completed the required number of supervised implantations during fellowship.

8.2.5 Indications. Failure of conservative therapy including active or passive therapy, medication management, or therapeutic injections. Habituation to narcotic analgesics in the absence of a history of addictive behavior does not preclude the use of neurostimulation. Only patients who meet the following criteria should be considered candidates for neurostimulation:

8.2.5.1 A diagnosis of a specific physical condition known to be chronically painful has been made on the basis of objective findings; and

8.2.5.2 All reasonable non-surgical treatment has been exhausted; and

8.2.5.3 Pre-surgical psychiatric or psychological evaluation has been performed and has demonstrated motivation and long-term commitment without issues of secondary gain; and

8.2.5.4 There is no evidence of addictive behavior. (Tolerance and dependence to narcotic analgesics are not addictive behaviors and do not preclude implantation.); and

8.2.5.5 The topography of pain and its underlying pathophysiology are amenable to stimulation coverage; and

8.2.5.6 A successful neurostimulation screening test of 2-3 days. A screening test is considered successful if the patient experiences a 50% decrease in pain, which may be confirmed by visual analogue scale (VAS).

8.2.5.7 For spinal cord stimulation, a temporary lead is implanted and attached to an external source to validate therapy effectiveness.

8.2.6 Complications. Serious, less common complications include spinal cord compression, paraplegia, epidural hematoma, epidural hemorrhage, undesirable change in stimulation, seroma, cerebrospinal fluid (CSF) leakage, infection, erosion, and allergic response. Other complications consist of dural puncture, hardware malfunction or equipment migration, pain at implantation site, loss of pain relief, chest wall stimulation, and other surgical risks. In recent studies, device complication rates have been reported to be 25% at 6 months, 32% at 12 months, and 45% at 24 months. The most frequent complications are reported to be electrode migration (14%) and loss of paresthesia (12%), up to 24% required additional surgery. In a recent review of spinal stimulation, 34.6% of all patients reported a complication, most of them being technical equipment-related issues or undesirable stimulation.

8.2.7 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 for non-high frequency devices, the patient must be awakened to establish full coverage from the placement of the lead. One of the most common failures is misplaced leads. Functional improvement is anticipated for up to 3 years or longer when objective functional improvement has been observed during the time of neurostimulation screening exam.

8.2.8 Post-operative Considerations. MRI is contraindicated after placement of neurostimulator. Work restrictions postplacement include no driving when active paresthesias are present. This does not apply to high frequency stimulators as no paresthesia is present. Thus, use of potentially dangerous or heavy equipment while the simulator is active is prohibited. The physician may also limit heavy physical labor.

8.2.9 A mandatory second opinion is required to confirm the rationale for the procedure for nonmalignant pain.

8.2.10 Post-operative Therapy. Active 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.

8.3 Intrathecal Drug Delivery

8.3.1 Description. This mode of therapy delivers small doses of medications directly into the cerebrospinal fluid. Clinical studies are conflicting regarding long-term, effective pain relief in patients with non-malignant pain. As with other routes of drug administration, escalation of dose may be required. Typically, pump refills are needed every 2-3 months.

8.3.2 General Indications. It may be considered only in rare cases where all other commonly used methods to control pain have failed and must be based on the recommendation of at least one physician experienced in chronic pain management in consultation with the primary treating physician. Patients should only be selected for intrathecal drug delivery if they have opioid-responsive pain but cannot tolerate the effects of systemic administration. The patient must have good to excellent pain relief with a test dose prior to pump implantation. The patient must be motivated for the procedure and must understand the potential for complications and requirements of treatment maintenance.

8.3.3 Surgical Indications. Failure of conservative therapy including active or passive therapy, medication management, or therapeutic injections. Only patients who meet the following criteria should be considered candidates for intraspinal analgesic infusions:

8.3.3.1 A diagnosis of a specific physical condition known to be chronically painful has been made on the basis of objective findings; and

8.3.3.2 All reasonable non-surgical treatment has been exhausted; and

8.3.3.3 Pre-surgical psychiatric or psychological evaluation has been performed and has demonstrated motivation and long-term commitment without issues of secondary gain;

8.3.3.4 There is no evidence of addictive behavior. (Tolerance and dependence to narcotic analgesics are not addictive behaviors and do not preclude implantation.); and

8.3.3.5 A successful trial. A screening test is considered successful if the patient experiences a 50% decrease in pain, which may be confirmed by VAS.

8.3.3.6 A mandatory second opinion is required to confirm the rationale for the procedure in non malignant pain.

8.4 Facet Rhizotomy

8.4.1 Description. A procedure designed to denervate the facet joint by ablating the periarticular facet nerve branches. There is good evidence to support this procedure for the cervical spine and some evidence in lumbar spine.

8.4.2 Indications. Pain of facet origin, unresponsive to active and/or passive therapy. All patients must have a successful response to diagnostic medial nerve branch blocks. A successful response is considered to be a 50% or greater relief of pain for the length of time appropriate to the local anesthetic.

8.4.3 Operative Treatment. Percutaneous radio-frequency rhizotomy is the procedure of choice over alcohol, phenol, or cryoablation. Position of the probe using fluoroscopic guidance is required.

9.0 Maintenance Management

9.1 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).

9.2 Maintenance care in CRPS and 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.

9.3 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:

9.3.1 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; ~~b.~~ modalities will emphasize self-management and self-applied treatment;

9.3.2 Management of pain or injury exacerbations will emphasize initiation of active therapy techniques and may require anesthetic injection blocks.

9.3.3 Dependence on treatment provided by practitioners other than the authorized treating physician will be minimized;

9.3.4 Periodic reassessment of the patient's condition will occur as appropriate.

9.3.5 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.

9.3.6 The following are specific maintenance interventions and parameters:

9.3.6.1 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, 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. Occasionally, compliance evaluations may be made through a 4-week membership at a facility offering similar equipment. Home exercise programs are most effective when done 3 to 5 times a week.

9.3.6.2 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.

9.3.6.2.1 Frequency: 2 to 3 times per week. Optimal duration: 1 to 3 months.

9.3.6.2.2 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.

9.3.6.3 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 sessions for one 12-month period.

9.3.6.4 Psychological Management. An ideal maintenance program will emphasize management options implemented in the following order: individual self-management (pain control, relaxation and stress management, etc.); group counseling; individual counseling, by a psychologist or psychiatrist; and in-patient treatment. Aggravation of the injury may require psychological treatment to restore the patient to baseline.

Maintenance duration: 6 to 10 visits for one 12-month period.

9.3.6.5 Non-Narcotic 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.

9.3.6.5.1 Maintenance duration: Usually, four medication reviews within a 12-month period.

9.3.6.5.2 Frequency depends on the medications prescribed. Laboratory and other monitoring as appropriate.

9.3.6.6 Narcotic Medication Management. As compared with other pain syndromes, there may be a role for chronic augmentation of the maintenance program with narcotic 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 including addiction and drug overdose. A patient should have met the criteria in the opioids section of these Guidelines before beginning maintenance narcotics. Laboratory or other testing may be appropriate to monitor medication effects on organ function.

9.3.6.6.1 The following management is suggested for maintenance narcotics:

9.3.6.6.2 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.

9.3.6.6.3 A narcotic medication regimen should be defined, which may 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-narcotic medications to control side effects, treat mood disorders, or control neuropathic pain; however, only one long-acting narcotic and one short acting narcotic for rescue use should be prescribed in most cases. Buccally absorbed opioids other than buprenorphine are not appropriate for these non-malignant patients. Transdermal opioid medications are not recommended, other than buprenorphine.

9.3.6.6.4 All patients on chronic narcotic medication dosages need to sign an appropriate narcotic contract with their physician for prescribing the narcotics.

9.3.6.6.5 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 may order random drug testing when deemed appropriate to monitor medication compliance.

9.3.6.6.6 Patients on chronic narcotic medication dosages must receive them through one prescribing physician or physician group.

9.3.6.6.6.1 Maintenance: Up to 12 visits within a 12-month period to review the narcotic plan.

9.3.6.6.6.2 Laboratory and other monitoring as appropriate.

9.3.6.7 Therapy Management. Some treatment may be helpful on a continued basis during maintenance care if the therapy maintains objective function and decreases medication use. Aggravation of the injury may require intensive treatment to get the patient back to baseline. In those cases, treatments and time frame parameters listed in the Active and Passive Therapy sections apply.

9.3.6.7.1 Active Therapy, Acupuncture, and Manipulation maintenance duration: 10 visits in a 12-month period.

9.3.6.8 Injection Therapy

9.3.6.8.1 Sympathetic Blocks. These injections are considered appropriate if they maintain or increase function. Maintenance blocks are usually combined with and enhanced by the appropriate neuropharmacological medication(s) and other care. It is anticipated that the frequency of the maintenance blocks may increase in the cold winter months or with stress.

Maintenance duration: Not to exceed 6 to 8 blocks in a 12-month period for a single. Increased frequency may need to be considered for multiple extremity involvement or for acute recurrences of pain and symptoms. For treatment of acute exacerbations, consider 2 to 6 blocks with a short time interval between blocks.

9.3.6.8.2 Trigger Point Injections and dry needling. 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 6 sessions per 12-month period.

9.3.6.8.3 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: 6 treatments per 12-month period (a treatment may involve injection at one or two levels.)

9.3.6.9 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 beyond the areas listed above.

Maintenance duration: Not to exceed 3 months for rental equipment. Purchase if effective.