



**New York**

**Non-Acute Pain**

**Medical Treatment Guidelines**

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## **A GENERAL GUIDELINE PRINCIPLES**

The principles summarized in this section are key to the intended application of the New York State Medical Treatment Guidelines (MTG).

### **Medical Care**

#### **A.1 MEDICAL CARE**

Medical care and treatment required as a result of a work-related injury should be focused on restoring functional ability required to meet the patient's daily and work activities and return to work, while striving to restore the patient's health to its pre-injury status in so far as is feasible.

#### **A.2 RENDERING OF MEDICAL SERVICES**

Any medical provider rendering services to a workers' compensation patient must utilize the Treatment Guidelines as provided for with respect to all work-related injuries and/or illnesses.

#### **A.3 POSITIVE PATIENT RESPONSE**

Positive results are defined primarily as functional gains which can be objectively measured. Objective functional gains include, but are not limited to, positional tolerances, range of motion, strength, endurance, activities of daily living (ADL), cognition, psychological behavior, and efficiency/velocity measures which can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation.

#### **A.4 RE-EVALUATE TREATMENT**

If a given treatment or modality is not producing expected results, the provider should either modify or discontinue the treatment regime. The provider should evaluate the efficacy of the treatment or modality 2 to 3 weeks after the initial visit and 3 to 4 weeks thereafter. Recognizing that treatment failure is at times attributable to an incorrect diagnosis should prompt the clinician to reconsider the diagnosis in the event of an unexpected poor response to an otherwise rational intervention.

## **Education**

### **A.5 EDUCATION**

Education of the patient and family, as well as the employer, insurer, policy makers and the community should be a primary emphasis in the treatment of work-related injury or illness. Practitioners should develop and implement effective educational strategies and skills. An education-based paradigm should always start with communication providing reassuring information 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 and prevention of future injury.

## **Time Frames**

### **A.6 DIAGNOSTIC TIME FRAMES**

Diagnostic time frames for conducting diagnostic testing commence on the date of injury. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document.

### **A.7 TREATMENT TIME FRAMES**

Treatment time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration may be impacted by disease process and severity, 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.

### **A.8 DELAYED RECOVERY**

For those patients who fail to make expected progress 6-12 weeks after an injury, reexamination in order to confirm the accuracy of the diagnosis and re-evaluation of the treatment program should be performed. Assessment for potential barriers to recovery (yellow flags/psychological issues) should be ongoing throughout the care of the patient. However, at 6-12 weeks, alternate treatment programs, including formal psychological or psychosocial evaluation, should be considered. Referrals to mental health providers (i.e.: psychology/psychiatry) for the evaluation and management of delayed recovery do not indicate or require the establishment of a psychiatric or psychological condition. The evaluation and management of delayed recovery does not require the establishment of a psychiatric or psychological claim.

## **Treatment Approaches**

### **A.9 ACTIVE INTERVENTIONS**

Active interventions emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive and palliative interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.

### **A.10 ACTIVE THERAPEUTIC EXERCISE PROGRAM**

Active therapeutic exercise program goals should incorporate patient strength, endurance, flexibility, range of motion, sensory integration, coordination, and education as clinically indicated. This includes functional application in vocational or community settings.

### **A.11 DIAGNOSTIC IMAGING AND TESTING PROCEDURES**

Clinical information obtained by history taking and physical examination should be the basis for selection and interpretation of imaging procedure results. All diagnostic procedures have variable specificity and sensitivity for various diagnoses.

When a diagnostic procedure, in conjunction with clinical information, provides sufficient information to establish an accurate diagnosis, a second diagnostic procedure would be redundant if it is performed only for diagnostic confirmation purposes. At the same time, a subsequent diagnostic procedure (that may be a repeat of the same procedure, when the rehabilitation physician, radiologist or surgeon documents the study was of inadequate quality to make a diagnosis) can be a complementary diagnostic procedure if the first or preceding procedures, in conjunction with clinical information, cannot provide an accurate diagnosis and is permissible under the MTG.

It is recognized that repeat imaging studies and other tests may be warranted by the clinical course and to follow the progress of treatment in some cases. It may be of value to repeat diagnostic procedures (e.g., imaging studies) during the course of care to reassess or stage the pathology when there is progression of symptoms or findings, prior to surgical interventions and therapeutic injections when warranted, and post-operatively to follow the healing process. Regarding CT examinations, it must be recognized that repeat procedures result in an increase in cumulative radiation dose and associated risks.

## **A.12 SURGICAL INTERVENTIONS**

Contemplation of surgery should be within the context of expected functional outcome. 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 imaging and other diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic condition(s). For surgery to be performed to treat pain, there must be clear correlation between the pain symptoms and objective evidence of its cause. In all cases, shared decision making with the patient is advised. The patient should be given the opportunity to understand the pros and cons of surgery, potential for rehabilitation as an alternative when applicable, evidence-based outcomes, and specific surgical experience.

## **A.13 PRE-AUTHORIZATION**

All diagnostic imaging, testing procedures, non-surgical and surgical therapeutic procedures within the criteria of the medical treatment guidelines and based on a correct application of the medical treatment guidelines are considered authorized, with the exception of the following procedures: Lumbar Fusion, Artificial Disc Replacements, Vertebroplasty, Kyphoplasty, Electrical Bone Growth Stimulators, Spinal Cord Stimulators, Intrathecal Drug Delivery (Pain Pumps), Osteochondral Autograft, Autologous Chondrocyte Implantation, Meniscal Allograft Transplantation and Knee Arthroplasty (Total or Partial Knee Joint Replacement). These are not included on the list of pre-authorized procedures. Providers who want to perform one of these procedures must request pre-authorization from the carrier before performing the procedure.

Second or subsequent procedures (the repeat performance of a surgical procedure due to failure of, or incomplete success from the same surgical procedure performed earlier, if the Medical Treatment Guidelines do not specifically address multiple procedures) also require pre-authorization.

## **A.14 PERSONALITY/PSYCHOLOGICAL/PSYCHOSOCIAL EVALUATIONS**

In select patients, diagnostic testing procedures may be useful when there is a discrepancy between diagnosis, signs, symptoms, clinical concerns or functional recovery. Psychological testing may provide differentiation between pre-existing depression versus injury-caused depression, as well as post-traumatic stress disorder, and other psychosocial issues that might include work or non-work-related issues when such conditions are identified in the patient.

For those patients who fail to make expected progress 6-12 weeks after an injury and whose subjective symptoms do not correlate with objective signs and tests, reexamination in order to confirm the accuracy of the diagnosis should be made. Formal psychological or psychosocial evaluation may be considered.

A professional fluent in the primary language of the patient is strongly preferred. When such a provider is not available, services of a professional language interpreter must be provided.

Frequency: One time visit for evaluation. If psychometric testing is indicated by findings in the initial evaluation, time for such testing should not exceed an additional two hours of professional time.

### **A.15 PERSONALITY/PSYCHOLOGICAL/PSYCHOSOCIAL INTERVENTION**

Following psychosocial evaluation, when intervention is recommended, such intervention should be implemented as soon as possible. This can be used alone or in conjunction with other treatment modalities.

- Time to produce effect: 2 to 8 weeks.
- Optimum duration: 6 weeks to 3 months.
- Maximum duration: 3 to 6 months. Counseling is not intended to delay but to enhance functional recovery. For select patients, longer supervision may be required, and if further counseling is indicated, documentation of the nature of the psychological factors, as well as projecting a realistic functional prognosis, should be provided by the authorized treating practitioner every 4 to 6 weeks during treatment.

## **Return to Work**

### **A.16 FUNCTIONAL CAPACITY EVALUATION (FCE)**

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

In most cases, the question of whether a patient can return to work can be estimated without an FCE.

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

An FCE may be considered at time of MMI, following reasonable prior attempts to return to full duty throughout course of treatment, when the treating physician is unable to make a clear determination on work status on case closure.

## **A.17 RETURN TO WORK**

For purposes of these guidelines, return to work is defined as any work or duty that the patient is able to perform safely. It may not be the patient's regular work. Ascertaining a return to work status is part of medical care, and should be included in the treatment and rehabilitation plan. It is normally addressed at every outpatient visit. A description of patient's status and task limitations is part of any treatment plan and should provide the basis for restriction of work activities when warranted. Early return to work should be a prime goal in treating occupational injuries. The emphasis within these guidelines is to move patients along a continuum of care and return to work, since the prognosis for returning an injured worker to work drops progressively the longer the worker has been out of work.

## **A.18 JOB SITE EVALUATION**

The treating physician may communicate with the employer or the employer's designee, either in person or by telephone, to obtain information regarding the demands of the patient's pre-injury job, including a description of the exertional demands of the job, the need for repetitive activities, load lifting, static or awkward postures, or any other factors that would pose a risk of re-injury or impedance of convalescence. When returning to work at the patient's previous job task/setting is not feasible, given the clinically determined restrictions on the patient's activities, inquiry should also be made about modified duty work settings, and a similar set of questions should be posed by the physician about work activities/demands in modified duty jobs.

Ideally, the physician would gain the most information from an on-site inspection of the job settings and activities; but it is recognized that this may not be feasible in most cases. If job videos/CDs/DVDs are available from the employer, these can contribute valuable information.

Frequency: 1 or 2 calls

- 1st call: Patient is in a functional state where the patient can perform some work.
- 2nd call: Patient has advanced to state where the patient is capable of enhanced functional demands suitable or appropriate for a work environment.

The physician shall document the conversation.

## **Other**

### **A.19 GUIDELINE RECOMMENDATIONS AND MEDICAL EVIDENCE**

The Workers' Compensation Board and its Medical Advisory Committee have not independently evaluated or vetted the scientific medical literature used in support of the guidelines, but have relied on the methodology used by the developers of various guidelines utilized and referenced in these Guidelines.

### **A.20 EXPERIMENTAL/INVESTIGATIONAL TREATMENT**

Medical treatment that is experimental/investigational and not approved for any purpose, application or indication by the FDA is not permitted under these Guidelines.

### **A.21 INJURED WORKERS AS PATIENTS**

In these Guidelines, injured workers are referred to as patients recognizing that in certain circumstances there is no doctor-patient relationship.

### **A.22 SCOPE OF PRACTICE**

These Guidelines do not address scope of practice or change the scope of practice.

## **B DEFINITION OF NON-ACUTE PAIN**

Pain is defined by the International Association for the Study of Pain as “an unpleasant sensory and emotional experience usually associated with actual or potential tissue damage, or described in terms of such damage.”

Acute pain is usually linked to a precipitating event (e.g., trauma or surgery). The pain symptom is often physiologically useful as it can protect against potentially dangerous tissue damage. Pain may follow a continuum from acute to non-acute. As pain is reported to persist, biopsychosocial concerns play an increasing role.

*Non-acute* pain is a biopsychosocial process that is recognized as occurring at which time the patient reports enduring pain that persists beyond the anticipated time of recovery and results in concurrent functional limitations.

A diagnosis of *non-acute* pain should be considered if:

- Pain has extended beyond the expected duration of healing and recovery based on the history, physical examination, special studies (if clinically indicated) and treatment.
- Pain has not responded to previous appropriate treatment (i.e., diagnostic and therapeutic modalities recommended in the existing Medical Treatment Guidelines), or for injuries not addressed by an existing Medical Treatment Guideline, the standard of care for that injury.
- Pain persists after reconsideration of initial diagnosis and consideration of alternative diagnosis(es).
- Pain that is accompanied by significant objectively documented functional impairment in spite of apparent healing of underlying pathology (i.e., significant documented change from pre-injury functional baseline).

## C INTRODUCTION

### C.1 KEY CONCEPTS

#### C.1.a Biomedical vs. Biopsychosocial Approaches to the Diagnosis, Treatment and Management of Pain

The traditional **biomedical** approach to explaining pain “assumes disease to be fully accounted for by deviations from the norm of measurable biological (somatic) variables” (Engel 1977). Thus, there is always a direct causal relationship between a specific pathophysiologic process and the presence and extent of a particular symptom.

While this model has served the medical community well in the treatment and cure of certain diseases (e.g., infectious diseases), it has generally failed in the treatment of non-acute illness, including persistent pain. For example, for decades there has been an approach to identify the “pain generator” and remove it by cutting it out or blocking it.

It is now understood that the classic biomedical approach to understanding and treating pain is incomplete. Its exclusive application may result in unrealistic expectations on the part of the physician and patient, inadequate pain relief, and excessive disability

in those with pain that persists well after the original injury has healed.

The **biopsychosocial** model proposed by Engel in 1977 approaches pain and disability as a complex interplay of biological, psychological and social factors which may be easily assessed, and focuses greater attention on the patient, rather than on presumed pathophysiology.

This approach recognizes that pain is ultimately the result of the pathophysiology plus the psychological state, cultural background/belief system, and relationship/interactions with the environment (workplace, home, disability system, and health care providers).

The following chart contrasts these two pain models (Hanson and Gerber 1993):

**Table 1: Pain Models**

Biomedical Model	Biopsychosocial Model
Most appropriate for acute pain conditions.	More useful for those with non-acute pain conditions.
Emphasizes peripheral nociception.	Recognizes the role that central mechanisms play in modulating peripheral nociception or generating the experience of pain in the absence of nociception.
Focus on physical disease mechanisms.	Recognizes the importance of illness behavior including cognitive and emotional responses to pain.
Reductionistic approach to understanding and treating pain.	Multidimensional systems approach to understanding and treating pain.
Reliance on medical management approaches.	Utilization of self-management approaches.

Linton identified strong evidence that psychosocial variables are strongly linked to the transition from acute to chronic pain disability and that psychosocial variables generally have more impact than biomedical or biomechanical factors on back pain disability (Linton 2000). Thus, when clinical progress is insufficient, the clinician should always be prepared to address psychosocial variables, in a coordinated, multidisciplinary manner.

### **C.1.b Medical vs. Self-Management Model**

Understandably, patients want their non-acute pain “cured” or eliminated. However, non-acute pain must be managed, not cured. Unlike the medical model, where responsibility resides primarily with the physician, the self-management approach places primary responsibility on the person experiencing the non-acute pain. It is important to educate patients on this distinction and encourage self-management in order to avoid persistent and unrealistic expectations for an elusive cure where none exists.

An unrealistic curative view, often unwittingly fostered by healthcare providers or others, may lead to repeated failures, delayed recovery, and unnecessary disability and costs. Endless tests and treatments keep the injured worker focused on his pain, not recovery. Effective treatment of the patient’s pain may be compromised by an emphasis on the injury, rather than the recovery.

Delays in appointments or inability to contact the physician may also play a part. Delays may make things seem “hopeless” and contribute to a worsening of the injured worker’s pain.

A clinical pitfall may be caused or can occur by over-interpretation of or by focus on findings (imaging or electrodiagnostic) that can be without clinical significance. For example, instead of telling the patient that the MRI reveals normal wear and tear and that surgery is not required at this point, the patient is told “Your back is a mess and there’s nothing I can do about it.”

The patient remembers that the MRI showed a serious, incurable back condition. The patient identifies himself or herself as a person with incurable non-acute pain. For that reason, the Medical Treatment Guidelines require diagnostic time frames for the performance of imaging studies. It has been observed that early MRIs or those without appropriate criteria often result in increased, not decreased, patient anxiety.

Other statements that may amplify the pain associated with a patient’s condition include:

- “I am sure we can fix this.”
- “We need to do some more tests.”
- “I know of a doctor in another state, maybe she can cure you.”

An alternative approach would include informing the patient that pain does not always mean that additional activities, including return to work, are causing further damage, but that increased activity may help with pain management, and that there are ways to effectively manage, not eliminate, pain.

### **C.1.c Delayed Recovery**

The transition from acute to non-acute pain is a critical time for the injured worker, as additional time away from work may result in adverse medical, family, economic, and psychological consequences (including overtreatment, depression and/or anxiety), which can exacerbate pain complaints. When the physician recognizes that the problem is persisting beyond the anticipated time of tissue healing, the working diagnosis and treatment plan should be reconsidered, and psychosocial risk factors should be identified and addressed.

### **C.1.d Importance of Early Identification**

Patients at risk for delayed recovery should be identified as early as possible.

Factors that help identify at-risk patients include:

- Those unresponsive to conservative therapies demonstrated to be effective for specific diagnoses;
- Those with significant psychosocial factors negatively impacting recovery;
- Loss of employment or prolonged absence from work;
- Those with previous history of delayed recovery or rehabilitation;
- Lack of employer support to accommodate patient needs; and
- Those with a history of childhood abuse (verbal, physical, mental).

Of these factors, lost time from work has the highest value in predicting those patients who will experience delayed recovery.

### **C.1.e Functional Restoration Approach to Non-Acute Pain Management**

Pain is most often self-limited and many injured workers may require little, if any, treatment. Others will have persistent pain, but can be managed with straightforward interventions and do not require complex treatment. However, for patients with more complex or refractory problems, a comprehensive multidisciplinary approach to pain management that is individualized, functionally oriented (not pain oriented), and goal-specific has been found to be the most effective treatment approach (Flor, Fydrich et al. 1992; Guzman, Esmail et al. 2001; Gatchel and Bruga 2005). Independent self-management is the long-term goal of all forms of functional restoration.

The process and principles of functional restoration can be applied by a physician or a well-integrated interdisciplinary team to a full range of problems that include non-acute conditions and are the basis for medical rehabilitation and disability management.

### **C.1.f Pain Outcomes and Endpoints**

Pain is subjective. It cannot be readily validated or objectively measured. Subjective reports of pain severity may not correlate well with its functional impact and, therefore it is important to document the extent that function is believed to be impacted by pain.

The physician should periodically review the course of treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of pain management depends on the physician's evaluation of progress toward treatment objectives. Progress may be demonstrated by the patient's decreased pain, decreased use of analgesics and increased level of function. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Fluctuations are likely to occur in a patient's condition during the natural history of an injury. Exacerbations and/or "breakthrough" pain may occur during the non-acute clinical course and adjustments to the treatment will be necessary.

It is important to remember that injured workers are entitled to appropriate medical care even after reaching maximum medical improvement status.

### **C.1.g Summary**

While biologic mechanisms play a role in the perception of pain, it is also important to recognize that psychological and environmental factors are as important. Recognition of these factors may allow the physician to better understand and treat the recently injured patient, identify the “at risk” patient, and refer the patient to the appropriate resources. A full patient assessment is required to determine the best approach in any given case.

Therapy for non-acute pain ranges from single modality approaches for the straightforward patient to comprehensive interdisciplinary care for the more challenging patient. Therapeutic components such as pharmacologic, interventional, psychological and physical have been found to be most effective when performed in an integrated manner. All therapies are focused on the goal of functional restoration rather than merely the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement. Typically, with increased function comes a perceived reduction in pain and increased perception of its control. The goal of treatment is medical care that leads to an improvement in the patient’s quality of life.

## **D EVALUATION AND DIAGNOSTIC PROCEDURES**

A standard approach should be used when diagnosing and evaluating a work-related chronic pain complaint to ensure that an accurate diagnosis and treatment plan can be established.

### **D.1 HISTORY TAKING AND PHYSICAL EXAMINATION (HX & PE)**

History taking and physical examination establish the foundation for a medical diagnosis and serve as the basis for and dictate subsequent stages of diagnostic and therapeutic procedures. When findings of clinical evaluations and those of other diagnostic procedures do not complement each other, the objective clinical findings should have preference. The medical records should document the following:

#### **D.1.a Pain History, History of Present Illness**

A thorough pain history is an important part of the evaluation of non-acute pain. In taking such a history, characterization of the patient’s pain and the patient’s response to pain is one of the key elements in developing a treatment plan.

History should ascertain the following elements:

- D.1.a.i Site of Pain: Localization and distribution of the pain help determine the type of pain the patient has (i.e., central versus peripheral). Use of a pain diagram to document distribution of pain may be useful.
- D.1.a.ii Onset: Circumstances during which the pain began (e.g., an accident, an illness, a stressful incident or spontaneous onset).
- D.1.a.iii Duration.
- D.1.a.iv Pain Characteristics: Such as burning, shooting, stabbing, or 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 the type of pain. Consideration should be given to the anatomical correlates of the pain, or lack of same.
- D.1.a.v Use of accepted pain assessment tool (e.g., Visual Analog Scale [VAS]).
- D.1.a.vi List of activities: Such as gait, weight bearing, or resistance, which aggravate or exacerbate, ameliorate, or have no effect on the level of pain. Including a discussion of the range of pain during the day and how activities, use of modalities, and other actions affect the intensity of pain.
- D.1.a.vii Associated Symptoms: Does the patient have numbness or paresthesia, dysesthesia, weakness, bowel or bladder dysfunction, decreased temperature, increased sweating, cyanosis or edema? Is there local tenderness, allodynia, hyperesthesia, or hyperalgesia?
- D.1.a.viii Sleep disturbances.
- D.1.a.ix Functional Limitations: What are the specific functional activities/ADLs that the patient describes that he or she is unable to engage in as a result of the pain? (e.g., cannot walk more than 5 consecutive minutes, cannot lift groceries, etc.)
- D.1.a.x Fear Avoidance: Does the patient report being afraid to move or engage in daily activities of living because of fear of further hurting self? (See Appendix A)

- D.1.a.xi Diagnostic Tests: All previous radiological and laboratory investigations should be reviewed and summarized.
- D.1.a.xii Prior Treatment: Chronological review of medical records including previous medical evaluations and response to treatment interventions. What does the patient believe has helped in the past?
- D.1.a.xiii Prior Surgery: Impact of previous surgical treatment on the pain.
- D.1.a.xiv Medications: History of and current use of medications, including over the counter and herbal/dietary supplements, to determine drug usage (or abuse), drug interactions and efficacy of treatment.  
  
Drug allergies and other side effects experienced with previous or current medication therapy.  
  
Adherence to currently prescribed medications should be documented. Ideally, this includes dosing schedules as reported by the patient or patient's representative.
- D.1.a.xv 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 should be explored, including the presence of psychosocial, psychiatric, or social factors.
- D.1.a.xvi Treatment Expectations: What does the patient believe is causing his/her pain? What does the patient expect from treatment? Does patient expect to be able to increase his/her abilities at the current job or be able to return to work at the pre-injury job?

**D.1.b Past Medical History**

History should ascertain the following elements:

- D.1.b.i Level of education and language barriers: The level of education and language barriers may influence ability to understand instructions, information and participate in treatment decisions. The patient's level of understanding may influence response to treatment.

- D.1.b.ii **Work History/Occupation:** To include both impact of injury on job duties and impact on ability to perform job duties and activities of daily living, work history, job description, mechanical requirements of the job, duration of employment, and job satisfaction. Where there any prior work accidents or injuries?
- D.1.b.iii Current employment status.
- D.1.b.iv Marital status.
- D.1.b.v **Family Environment:** Does the patient live with family or friends? Responses to such questions may provide insight into the nature of the support system.
- D.1.b.vi **Cultural Considerations:** For example, ethnicity of the patient, including any existing language barriers, may influence the patient's perception of and response to pain.
- D.1.b.vii **Belief System:** Patients should be asked about their value systems, including spiritual and cultural beliefs, in order to determine how these may influence the patient's and family's response to illness and treatment recommendations. Are there any religious and/or cultural beliefs that may affect medical care?
- D.1.b.viii **Review of Systems Check List:** Determine if there is any interplay between the pain complaint and other medical conditions.
- D.1.b.ix **Pre-existing Conditions:** Treatment of the condition(s) is appropriate when the pre-existing condition(s) affects recovery from non-acute pain. The pre-existing condition(s) should be reasonably interrelated to the pain complaint and to the delayed recovery. This treatment must address specific goals that are pre-identified, monitored and met as part of the comprehensive treatment plan.
- D.1.b.x **Psychosocial History and History of Substance Abuse:** Has the patient taken any medication or drugs not prescribed by a treating physician or other prescriber? Has the patient used drugs in a manner that was not according to instructions?
- D.1.b.xi **Alcohol Use:** Quantify, i.e., drinks per week.
- D.1.b.xii **Smoking History:** Include use of nicotine substitutes.

D.1.b.xiii History of Abuse: Physical, emotional, sexual.

**D.1.c Physical Examination**

Should include accepted exam techniques and tests applicable to the area being examined:

D.1.c.i Vital signs.

D.1.c.ii Accepted pain assessment tool (e.g., Visual Analog Scale [VAS] or Numerical Rating Scale [NRS]).

D.1.c.iii General inspection: Including posture, stance, gait.

D.1.c.iv General physical examination, as indicated: Including chest, abdominal, vascular or other systems, to rule out other potential sources of non-acute pain. A more focused exam may be performed based on clinical circumstances.

D.1.c.v Neurologic Evaluation: Includes examination of cranial nerves, muscle tone and strength, atrophy, detailed sensory examination, motor evaluation (station, gait, coordination), spinal cord and peripheral nervous system, reflexes (normal tendon reflexes and presence or absence of abnormal reflexes such as frontal lobe release signs or upper motor neuron signs), cerebellar testing and provocative neurological maneuvers (i.e., nerve tension testing). When the Lasegue test (Straight Leg Raise test) is performed, a result is generally not considered to be positive at an elevation less than 25 or greater than 60 degrees (and degrees should always be reported).

D.1.c.vi Sensory Evaluation: Routine quantitative sensory testing, such as Semmes-Weinstein monofilaments, may be useful in identifying sensory abnormalities.

D.1.c.vii Musculoskeletal Evaluation: Includes range-of-motion, segmental mobility, musculoskeletal provocative maneuvers, palpation, observation, and functional activities. All joints, muscles, tissue texture, ligaments, and tendons should be examined for asymmetry, swelling, laxity, and tenderness. A portion of the musculoskeletal evaluation is the myofascial examination. The myofascial examination includes palpating soft tissues for evidence of spasm and trigger points.

D.1.c.viii Electrodiagnostic Studies (EDX) (i.e., EMG/NCV): Are separate diagnostic procedures and are addressed in

specific sections of the relevant medical treatment guidelines.

D.1.c.ix Evaluation of non-physiologic findings:

**D.1.c.ix.a** If applicable, Waddell Signs, which include 5 categories of clinical signs (1) tenderness: superficial and non-anatomic, (2) pain with simulation: axial loading and rotation, (3) regional findings: sensory and motor inconsistent with nerve root patterns (4) traction/inconsistency in straight leg raising findings, and (5) over-reaction to physical examination maneuvers.

Significance may be attached to positive findings in 3 out of 5 of these categories, but not to isolated findings. Waddell Signs cannot be used to predict or diagnose malingering. The presence of 3 out of 5 signs may most appropriately be viewed as a “yellow flag”, or screening test, alerting clinicians to those patients who require a more comprehensive assessment (i.e., psychological or psychosocial evaluation).

**D.1.c.ix.b** Variability on formal exam including variable sensory exam, inconsistent tenderness, and/or swelling secondary to extrinsic sources.

**D.1.c.ix.c** Inconsistencies between formal exam and observed abilities of range-of-motion, motor strength, gait and cognitive/emotional state should be noted in the assessment.

**D.1.d Red Flags**

Assessment (history and physical exam) should include evaluation for red flags. These findings or indicators may include fractures, dislocation, infection, tumor, progressive deficit.

**D.2 PERSONALITY/ PSYCHOLOGICAL/PSYCHOSOCIAL  
CLINICAL EVALUATION FOR PAIN MANAGEMENT**

Psychosocial evaluations should determine if further psychosocial or behavioral interventions are indicated for patients diagnosed with non-acute 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.

**D.2.a Clinical Evaluation**

A psychiatrist or psychologist should perform a clinical evaluation, which includes:

- D.2.a.i History of Injury. The history of the injury should be reported in the patient's words or using similar terminology. Caution must be exercised when using translators.
  - D.2.a.i.a Nature of injury.
  - D.2.a.i.b Psychosocial circumstances of the injury.
  - D.2.a.i.c Current symptoms
  - D.2.a.i.d Extent of medical corroboration.
  - D.2.a.i.e Treatment received and results.
  - D.2.a.i.f Compliance with treatment.
  - D.2.a.i.g Coping strategies used, including perceived locus of control, catastrophizing, and risk aversion.
  - D.2.a.i.h Perception of medical system and employer.
  - D.2.a.i.i History of response to prescription medications.
- D.2.a.ii Health History.
  - D.2.a.ii.a Medical history.
  - D.2.a.ii.b Psychiatric history.
  - D.2.a.ii.c History of alcohol use or substance abuse.
  - D.2.a.ii.d Activities of daily living.
  - D.2.a.ii.e Previous injuries, including disability, impairment, and compensation.
- D.2.a.iii Psychosocial History.

- D.2.a.iii.a Childhood history, including abuse/neglect.
- D.2.a.iii.b Educational history.
- D.2.a.iii.c Family history, including disability.
- D.2.a.iii.d Marital history and other significant adulthood activities and events.
- D.2.a.iii.e Legal history, including criminal and civil litigation.
- D.2.a.iii.f Employment history.
- D.2.a.iii.g Military duty.
- D.2.a.iii.h Exposure to significant trauma.
- D.2.a.iii.i Signs of pre-injury psychological dysfunction.
- D.2.a.iii.j Current and past interpersonal relations, support, living situation.
- D.2.a.iii.k Financial history.
- D.2.a.iv Mental status exam: Including cognition, affect, mood, orientation, thinking, and perception.
- D.2.a.v Assessment of any danger posed to self or others.
- D.2.a.vi Psychological test results, if performed.
- D.2.a.vii Current psychiatric diagnosis: Consistent with the standards of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders.
- D.2.a.viii Pre-existing psychiatric conditions: Treatment of these conditions is appropriate when the pre-existing condition affects recovery from non-acute pain.
- D.2.a.ix Treatment recommendations: With respect to specific goals, frequency, timeframes, and expected outcomes.

## **D.2.b Tests of Psychological Functioning**

Psychometric testing is useful in the assessment of mental conditions, pain conditions, and cognitive functioning. Psychometric testing is a valuable component of a consultation to assist the physician in making a more effective treatment plan, vocational plan, and in the

evaluation of treatment effectiveness. (See Appendix B for examples of frequently used psychometric tests.)

### **D.3 DIAGNOSTIC STUDIES (Imaging, Electrodiagnostic Studies (EDX), Special Testing, Laboratory Testing)**

Diagnostic studies may be useful when specific indications, based on history and physical examination, are present. Physicians should refer to the Medical Treatment Guidelines for the appropriate body part for detailed information about specific testing procedures. Tests should be performed to rule in or out specific diagnoses. (Refer to General Principle A.11 for guidelines on the performance of diagnostic or repeat diagnostic procedures.)

## **E NON-PHARMACOLOGICAL APPROACHES**

### **E.1 DELAYED RECOVERY**

The transition from acute to non-acute pain is a critical time for the injured worker. By definition, patients with non-acute pain will fit into the category of delayed recovery. When there is delayed recovery beyond the anticipated time of tissue healing, the physician should:

- Reconsider the working diagnosis and treatment plan.
- Identify, address and document psychosocial risk factors which impact functional recovery:
  - Demoralization, including but not limited to losses related to inability to work.
  - Distress in daily life.
  - Maladaptive (cognitive and behavioral) responses.
  - Catastrophizing (doctors are encouraged to reinforce appropriate expectations).
  - Fear avoidance (doctors are encouraged to reassure patients regarding fear of pain causing activities and re-injury and focus on active as opposed to passive treatment whenever possible).
  - Medication related issues, including, but not limited to, addiction and untoward medication side effects.
  - Ongoing medical care issues, including, but not limited to, frustration with “care that does cure” and/or payment responsibility issues.

- Identify primary psychiatric illness/mental condition.
- Timely assess, appropriately reassure and/or refer to a mental health professional and/or Interdisciplinary/Functional Restoration Pain Management Program as clinically indicated.\*

\*It is important to note that a referral to a mental health provider or pain management program does not imply that the patient's claim is valid or invalid or that the patient is malingering or has a related psychiatric diagnosis. Misapplication can cause further stigmatization or demoralization and is to be avoided. These referrals should be regarded as an integral part of the assessment of non-acute/delayed recovery which can identify social, cultural, coping or other variables, which if appropriately addressed may positively impact the patient's recovery process. It is recognized that it may be difficult to obtain these services. Referrals to mental health providers (i.e.: psychology/psychiatry) for the evaluation and management of delayed recovery do not indicate or require the establishment of a psychiatric or psychological condition. The evaluation and management of delayed recovery does not require the establishment of a psychiatric or psychological claim.

## **E.2 PSYCHOLOGICAL EVALUATION AND INTERVENTION**

### **E.2.a Evaluation**

- For patients who fail to make expected progress after an injury, a formal psychological or psychosocial evaluation should be considered to identify psychosocial barriers to recovery.
- A comprehensive psychological evaluation might assist in identifying comorbid psychiatric risk factors or “red flags” (e.g., psychosis, active suicidality) as well as secondary risk factors or “yellow flags” (e.g., job dissatisfaction) with appropriate referral as indicated. Assessment for potential barriers to recovery (yellow flags/psychological issues) should be ongoing throughout the care of the patient.
- The interpretations of the evaluation may provide clinicians with a better understanding of the patient, allowing for a more effective treatment plan and rehabilitation.
- Tests of Psychological Functioning or Psychometric testing, when indicated, can be a valuable component of the psychological evaluation.
  - Testing can be useful in the assessment of mental conditions, pain conditions, cognitive functioning, and

motivation, as well as in treatment planning, vocational planning and evaluation of treatment.

- Some of these tests are available in Spanish or other languages and many are written at a 6<sup>th</sup> grade level.
  - A provider fluent in the patient's primary language is strongly preferred, or when such a provider is not available, the services of a professional language interpreter must be provided.
- Psychometric tests that provide validity scales, such as the MMPI, are generally most advisable when the impact of potential secondary gain issues and veracity of the presentation of the illness need to be considered.
  - It is important to determine if psychosocial or behavioral interventions are indicated.

#### **E.2.b Intervention**

- Psychosocial treatment is an important component in the management of a patient with non-acute pain and should be implemented as soon as the problem is identified.
- Examples of psychosocial interventions include psychotherapeutic treatment and cognitive-behavioral therapy, including biofeedback and relaxation training.
- Interventions should emphasize patient coping, adaptation, self-management and self-efficacy, and reduction of disability.
- Treatment can occur in a variety of settings: in an individualized model or a multidisciplinary or interdisciplinary pain management model.
- Use of medication to treat a diagnosed condition may be ordered by the treating physician or psychiatrist.
- Routine prescribing of sedative or hypnotic medications should be delayed pending a psychiatric evaluation and diagnosis, when appropriate.
- For all psychological/psychiatric interventions, there must be an assessment and treatment plan with measurable behavioral goals, time frames and specific interventions planned.

### **E.3 NON-PHARMACOLOGIC TREATMENT OPTIONS**

The *New York Non-Acute Pain Medical Treatment Guidelines* do not contain specific recommendations for other non-pharmacologic treatment modalities such as physical medicine modalities or injection therapies. These other treatment options, when clinically indicated, should follow the recommendations in the relevant Medical Treatment Guidelines.

When an injury not addressed by an existing Medical Treatment Guideline results in non-acute pain, the standard of care for that injury should be observed.

### **E.4 NON-ACUTE PAIN MANAGEMENT PROGRAMS (INTERDISCIPLINARY OR FUNCTIONAL RESTORATION PAIN MANAGEMENT PROGRAM)**

Should be considered for treatment of patients with non-acute pain who have not demonstrated functional/behavioral gains with less intensive modes of treatment.

#### **E.4.a Interdisciplinary or functional restoration program**

These programs utilize a comprehensive team approach:

- The focus of treatment is on the restoration of function.
- The team maintains consistent integration and communication to ensure that all team members are aware of the plan of care for the patient, exchange information and implement the care plan.
- The core interdisciplinary team often consists of a physician, nurse, psychologist, social worker, physical therapist and occupational therapist, with additional professionals as indicated based upon the patient's needs.
- Team oversight is provided by a physician (MD/DO).

#### **E.4.b Core components of an interdisciplinary pain program**

Core components may include:

- Initial comprehensive interdisciplinary evaluation that addresses the physiologic, psychological, medical and sociologic needs of the patient and leads to a detailed treatment plan.

- Regular team meetings to review patient progress and to amend the treatment plan as necessary.
- Focus on restoration of function (emphasize functional improvement over the elimination of pain; for example, a reasonable goal would be increased functionality, decreased treatment dependence and enhanced quality of life even if subjective report of pain persists).
- Goal-specific or goal-oriented (measurable goals, specific time frames for meeting goals and objectively measured progress).
- Multimodal physical rehabilitation and exercise therapy.
- Cognitive Behavioral Interventions (emphasis on promoting self-management, self-efficacy, activity vs. passivity, adaptation, coping skills, relaxation training with or without biofeedback).
- Medical Management (including medication tapering).
- Education.
- Vocational rehabilitation when indicated.
- Treatment of addiction when indicated.
- After-discharge plan of care.

## **E.5 MULTIDISCIPLINARY PROGRAMS**

In contrast, Multidisciplinary Programs may include several health care professionals but integration of services and communication among providers may be limited, and there is often a focus on interventional pain management. Interdisciplinary programs involve greater coordination of services, communication and a focus on functional restoration, without a focus on interventional pain management.

## **E.6 GOALS OF PAIN MANAGEMENT PROGRAMS**

- Maximize function while minimizing pain.
- Provide measurable improvement in physical/functional capabilities.
- Return to work (RTW).
- Assist patient in assuming self-management responsibilities.

- Maintenance of functional gains upon discharge with appropriate provision for after-discharge planning/follow-up.
- Decrease medication utilization.
- Reduce health care utilization (decrease focus on medical procedures).
- Independent self-management is the long-term goal of all forms of functional restoration.

## **E.7 TYPES OF PROGRAMS**

- Outpatient
- Inpatient
- If functionally based outpatient programs cannot be accessed, in some instances, telephonic wellness and functional improvement programs that include coaching, education, and support can also be considered as an alternative.

## **E.8 DURATION OF PROGRAMS/INTERVENTIONS**

### **E.8.a Inpatient or Outpatient Pain Management Programs**

Optimum Duration: 3-8 weeks\*

\*In limited instances reassessment for a repeat shortened stay at an interdisciplinary pain program might be advised if prior functional gains are documented or have declined.

### **E.8.b Cognitive Behavioral Therapy**

Cognitive Behavioral Therapy (CBT) can be done in groups or individually. This treatment is often provided at an interdisciplinary pain program. A psychological evaluation is advised prior to the initiation of CBT to identify any potential barriers to this treatment, or relative contraindications. Treatment with CBT does not imply that there is a concurrent psychiatric diagnosis; the treatment can be considered to address psychosocial issues often associated with non-acute pain irrespective of any other documented or presumed psychopathology.

Optimum Duration: 10-16 treatments with documentation of progress toward achievement of measurable goals every two weeks.

Maximum Duration: 16 treatments.

**E.8.c Psychological Evaluations**

Frequency: One-time visit for evaluation. If psychometric testing is indicated by findings in the initial evaluation, time for such testing should not exceed two hours of professional time.

**E.8.d Psychological Intervention**

Optimum duration: 6 weeks to 3 months.

Maximum duration: 3-6 months. For select patients longer supervision may be required and if further counseling is indicated, documentation of the nature of the psychological factors, as well as projecting a realistic functional prognosis should be provided by the treating practitioner every 4 weeks during treatment.

**E.8.e Biofeedback**

Biofeedback is a form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient through visual, auditory or tactile means, with coaching by a biofeedback specialist.

Treatment is individualized to the patient's work-related diagnosis and needs. Home practice of skills is required for mastery and may be facilitated by the use of home training tapes. The ultimate goal of biofeedback treatment is the 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.

Biofeedback is not appropriate for individuals suffering from acute pain or acute injury. It may be appropriate for non-acute pain when combined with a program including functional restoration.

- Time to Produce Effect: 3 to 4 sessions.
- Frequency: 1 to 2 times per week.
- Optimum Duration: 5 to 6 sessions.
- Maximum Duration: 10 to 12 sessions. Treatment beyond 12 sessions must be documented with respect to need, expectation, and ability to facilitate positive functional gains.

## **F PHARMACOLOGICAL APPROACHES**

### **F.1 NON-OPIOID MEDICATIONS AND MEDICAL MANAGEMENT**

(For Opioids, see Section F.2 OPIOIDS: INITIATING, TRANSITIONING AND MANAGING LONG-TERM ORAL OPIOIDS)

#### **F.1.a Introduction**

- There is no simple formula for pharmacological treatment of patients with non-acute, non-malignant 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.
- Appropriate use of pharmacological agents depends on the patient's age, past history (including history of substance abuse), drug allergies and the nature of all medical problems.

#### **F.1.b Goals**

- The goal of treatment is to improve function with a focus on the development of self-management skills.
- Control of non-acute pain is expected to involve the use of medication.
- Patients should understand that medications alone are unlikely to provide complete pain relief.
- In addition to medications, continuing participation in a self-management plan (as described in this guideline) is essential for successful management of non-acute pain.

#### **F.1.c Pharmacological Principles**

- The physician should thoroughly understand pharmacological principles when dealing with the different drug families, their respective side effects, drug interactions, bioavailability profiles, and primary reason for each medication's usage.
- Side effects as well as the potential for secondary effects should be appropriately monitored.
- Interactions between prescribed medications and over-the-counter medications have to be considered, as well as other

medical conditions that may interfere with the dosages and intervals of medications.

- All medications should be given an appropriate trial in order to test for therapeutic effect.
- The length of an appropriate trial varies widely depending on the individual drug.
- It is recommended that patients with non-acute pain be maintained on drugs that have the least serious side effects.
- As in the case with opiate medications, ongoing consideration should be given to tapering medication when possible.
- Drug therapy requires close monitoring of the patient's response to therapy, flexibility on the part of the physician and a willingness to change treatment when circumstances change.
- Many of the drugs discussed in the medication section were licensed for indications other than analgesia. However, there is evidence to support that these medications are effective in the control of some types of non-acute pain.
- In addition, there is no evidence-based support for the increased efficacy of brand name medication in this setting. Therefore, brand name medications are generally not recommended except in specific situations with supporting medical documentation.
- Nutraceuticals are not recommended.
- Topical, oral and/or systemic compound medications are not recommended.

#### **F.1.d Neuropathic Pain**

- Neuropathic pain can be treated with a variety of medications.
- It is suggested that patients with neuropathic pain be trialed with a tricyclic medication initially, as low dose medication in this category is frequently tolerated and performs sufficiently.
- If this fails, or if side effects are not tolerated, or a patient has medical issues precluding the use of this class of drugs, other appropriate medications can be tried.

- Second line drugs include the anti-convulsants gabapentin and pregabalin.
- Third line drugs are the Serotonin Norepinephrine Reuptake Inhibitors (SNRI) and topical lidocaine.
- Fourth line drugs are opioids, tramadol, and tapentadol.
- Other medications have few supporting clinical trials, but may be helpful in some patients.
- Concomitant use of multiple drugs of the same class is not recommended.
- Limit the prescribed dose of drugs to the FDA approved dosage.

#### **F.1.e Medications**

For the clinician to interpret the following material, it should be noted that: (1) the listing is a brief overview of pharmacological alternatives, (2) drugs in each class and drug profiles are not complete, (3) dosing of drugs will depend upon the specific drug, especially for off-label use, and (4) special consideration and caution should be used for women who are pregnant, may become pregnant, or are breast feeding. Clinicians should refer to standard medical texts and sources of medical prescribing or consult a pharmacist for full prescribing information.

The following drug classes are listed in alphabetical order. This list is not intended to be a substitute for traditional medical information or prescribing. It is offered only as a guide.

Recommendations:

F.1.e.i **ACETAMINOPHEN** is an effective analgesic and antipyretic without anti-inflammatory activity. Acetaminophen is generally well tolerated, causes little or no gastrointestinal irritation, and is not associated with ulcer formation. Acetaminophen has been associated with liver toxicity when the recommended daily dose is exceeded or in patients who chronically use alcohol. Patients may not realize that many over-the-counter preparations may contain acetaminophen. In general, the total daily dose of acetaminophen should not exceed 3 grams per 24-hour period from all sources, including narcotic-acetaminophen combination preparations. Patients who consume three or more alcoholic drinks per

day are at greater risk for liver toxicity, and consideration should be given to the use of other analgesics or limiting the acetaminophen dose to 2 grams per 24-hour period from all sources. Liver function monitoring is recommended as clinically indicated.

F.1.e.ii **ALPHA-ACTING AGENTS** (e.g., clonidine): Given limited experience with their use, they cannot be considered first-line or second-line analgesics, but a trial of their use may be warranted in some cases of refractory pain.

F.1.e.iii **ANTICONVULSANTS** are not considered first-line medications in the treatment of non-acute pain. All patients on these medications should be monitored for suicidal ideation, hepatic and renal functioning as well as consideration of the potential for medication interaction.

Anticonvulsants are not recommended for axial spine pain (neck or back pain without documented radiation) unless there is evidence of a related neuropathic component. These agents can also be considered in the setting of post-traumatic migraine headache.

F.1.e.iii.a **Carbamazepine** is recommended as a potential adjunct for chronic radicular or neuropathic pain after attempting other treatments (e.g., other medications and other therapeutic modalities).

Carbamazepine has important effects as an inducer of hepatic enzymes and may increase the metabolism of other drugs enough to reduce therapeutic efficacy in patients taking interacting drugs.

Oxcarbazepine and lamotrigine may be useful if the results from carbamazepine are insufficient for pain relief.

F.1.e.iii.b **Gabapentin** may be considered for the treatment of severe neurogenic claudication from spinal stenosis or chronic radicular pain syndromes, and for the treatment of neuropathic pain, although in general, gabapentin is not superior to amitriptyline. Given in combination with tricyclics (nortriptyline), gabapentin provides more

effective pain relief than monotherapy with either drug. Gabapentin given with opioids (morphine) may result in lower side effects and greater analgesia at lower doses than usually required with either medication alone. Gabapentin is not recommended for axial pain or non-neuropathic pain.

Should be initiated at low-dose to avoid somnolence and may require 4-to-8 weeks for titration. Maximum dosage to 1800 mg and in rare instances up to 2400 mg per day.

F.1.e.iii.c **Pregabalin** may be considered in the treatment of patients with neuropathic pain as a second line agent after a trial of tricyclics. Approved for neuropathic pain associated with diabetic peripheral neuropathy, post-herpetic neuralgia, fibromyalgia and post-spinal cord injury pain.

Increase dose over several days. Doses above 150 mg are usually required.

Full benefit may not be achieved for 6 to 8 weeks.

F.1.e.iii.d **Topiramate** is recommended for limited use when there has been a failure of multiple other modalities including other medication and therapeutic modalities. If utilized, topiramate would be used as a third or fourth line medication in appropriate patients.

F.1.e.iii.e **Lamotrigine** is not recommended for most patients.

F.1.e.iv **ANTIDEPRESSANTS** are classified into a number of categories based on their chemical structure and their effects on neurotransmitter systems. Pain responses may occur at lower doses with shorter response times than observed when these agents 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.

All patients being considered for anti-depressant therapy should be evaluated and continually monitored for suicidal ideation and mood swings. Many antidepressant medications have the potential to lower seizure threshold. Compliance and functional recovery may be compromised by secondary weight-gain and fatigue. In general, side effects can be mitigated if a low dose is initiated and slowly increased as tolerated. When discontinuing antidepressant medication, particular attention is required for the potential for withdrawal reactions, especially in the case of venlafaxine and certain tricyclics.

Antidepressant medications may be helpful when there is nocturnal sleep disruption. In this case, tricyclic and tetracyclic (e.g., trazodone) antidepressants can be considered at a bedtime dose at lower levels than those used for treatment of depression.

**F.1.e.iv.a Tricyclics (TCAs)** (e.g., amitriptyline, desipramine, nortriptyline, doxepin, imipramine, trimipramine) are recommended for radicular pain. Higher doses of amitriptyline may produce more cholinergic side effects than newer tricyclics such as nortriptyline and desipramine. Doxepin and trimipramine also have sedative effects.

Low doses are commonly used for chronic pain and/or insomnia.

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 age 40 or older, especially if higher doses are used. The overall potential for anti-cholinergic side effects when TCAs are prescribed always needs to be considered, particularly with older patients.

**F.1.e.iv.b Selective Serotonin Reuptake Inhibitors (SSRIs)** (e.g., citalopram, fluoxetine, paroxetine, sertraline, fluvoxamine, escitalopram) are not recommended for neuropathic pain. SSRIs are used generally for depression rather than neuropathic pain and

should not be combined with moderate to high-dose tricyclics.

The potential for a serotonergic reaction should always be considered when prescribing SSRIs. This reaction may take the form of increased anxiety and agitation.

F.1.e.iv.c **Selective Serotonin Norepinephrine Reuptake Inhibitors (SSNRI)/Serotonin Norepinephrine Reuptake Inhibitors (SNRI)** (e.g., venlafaxine, duloxetine and minalcipram). Duloxetine has been FDA approved for treatment of diabetic neuropathic pain, fibromyalgia and chronic musculoskeletal pain. Minalcipram has been FDA approved for treatment of fibromyalgia and has a success rate similar to imipramine. This class of drugs is not recommended in patients as a first- or second-line treatment and is reserved for patients who fail other regimes due to side effects.

F.1.e.iv.d **Atypical Antidepressants/Other Agents** (e.g., bupropion, mirtazapine, nefazodone) may be used for depression; however, they are not appropriate for neuropathic pain.

F.1.e.v **COMPOUND MEDICATIONS**: Topical, oral, and/or systemic compound medications are not recommended.

F.1.e.vi **GLUCOSAMINE/CHONDROITIN** is not recommended.

F.1.e.vii **HYPNOTICS AND SEDATIVES** (e.g., benzodiazepines, zaleplon, eszopiclone, zolpidem): Due to the addiction potential, withdrawal symptoms, and sedating side effects, benzodiazepines and other similar drugs found in this class are not generally recommended. They should be used with extreme caution when the patient is on chronic opioids.

When used, extensive patient education should be documented.

Some of these medications have long half-lives and next-day somnolence and sleep apnea can occur or be aggravated due to these medications.

Retrograde amnesia can occur and is implicated in “sleep driving,” “sleep eating” and other activities.

Many unintentional drug deaths are related to concomitant opioid and benzodiazepine drug use.

Most insomnia in non-acute pain patients should be managed primarily through behavioral interventions, with medications as secondary measures.

F.1.e.viii **N-METHYL-D-ASPARTIC ACID RECEPTOR ANTAGONISTS** (e.g., ketamine): Either in oral or dermal routes, are not recommended.

F.1.e.ix **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 patient to a specific medication is unpredictable. For this reason a range of orally administered NSAIDs may be tried in each case with the most effective preparation being continued. Patients should be closely monitored for adverse reactions.

The US Food and Drug Administration advises that all NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Prescribers should be aware of the most updated information on this topic. Some NSAIDs may have more favorable cardiovascular risk factors than others.

Administration of proton pump inhibitors, histamine 2 blockers, or misoprostol, a prostaglandin analog, along with these NSAIDs may reduce the risk of duodenal and gastric ulceration associated with NSAID use but 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 should be used with caution in all asthma patients. NSAIDs are associated with abnormal renal function, including renal failure, as well as abnormal liver function. Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent upon the patient’s age, general health status and should be within parameters listed for each specific medication. Complete blood count (CBC), liver and renal

function should be monitored in patients on chronic NSAIDs.

In patients receiving low-dose aspirin for primary or secondary cardiovascular disease prevention, to minimize the potential for the NSAID to counteract the beneficial effects of aspirin, aspirin should be taken two hours before or at least eight hours after the NSAID.

Chronic use of NSAIDs is generally not recommended. Chronic NSAIDs may be used cautiously in selected cases with regular monitoring.

F.1.e.ix.a **Non-selective Nonsteroidal Anti-Inflammatory Drugs** are generally recommended as first-line medications.

Serious gastrointestinal toxicity, such as bleeding, perforation, and ulceration can occur at any time, with or without warning symptoms in patients treated with traditional NSAIDs. Patients at particularly high risk for GI bleeding include those with a history of prior GI bleed, diabetes, alcohol use, smoking, corticosteroid or anticoagulant use, patients older than 65 or those who have a longer duration of therapy.

Physicians should inform patients about the signs and/or symptoms of serious gastrointestinal toxicity and what steps to take if they occur.

Anaphylactic reactions may occur in patients taking NSAIDs.

NSAIDs may interfere with platelet function.

Fluid retention and edema, and renal toxicity in those with underlying reduction of renal function have been observed in some patients taking NSAIDs.

F.1.e.ix.b **Selective Cyclo-oxygenase-2 (COX-2) Inhibitors**: COX-2 inhibitors should not be first-line for low risk patients who will be using an NSAID short-term but are indicated in select patients for whom traditional

NSAIDs are not tolerated. Patients who receive COX-2 inhibitors should take the lowest effective dose for the shortest time necessary to control symptoms.

The major advantages of selective COX-2 inhibitors over traditional NSAIDs are that they have less GI toxicity and no platelet effects.

Serious upper GI adverse events can occur even in asymptomatic patients who are taking COX-2 inhibitors. Patients at a high risk include those with a history of prior GI bleed, diabetes, alcohol use, smoking, corticosteroid or anticoagulant use, patients older than 65 or those who have a longer duration of therapy.

COX-2 inhibitors can worsen renal function in patients with renal insufficiency; thus, renal function may need monitoring.

Selective COX-2 inhibitors should be used with great caution in patients with ischemic heart disease and/or stroke and avoided in patients with risk factors for coronary heart disease. In these patients it appears to be safest to use acetaminophen, aspirin or non-selective NSAIDs as first-line therapy.

Celecoxib is contraindicated in sulfonamide allergic patients.

F.1.e.x     **SKELETAL MUSCLE RELAXANTS** (e.g., baclofen, cyclobenzaprine, carisoprodol, metaxalone, tizanidine) 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, severe sedation, seizure risk following abrupt withdrawal, and documented contribution to deaths of patients on chronic opioids due to respiratory depression.

F.1.e.xi    **TOPICAL DRUG DELIVERY** (e.g., capsaicin, lidocaine, topical NSAIDs and topical salicylates and non-salicylates) may be an acceptable form of treatment in selected patients. A topical agent should be prescribed with strict instructions for application and 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 and thus may be better used episodically. These agents may be used in those patients who prefer topical treatments over oral medications. Localized skin reactions may occur, depending on the medication agent used.

Physicians should consider that topical medication can result in toxic blood levels.

F.1.e.xi.a **Capsaicin** offers a safe and effective alternative to systemic NSAIDs, although its use is limited by local stinging or burning sensation that typically disappears with regular use. Patients should be advised to apply the cream on the affected area with a plastic glove or cotton applicator to avoid inadvertent contact with eyes and mucous membranes. Long-term use of capsaicin is not recommended.

F.1.e.xi.b **Topical lidocaine** is only indicated when there is documentation of a diagnosis of neuropathic pain. In this instance, a trial for a period of not greater than four weeks can be considered, with the need for documentation of functional gains as criteria for additional use.

F.1.e.xi.c **Topical NSAIDs** (e.g., diclofenac gel) may achieve tissue levels that are potentially therapeutic. Overall the low level of systemic absorption can be advantageous, allowing the topical use of these medications when systemic administration is relatively contraindicated (such as patients with hypertension, cardiac failure, peptic ulcer disease or renal insufficiency).

F.1.e.xi.d **Topical salicylates or nonsalicylates** (e.g., methyl salicylate) overall do not appear to be more effective than topical NSAIDs. May be used for a short-term course especially in patients with chronic conditions in whom systemic medication is relatively contraindicated or as an adjuvant to systemic medication.

## **F.2 OPIOIDS: INITIATING, TRANSITIONING AND MANAGING LONG-TERM ORAL OPIOIDS**

### **F.2.a Long-Term Use of Opioids in the Opioid-Naïve Patient: Opioid Therapeutic Trial**

#### F.2.a.i Overview

An opioid trial is a period of time during which the effectiveness of using opioids is tested to see if the goals of increased function and decreased pain are met.

When considering long-term opioid use, physicians should make sure that:

- Other pain management regimes, including physical, behavioral and non-opioid measures have failed, and
- A successful opioid trial between 30 and 60 days, during which the patient demonstrated sustained improvement in function and pain levels, has been completed.
- Patients should be monitored weekly.

#### F.2.a.ii Goals and Objectives of Opioid Trial

A successful trial should meet the following goals:

- Improved function, including return to work and/or increase in activities of daily living, and at least a 30% reduction in pain,<sup>1</sup> supported by validated objective measures of improved function and pain which should be clearly documented. (See General Principles A.1, Medical Care; A.3, Positive Patient Response; and A.4, Re-evaluate Treatment.);
- No significant adverse side effects; and

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<sup>1</sup> A 30% level of pain relief on validated pain measures (e.g. VAS=3 points improvement) is necessary to support analgesic efficacy. (FDA requirement)

- No aberrant drug related behaviors.

If trial goals are not met within 30 to 60 days, the trial should be discontinued, opioids tapered/discontinued and an alternative approach taken to treating the pain.

In a certain percentage of patients, it will become evident early in the trial period that they are not responding to this mode of therapy. For these patients, in order to minimize the risk of adverse clinical outcomes such as clinical dependence, the opioid trial should be discontinued as soon as clinically feasible. This guidance should not be construed as requiring a full 60-day trial period.

#### F.2.a.iii Risk Assessment/Stratification

Prior to considering a therapeutic opioid trial, physical and psychological assessment, including a full evaluation for alcohol or drug addiction, dependence or abuse, should be conducted.

- Screening for potential comorbidities and risk factors is crucial so that anticipated risk can be monitored accordingly. Personal or family history of substance abuse is the strongest predictive factor for misuse.
- Assessment of substance abuse, misuse or addiction risk, using the Opioid Risk Tool (ORT), a validated clinical instrument (See Table 2: Opioid Risk Tool [ORT]).
- The patient should be stratified as to low, medium or high risk for abuse.
  - High-risk patients are those with active substance abuse of any type or a history of prescription opioid abuse. In general, these patients should not be placed on chronic opioids.
    - High-risk patients who are deemed appropriate for chronic opioid treatment should be treated by a physician specializing in addiction medicine.
    - Patients with a past history of substance abuse or other psychosocial risk factors

should be co-managed with a physician specializing in addiction medicine.

**Table 2: Opioid Risk Tool (ORT)**

**FIGURE. OPIOID RISK TOOL**

		Mark each box that applies	Item score if female	Item score if male
1. Family history of substance abuse:	• Alcohol	<input type="checkbox"/>	1	3
	• Illegal drugs	<input type="checkbox"/>	2	3
	• Prescription drugs	<input type="checkbox"/>	4	4
2. Personal history of substance abuse	• Alcohol	<input type="checkbox"/>	3	3
	• Illegal drugs	<input type="checkbox"/>	4	4
	• Prescription drugs	<input type="checkbox"/>	5	5
3. Age (mark box if 16-45)		<input type="checkbox"/>	1	1
4. History of preadolescent sexual abuse		<input type="checkbox"/>	3	0
5. Psychological disease	• Attention-deficit disorder, obsessive-compulsive disorder, bipolar disorder, schizophrenia	<input type="checkbox"/>	2	2
	• Depression	<input type="checkbox"/>	1	1

Total Score \_\_\_\_\_ Risk Category \_\_\_\_\_  
 Low Risk: 0 to 3      Moderate Risk: 4 to 7      High Risk: 8 and above

Source: Webster LR, Webster R. Predicting aberrant behaviors in opioid-treated patients: Preliminary validation of the opioid risk tool. *Pain Med.* 2005;6(6):432.

**F.2.a.iv Therapeutic Trial Criteria (Opioid-Naïve Patient)**

When considering opioid therapy in an opioid-naïve patient, the following trial criteria must be met:

- The failure of pain management alternatives including active therapies, cognitive behavioral therapy, pain self-management techniques, and other appropriate medical techniques.
- Careful evaluation and documentation of the patient’s pain condition, general medical condition, psychosocial history, psychiatric status, and substance use history.
- No untreated psychosocial issues driving or complicating the clinical presentation.
- Opioids should be considered only when the potential benefits are likely to outweigh potential harm and the clinician is willing to commit to continue monitoring the effects of treatment,

including a plan to discontinue opioid therapy if necessary.

- The trial should commence with a baseline assessment of function and pain.
- The treatment plan should include continuation of appropriate adjuvant therapies consistent with recommendations in the *New York Non-Acute Pain Medical Treatment Guidelines* to relieve pain and help the patient cope with the condition.
- The treatment plan should include appropriate coordination of care.
- The patient should have a thorough understanding of all of the expectations for opioid use including the need for a therapeutic trial.
- The physician and patient must agree upon defined functional as well as pain goals.
- The full spectrum of side effects should be reviewed, and a *Patient Informed Consent for Opioid Treatment Form* explaining the risks and benefits of opioids must be signed by the patient and the physician. (See Appendix F)
- A written *Patient Understanding for Opioid Treatment Form* outlining the provider's and patient's responsibilities in opioid therapy (including acknowledgement that prescriptions will be obtained from a single practitioner) must be signed by the patient and physician. (See Appendix G)
- Physicians prescribing opioid therapy must comply with I-STOP and other relevant legislation.
- Physicians should complete the education recommended by the FDA, namely the Risk Evaluation and Mitigation Strategies (REMS).

F.2.a.v Therapeutic Trial

- There is no evidence that any one opioid is superior to any other for initial therapy.

- The trial should document sustained improvement in pain control (at least a 30% reduction on validated pain measures) and improved functional status, including return to work and/or increase in ability to perform activities of daily living.
- When conducting a trial of opioid therapy, start with a low dosage, increase gradually and monitor opioid effectiveness until optimal dose is attained. (See Appendix D: Dosing Thresholds for Selected Opioids)
- Follow-up every 7-10 days is advised to titrate dosage and assess clinical efficacy.
- During dosage titration, advise the patient to avoid engaging in safety-sensitive occupational and non-occupational activities, including but not limited to: operating motor vehicles or other powered equipment; working at heights or in confined spaces; operating equipment or machinery with high likelihood of laceration, puncture or crush injuries; use of combustible or caustic chemicals; or engaging in any activity where reduced alertness or mental acuity could pose a threat to workplace or public safety, until a stable dosage is established and it is certain that the opioid does not cause sedation.
- Urine Drug Testing (UDT) – See Section F.3.d, Urine Drug Testing (UDT) for Monitoring Opioid Therapy.
- Random pill counts. Unannounced pill counts are recommended as indicated according to risk categories or risk factors.
- If goals are not being met the opioid trial should be reassessed.

**F.2.b Long-Term Use of Opioids: Transitioning/Managing Patients ON Existing Opioid Therapy**

F.2.b.i Overview

The physician treating a patient on long-term opioids should initiate a re-assessment/re-evaluation of the patient's medical status, transitioning to management and treatment according to the principles for safe long-term

opioid management and guidelines for optimizing opioid care. (See Sections F.2.c and F.3)

Patients **WHO ARE ON** long-term opioids should not have their medications discontinued simply because they have not met the trial criteria or the criteria for safe long-term opioid management detailed in this guideline. It should be noted that the *New York Non-Acute Pain Medical Treatment Guidelines* does not require the cessation of opioids for this subset of patients who have been on long-term opioid therapy. The goal is to transition to the standards of care identified below and avoid abrupt discontinuation of opioids in patients who have been receiving long-term therapy prior to the initiation of the *New York Non-Acute Pain Medical Treatment Guidelines*.

F.2.b.ii Approach

- Careful re-evaluation and documentation of the patient's pain condition, general medical condition, psychosocial history, psychiatric status and substance use history to determine the effectiveness and safety of existing opioid therapy.
- Physical and psychological and/or psychiatric assessment including a full evaluation for alcohol or drug addiction, dependence or abuse.
  - Risk Assessment: Screening for potential comorbidities and risk factors is crucial so that anticipated risk can be monitored accordingly. Note: Personal or family history of substance abuse is the strongest predictive factor for misuse.
  - Risk Stratification: The patient should be stratified as to low, medium or high risk for abuse based on behaviors, validated clinical instruments and prior history of abuse.
  - The risk of substance abuse, misuse or addiction should be assessed by recommended and validated clinical instruments (See Table 2: Opioid Risk Tool [ORT]).

- When evaluation identifies untreated psychosocial issues driving or complicating the clinical presentation, appropriate referral should be offered.
- Identification and/or continuation of appropriate adjuvant non-opioid therapies consistent with recommendations in the *New York Non-Acute Pain Medical Treatment Guidelines* to relieve pain, improve function and help the patient cope with the condition.
- Establish an initial frequent schedule for regular monitoring and re-evaluation to determine the effectiveness and safety of the existing opioid therapy, need for modification/ discontinuation of opioids, developing plan for monitoring including UDT, pill count, need for specialty consultation/co-management, initiation of non-opioid adjuvant therapies, review and completion of Patient Understanding for Opioid Treatment Form and Patient Informed Consent for Opioid Treatment Form.
- Physicians should be knowledgeable about and maintain compliance with relevant Federal and state controlled substance legislation and regulations.
- The goal is to transition to the standards of care identified below and avoid abrupt discontinuation of opioids in patients who have been receiving long-term therapy prior to the initiation of the *New York Non-Acute Pain Medical Treatment Guidelines*.
- Consideration of other co-morbid conditions that need to be addressed (for example, depression, anxiety, morbid obesity), with appropriate referrals as indicated.

## **F.2.c Ongoing, Long-Term Opioid Management**

### **F.2.c.i Overview**

Once a decision is made to institute and/or continue (for those practitioners who did not start these medications) chronic opioid therapy, the physician is responsible for routinely monitoring the safety and effectiveness (improved patient function and pain control/relief) of ongoing treatment.

F.2.c.ii Principles for Safe Management include:

- Long-term opioid therapy should only be initiated on the basis of an explicit decision and agreement between the patient and physician (Patient Informed Consent for Opioid Treatment Form [Appendix F] and Patient Understanding for Opioid Treatment Form [Appendix G]).
- When opioid dose, type, or patient condition changes, the Patient Informed Consent for Opioid Treatment and Patient Understanding for Opioid Treatment forms must be updated and properly signed by the patient and the physician.
- Prescriptions from a single practitioner and a single pharmacy.
- Physicians should prescribe narcotics in compliance with state and Federal law.
- Lowest possible effective dose. The phenomenon of tolerance must be balanced with pain relief. Strategies to achieve the lowest possible effective dose may include opioid rotations, occasional opioid dose reductions, or possible reinstatement of previously successful treatment plans.
- Continuing review of overall therapy plan with regard to non-opioid means of pain control and maintenance of functional status to include identification and/or continuation of appropriate adjuvant non-opioid therapies consistent with recommendations in the *New York Non-Acute Pain Medical Treatment Guidelines* to relieve pain and help the patient cope with the condition.
- All efforts to encourage and reinforce active exercise (as opposed to passive) to enable and support patient self-management.
- Monitoring/Screening
  - Ongoing review/reassessment and documentation of pain relief, functional status, appropriate medication use, and adverse side effects, periodically and as warranted by

changing circumstances (pain intensity, level of function, progress toward goals). This must be documented at each patient encounter.

- Risk assessment/stratification for guiding approach to frequency of monitoring:
  - In patients at low risk for adverse outcomes and on stable doses of opioids, monitoring at least once every three to six months may be sufficient.
  - Patients with prior history of an addictive disorder, employed in an occupation demanding mental acuity, older patients, patients with unstable or dysfunctional social environment and those with comorbid psychiatric or medical conditions require more frequent monitoring.
  - For patients at a very high risk for adverse outcomes, weekly monitoring and co-management with a physician specializing in addiction medicine may be a reasonable strategy.
  - Monitoring of behavior for signs of possible substance abuse indicating an increased risk for addiction and possible need for consultation with a physician specializing in addiction medicine.
- Urine drug testing should be performed randomly at least once a year and more frequently as deemed appropriate by the prescribing physician according to risk category (See Table 4: UDT Risks and Frequency of Testing).
- It is recommended that unannounced pill counts be performed as indicated according to risk category or risk factors. For aberrant behavior, unannounced pill counts are strongly recommended.
- If no reasons for dose reduction or discontinuation of opioids are identified, and the patient demonstrates benefit from the opioid therapy

(supported by validated measures of improved function and pain), continuation of opioids can be appropriate. Ongoing therapy, however, requires ongoing assessment/monitoring.

- Use limited to maximum of two opioids:
  - A long-acting opioid for maintenance of pain relief and a short-acting opioid for limited rescue use when pain exceeds the routine level.
  - If more than two opioids are being considered for long-term use, a second opinion from a specialist who is Board Certified in Addiction Medicine or Pain Medicine is strongly recommended.
  - All opioid medications should be used with caution in patients with a potential for abuse.
  - Buccal-delivered medications should not be used in this population.
  - Acetaminophen warning with combination products: hepatotoxicity can result from prolonged use of doses in excess of recommended maximum daily doses of acetaminophen, including over the counter medications. (See Section F.1.e.i, "Acetaminophen")

### **F.3 Guidelines for Optimizing Opioid Treatment**

#### **F.3.a Introduction**

Patients on chronic opioid therapy need regular monitoring and re-evaluation to measure patient adherence and progress towards treatment goals, with documentation in the medical record at each patient visit. The Pain Assessment and Documentation Tool (PADT) is an effective approach for systematically documenting each encounter and assisting in organizing the management and review of care. (See Appendix C)

#### **F.3.b Assessing Effects of Long-Term Opioid Therapy**

F.3.b.i The physician should assess/re-assess risks and benefits of the patient's current opioid therapy including:

- Function and pain status.

- Possible adverse effects of current opioid doses (See Table 3: Adverse Effects of Opioids).
- Age of Patient (elderly).
- Potential psychiatric disorders affecting treatment.
- Possible conditions that may potentiate opioid adverse effects such as COPD, CHF, sleep apnea, or history of renal/hepatic dysfunction (including newly diagnosed conditions and associated medications).
- Possible drug combinations that may potentiate opioid adverse effects such as sedative-hypnotics, benzodiazepines or barbiturates unless there is a specific medical and/or psychiatric indication for the combination (and increased monitoring is performed).

F.3.b.ii If there is evidence of significant adverse effects from opioid therapy, the physician should reduce the opioid dose and reassess the patient's status.

- Tapering/discontinuation of opioids may be necessary due to the development of tolerance, hyperalgesia, decreased effects from an opioid, lack of compliance with the opioid contract or intolerable side effects.
- Inpatient treatment may be required for addiction or opioid tapering in complex cases.

**Table 3: Adverse Effects of Opioids**

<b>Common Initial Side Effects</b>	<ul style="list-style-type: none"> <li>• Nausea</li> <li>• Vomiting</li> <li>• Drowsiness/sedation</li> <li>• Unsteadiness</li> <li>• Confusion</li> </ul>
<b>Occasional Side Effects</b>	<ul style="list-style-type: none"> <li>• Dry mouth</li> <li>• Sweating</li> <li>• Pruritus</li> <li>• Hallucinations</li> <li>• Myoclonus</li> </ul>
<b>Other Side Effects</b>	<ul style="list-style-type: none"> <li>• Respiratory depression</li> <li>• Psychological dependence</li> </ul>
<b>Long Term Side Effects</b>	<ul style="list-style-type: none"> <li>• Constipation            Constipation should be <i>anticipated</i> and treated prophylactically with stool softeners, laxatives and increased fluids as clinically indicated.</li> <li>• Nausea</li> <li>• Vomiting</li> <li>• Sexual dysfunction</li> </ul>
<b>Drug Metabolism Interactions</b>	<ul style="list-style-type: none"> <li>• Avoid mixed opioid agonist-antagonists.</li> <li>• Sedating medications (benzodiazepines, antihistamines, diphenhydramine, and prescription medications such as hydroxyzine, hypnotics)</li> <li>• Alcohol</li> </ul>
<b>Hyperalgesia</b>	<ul style="list-style-type: none"> <li>• An exaggerated pain response from a usually painful stimulation</li> </ul>
<b>Allodynia</b>	<ul style="list-style-type: none"> <li>• Pain due to a non-noxious stimulus that does not normally provoke pain</li> </ul>
<b>Tolerance Dependence Addiction</b>	<ul style="list-style-type: none"> <li>• Tolerance – occurs when higher and higher doses of an opioid are required to maintain the same degree of analgesia</li> <li>• Dependence – appropriate use with withdrawal symptoms if the drug is stopped</li> <li>• Addiction – escalating, uncontrolled use</li> </ul>

- F.3.b.iii If there are no indications for dose reduction or discontinuation of opioids, and the patient demonstrates benefit from the opioid therapy (supported by validated measures of improved function and pain), continuation of opioids can be appropriate. Ongoing therapy, however, requires ongoing assessment/monitoring. At this juncture, the treating physician may be asked to assess the patient's mental acuity, alertness and ability to safely engage in work activities in the context of ongoing opioid therapy. Absent objective functional improvement, physicians shall initiate efforts to wean and/or discontinue opioid use.
- F.3.b.iv The patient should not engage in safety-sensitive activities, or activities that could cause risk to individual, workplace or public safety when mental acuity or alertness is diminished as a result of opioid therapy. Such activities include, but are not necessarily limited to: operation of powered vehicles; working at heights or in confined spaces; and operating power tools or machinery with potential for serious injury if operated incorrectly.

**F.3.c Patient Informed Consent for Opioid Treatment Form and Patient Understanding for Opioid Treatment Form**

- F.3.c.i Patient Informed Consent for Opioid Treatment Form (Appendix F) contains the following:
- Potential side effects from the medication including but not limited to: confusion/clouded judgment, nausea, constipation, vomiting, sleepiness/drowsiness, problems with coordination, balance and decreased reaction time, breathing too slowly (including possibility that breathing can stop and lead to death), aggravation of depression, and dry mouth.
  - Hyperalgesia. In some patients increased dose of opioids may decrease pain threshold and increase sensitivity to pain. Symptoms often improve with decrease in opioid dose.
  - Side effects may be worse if opioids are mixed with other drugs, including alcohol.
  - Risks, tolerance, dependence, and addiction.

- Males. Low testosterone levels (may affect sexual desire and sexual performance).
- Females. Pregnancy while taking opioids, potential dependence of new born baby.

F.3.c.ii Patient Understanding for Opioid Treatment Form (Appendix G) contains the following:

- Patient agrees to take medications at dosage and frequency as prescribed and obtain medication at one pharmacy.
- Medications will be obtained from the physician who signs the form, or during his/her absence, by the covering physician.
- Requirement to continue active therapy.
- Understanding of the need to pursue other pain management techniques in order to function with non-acute pain.
- Treatment goals which must include improvement in pain and function including return to work for most cases.
- Need to avoid alcohol and other drugs that are not part of the treatment plan.
- Expectation of UDT and blood tests and consequences of unexpected results, including a discussion regarding how screens positive for non-prescribed drugs or alcohol will be handled.
- Reasons for termination of opioid management (e.g., non-compliance, diversion).
- Reasons for tapering or termination of opioids (e.g., lack of progress toward therapeutic goals, intolerable side effects): if an opioid trial or treatment fails, tapering or termination is usually done over 30 days or by referral for addiction treatment.
- Safe storage of medications.

### **F.3.d Urine Drug Testing (UDT) for Monitoring Opioid Therapy**

#### **F.3.d.i UDT Introduction**

The purpose of drug testing is to identify aberrant behavior, undisclosed drug use and/or abuse, and verify compliance with treatment. When used with the appropriate level of understanding, UDT can improve the physician's ability to safely and appropriately manage opioid therapy. Random UDT is recommended as a tool to monitor compliance with prescribed substances, and/or identify use of undisclosed substances which will impact treatment decisions.

UDT results, in and of themselves, do not suggest a definitive course of action, but rather should be interpreted in the context of the individual patient's clinical circumstances. The test should be used in conjunction with other clinical information when decisions are to be made to continue, adjust or discontinue treatment. This information includes clinical observation, results of addiction screening, pill counts, and prescription drug monitoring reports. The prescribing physician should also pay close attention to information provided by family members, other providers and case managers, and pharmacy personnel. Physicians should consider a differential diagnosis of abnormal UDT results including drug abuse or addiction, self-treatment of poorly controlled pain, psychosocial issues or diversion.<sup>2</sup>

- Urine Drug Testing is a mandatory component of chronic opioid management, as part of the baseline assessment and ongoing re-assessment of opioid therapy. (See Table 4: Urine Drug Testing (UDT) Risks and Frequency of Testing)
- Baseline UDT should be obtained on all transferring patients who are already using opioids or when a patient is being considered for ongoing opioid therapy.

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<sup>2</sup> APS-AAPM Opioid Treatment Guidelines

**Table 4: Urine Drug Testing (UDT) Risks and Frequency of Testing**

Risk Category (Score)	Random UDT Frequency
Low Risk (0-3)	Periodic (At least once/year)
Moderate Risk (4-7)	Regular (At least 2/year)
High Risk ( $\geq 8$ or opioid dose $>100$ mg/MED/day)	Frequent (At least 3-4/year)
Aberrant Behavior	At time of visit <i>Note: address aberrant behavior in person, not by phone</i>

- Prior to testing, the physician should inform the patient of the reason for the testing, the expectation of future testing (which may be unscheduled) to show adherence with the Patient Understanding for Opioid Treatment Form, and the consequences of unexpected results.
- Physician should repeat UDT randomly based upon patient's risk category (See Table 2: Opioid Risk Tool [ORT])
- If a patient demonstrates aberrant behavior (e.g., lost prescriptions, multiple requests for early refill, opioids from multiple physicians, unauthorized dose escalation, apparent intoxication, etc.), test at that visit.

F.3.d.ii Confidentiality and Reporting UDT Results

- The patient has the right to refuse a urine drug test, but will receive no prescription for opiate medication as a consequence of the refusal.
- UDT results are not to be released to the carrier, employer or the Board. However, the treating physician must certify the patient's adherence to or

noncompliance with the Patient Understanding for Opioid Treatment Form in the medical record. Noncompliance would include evidence that patient is taking any non-prescribed drug(s) or not taking those drugs prescribed as part of treatment.

- Employers cannot use test results to fire or discipline a worker in any discriminatory manner.
- The recommendations in the *New York Non-Acute Pain Medical Treatment Guidelines* do not apply to acute care situations.
- Guideline-specific criteria will be used to determine when and at what frequency UDT should be used.

#### F.3.d.iii Methods of Urine Drug Testing

Two main types of UDT are available (see additional information, Appendix E: Urine Drug Testing):

- a) Immunoassay drug testing (initial drug test or screen).
  - Is the most common method of testing.
  - Initial drug test or screen.
  - Can be performed in a lab or office (at the point-of-care).
  - UDT can detect the presence or absence of a drug or drug class, but not how much of a drug was used.
  - Advantage of immunoassays are their ability to concurrently test for multiple drug classes, provide rapid results and guide appropriate utilization of confirmatory testing.
  - Immunoassays can react with other drugs and vary in sensitivity and specificity.
  - Unexpected immunoassay results should be interpreted with caution and verified by confirmatory testing.

- Office protocols and procedures should be developed to ensure appropriate collection of urine drug samples.
- b) High performance chromatography/mass spectrometry (confirmatory drug test).
- If verification or identification of a specific drug and/or metabolite is needed, then confirmatory testing is recommended.
  - Laboratory based confirmation uses gas chromatography/mass spectrometry or liquid chromatography/tandem mass spectrometry (GC/MS or LC/MS).

F.3.d.iv Interpreting Results

- Interpreting UDT results can be challenging, especially when the parent drug can be metabolized to other commonly prescribed drugs.
- When an immunoassay result is unexpected, a confirmatory test using GC/MS or LC/MS should be ordered.

**Table 5: Red Flag Results**

Red Flag Results
Negative for opioid(s) prescribed
Positive for amphetamine or methamphetamine
Positive for cocaine or metabolites
Positive for drug not prescribed (benzodiazepines, opioids, etc.)
Positive for alcohol

- Negative results:

If confirmatory testing and clinical judgment substantiate a red flag (see Table 5: Red Flag Results) and the result is negative for the prescribed opioid(s), the patient should be called back for a pill count and repeat urine test. If the urine is still negative, the patient should return to the office in two days and be evaluated for evidence of withdrawal. If no evidence of withdrawal, consider stopping opioid(s) as diversion is suspected.

- Positive results:

If confirmatory testing and clinical judgment substantiate a red flag (See Table 5: Red Flag Results) and the result is positive for a non-prescribed scheduled drug or other drugs without a valid medical explanation, the provider needs to understand the medical significance of this result. Once an assessment of the significance of the positive urine drug test is made, options such as reiteration of the Patient Understanding for Opioid Treatment, weaning or termination of opioid prescription, more frequent monitoring, referral to specialty care must be considered, particularly in the absence of a valid explanation.

- Minimally, in the setting of the above, several actions should be adhered to, including (1) the injured worker is to be considered “high risk”, with testing frequency to be reflected as described for this new categorization; (2) random pill counts are to occur on a periodic basis, at least quarterly.
- If there subsequently is a second positive urine drug test without valid explanation, e.g., finding a non-prescribed scheduled drug, finding of any drug without a valid medical explanation, or a deviation from anticipated medication frequency count, then medication tapering is to immediately commence, for a period of time not to exceed more than one month (unless clearly articulated medical contraindications exist).

- As an alternative, a 3-5 day inpatient medically assisted withdrawal (detox) program can be considered, possibly in conjunction with longer term support (e.g., Alcoholics Anonymous, Narcotics Anonymous, group meetings, office visits, etc.), as indicated.
- Note that any of the following should also trigger placement of the patient to the “high-risk” category: selling prescription drugs, forging prescriptions, stealing or borrowing drugs, frequently losing prescriptions, aggressive demand for opioid medication beyond reasonable clinical parameters, unsanctioned use of opioid medication, unsanctioned dose escalation, receiving opiate medication from multiple providers, recurring Emergency Department visits for pain medication.
- Contact your local laboratory director for assistance in interpreting drug testing results.

#### **F.3.e Optimizing Opioid Doses**

- Use the lowest possible effective dose of opioids and for opioid-naïve patients, titrate slowly.
- Although progressively higher doses may improve symptom control, repeated dose escalations can be a marker for abuse or diversion or can paradoxically induce abnormal pain sensitivity including hyperalgesia and allodynia.
- For patients taking more than one opioid, the morphine equivalent doses (MED) of the different opioids must be added together to determine the cumulative dose.
- Opioid rotation (discontinuing an opioid and switching to another) is a possible option for patients who have inadequate symptom relief despite dose escalations or who develop intolerable side effects.
- However, if the opioid treatment is benefitting the patient as demonstrated by objective measures of function and pain, then it may be appropriate to continue the high dose while maintaining appropriate rigorous patient monitoring.

F.3.e.i Equianalgesic Doses (ED)

Conversions from one opioid to another are estimates generally based on equianalgesic dosing (see Table 6). As a result of large patient variability in response to opioids, **it is recommended that, after calculating the appropriate conversion dose, the dose should be reduced by 50% to insure patient safety.**

- Opioid withdrawal symptoms are unpleasant but not life threatening. However, overdose is life threatening. Patients (family or friends) should be warned about signs of overdose (slurred speech, emotional lability, ataxia, nodding off during conversation and/or activity).
- It is safer to underdose.
- Patient should be evaluated shortly after switching to a new opioid to monitor for pain and potential side effects.
- High dose or prolonged use can result in opioid induced hyperalgesia.

**Table 6: Oral Opioid Analgesic Equivalence (ED) to Oral Morphine 30 mg**

	Approximate equivalence to oral morphine	To convert from oral morphine multiply by:
Morphine (reference)	30 mg	1
Codeine	200 mg	6.67
Fentanyl transdermal	See Table 7	
Hydrocodone	30 mg	1
Hydromorphone	6 mg	0.2
Oxycodone	20 mg	0.667

	<b>Approximate equivalence to oral morphine</b>	<b>To convert from oral morphine multiply by:</b>
Meperidine*	300 mg	10
Methadone, Tramadol and Tapentadol	Dose equivalents unreliable	

\*Meperidine is not recommended for the treatment of non-acute pain.

**Table 7: Equivalence Between Oral Morphine and Transdermal Fentanyl  
(use *only* when converting from another opioid to fentanyl patch)**

<b>Current Morphine Equivalence (<i>mg/day</i>)</b>	<b>Recommended Transdermal Fentanyl Patch Dose (<i>72 hour patch</i>)</b>
60-134 mg	25 mcg/hr
135-224 mg	50 mcg/hr
225-314 mg	75 mcg/hr
315-404 mg	100 mcg/hr

Use Table 7 to find the calculated 24-hour Equivalent Dose and the corresponding fentanyl patch dose.

- Initiate fentanyl patch using the recommended dose and titrate patients no more frequently than 3 days after the initial dose and every 6 days thereafter until analgesic efficacy is attained.
- **Conversion from fentanyl patch to another opioid can overestimate the dose of the new agent and may result in overdose.**
- The majority of patients are adequately maintained with fentanyl patch administered every 72 hours. Some patients may not achieve adequate analgesia using this dose interval and may require the patch to be applied at 48-hour intervals. An increase in the patch dose should be evaluated in order to maintain patients on a 72-hour regimen, before attempting a change to a 48-hour dose interval.
- Doses of fentanyl patch above 25 mcg/hr or intervals shorter than 72 hours require either that the patient demonstrates improvement in pain and function without aberrant behavior, or that a consultation

with either a pain management expert or a physician specializing in addiction medicine be obtained.

- Fentanyl Immediate Release (Transmucosal) is not recommended.

F.3.e.ii Opioid Doses  $\geq$  100 mg/MED

- In general, the total daily dose of opioid should not exceed 100 mg/oral MED.
- Risk for overdose or adverse effects substantially increases at doses > 100 mg/oral MED.
- Except for pain management or addiction medicine specialists, a provider should not prescribe more than 100 MED/day without either the patient demonstrating improvement in pain and function without aberrant behavior or first obtaining a consultation from a pain management specialist or a physician specializing in addiction medicine (see Table 8: Guidance for Seeking Consultative Assistance).
- If dosing reaches 100 mg/MED/day and the patient has not received pain relief or has developed hyperalgesia, dose reduction or discontinuation is warranted.
- Persistent doses > than 100mg/MED/day by any medical provider may be subject to a secondary review by an external consult in pain management or addiction medicine.
- For patients taking more than one opioid, the MED doses of the different opioids must be added together to determine the cumulative dose (see Table 9 for calculating MED).
- A MED dose calculator is available at:  
<http://agencymeddirectors.wa.gov/mobile.html>
- Washington State's MED dose calculator and/or Table 9 **should NOT be used to determine doses when converting a patient from one opioid to another.** This is especially important for fentanyl and methadone conversions. Equianalgesic

dose ratios are only approximations and do not account for genetic factors, incomplete cross-tolerance, and pharmacokinetics.

**TABLE 8: Guidance for Seeking Consultative Assistance**

<b>Prescribing Opioid Doses</b>	
<b>&lt;100 mg MED/day</b>	<b>≥ 100 mg MED/day</b>
No assistance from a pain management consultant needed if the prescriber is documenting sustained improvement in both function and pain.	No assistance from a pain management consultant needed if the prescriber is documenting sustained improvement in both function and pain.
<p>Consider getting consultative assistance if frequent adverse effects or lack of response is evident in order to address:</p> <ul style="list-style-type: none"> <li>• Evidence of undiagnosed conditions;</li> <li>• Presence of significant psychological condition affecting treatment; and</li> <li>• Potential alternative treatments to reduce or discontinue use of opioids.</li> </ul>	<p>In general, the total daily dose of opioid should not exceed 100 mg oral MED.</p> <p>Risks substantially increase at doses at or above 100 mg, so early attention to this benchmark dose is worthwhile.</p>
	<p>Seek assistance from a pain management consultant to address:</p> <ul style="list-style-type: none"> <li>• Potential alternative treatments to opioids;</li> <li>• Risk and benefit of a possible trial with opioid dose above 100 mg MED/day;</li> <li>• Most appropriate way to document improvement in function and pain; and</li> <li>• Possible need for consultation from other specialists.</li> </ul>

**Table 9: MED Dose Calculator (Opioid Analgesic Equivalence Ratio to Oral Morphine)**

	To convert to MED calculate 24 hour total opioid dose and multiply by:*
Morphine (reference)	1
Codeine	0.15
Fentanyl transdermal	2.4
Hydrocodone	1
Hydromorphone	5
Oxycodone	1.5
Oxymorphone	3
Meperidine**	0.1
Methadone	4
Tapentadol	0.367
Tramadol	0.2

\*See Example below

\*\*Meperidine is not recommended for the treatment of non-acute pain.

**Example:** Calculating Morphine Equivalent Dose (MED)

If a patient takes six hydrocodone 5 mg / acetaminophen 500 mg and two 20 mg oxycodone extended release tablets per day, the cumulative dose using Morphine 30 mg as the reference, may be calculated as follows:

- 1) Hydrocodone 5 mg x 6 tablets per day = 30 mg per day.
- 2) Oxycodone 20 mg x 2 tablets per day = 40 mg per day
- 3) Cumulative dose is 30 mg + 60 mg = 90 mg morphine equivalents per day

Reference: Morphine 30 mg	Opioid dose/24 hours for each drug	To convert to oral morphine equivalent multiply by:	MED
Hydrocodone	5 mg x 6 = 30 mg/day	1	30 mg
Oxycodone	20 mg x 2= 40 mg/day	1.5	60 mg
Cumulative MED=90 mg			

F.3.e.iii Reasons to Discontinue Opioids and/or Refer to a Physician specializing in Addiction Medicine or Pain Management:

- No improvement in function and pain, or
- Opioid therapy produces significant adverse effects (see Table 3: Adverse Effects of Opioids), or
- Patient exhibits aberrant behavior, drug seeking behaviors or diversions such as:
  - Selling prescription drugs.
  - Forging prescriptions.
  - Stealing or borrowing drugs.
  - Frequently losing prescriptions.
  - Aggressive demand for opioids.
  - Unsanctioned use of opioids.
  - Unsanctioned drug escalation.
  - Concurrent use of illicit drugs.
  - Injecting oral/topical opioids.
  - Failing drug screen (concurrent use of alcohol or non-prescribed drugs).
  - Getting opioid from multiple prescribers/pharmacies.
  - Missing appointments.
  - Not following other components of the treatment plan (physical therapy, exercise, etc.).
  - Recurring emergency visits for obtaining additional pain medication.

F.3.e.iv General Guidelines for Opioid Tapering/Discontinuation

Medically, weaning from opioids can be done safely without significant health risks by slowly tapering the opioid dose and taking into account the following:

- A decrease by 10% of the original dose per week is usually well tolerated with minimal physiological adverse effects.
- Some patients can be tapered more rapidly (over 6 to 8 weeks) without problems.
- If opioid abstinence syndrome is encountered, it is rarely medically serious although symptoms may be unpleasant.
- Symptoms of abstinence syndrome, such as nausea, diarrhea, muscle pain and myoclonus can be managed with clonidine 0.1- 0.2 mg orally every 6 hours or clonidine transdermal patch (0.1 mg/24 hours), with weekly evaluations during the taper while monitoring often for significant hypotension and anticholinergic side effects.
- In some patients it may be necessary to slow the taper timeline to monthly, rather than weekly dosage adjustments.
- Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued.
- Rapid re-occurrence of tolerance can occur for months or years after prior chronic use.
- Consider using adjuvants, such as antidepressants, to manage irritability or sleep disturbance, or anticonvulsants for neuropathic pain.
- Do not treat withdrawal symptoms with opioids or benzodiazepines after discontinuing opioids.
- Referral for counseling or other support during this period is recommended if there are significant behavioral issues.
- Referral to a physician specializing in addiction medicine or to a pain specialist and/or an inpatient/outpatient medically assisted detoxification program should be made for complicated withdrawal symptoms.

- F.3.e.v Recognizing and Managing Behavioral Issues during Opioid Tapering
- Special care needs to be taken to preserve the patient-physician therapeutic relationship during this time to avoid precipitating doctor-shopping, illicit drug use or other risky patient behaviors.
  - Extremely challenging behavioral issues may arise during the period of an opioid taper.
  - Appropriate referral/consultation should be made. For example, suicidal ideation with plan or intent should prompt immediate psychiatric consultation.
- F.3.e.vi Specialty Consultations (See Table 8: Guidance for Seeking Consultative Assistance)
- Addiction/Pain Medicine
    - High risk patients.
    - Moderate risk patients, referral or co-management.
    - Tapering/discontinuation of opioids.
    - Complex problems.
    - Aberrant drug behaviors.
    - If more than two opioids are being considered for long-term use, a second opinion from a specialist who is Board Certified in Addiction or Pain Medicine is strongly recommended.
    - Opioid doses  $\geq 100$  mg/MED/day (see Section F.3.e.ii), including Fentanyl (see Section F.3.e.i)
    - Methadone/buprenorphine treatment.
    - Addiction management.
  - Psychiatry
    - Deteriorating psychological state (suicidal ideation) during opioid withdrawal.

- Symptoms of mood, anxiety and psychotic disorders.
- Undiagnosed psychiatric/psychological disorders.
- Other consultation to address cases of severe pain with no improvement despite treatment with opioids, including neurology, physical medicine, orthopedics, rheumatology, anesthesiology, oncology as clinically indicated by the patient's signs and symptoms.
- Consultation should address possible undiagnosed conditions, psychological conditions and alternative treatment.
- Inpatient treatment may be required for addiction or opioid tapering in complex cases.

## **F.4 OPIOID-RELATED MEDICATIONS: Tramadol, Methadone, Buprenorphine, Tapentadol**

### **F.4.a Tramadol**

Tramadol is an opioid partial agonist that does not cause GI ulceration or exacerbate hypertension or congestive heart failure. Side effects similar to opioids may limit its use.

It should not be considered a first line medication. It provides pain relief equivalent to that of commonly prescribed NSAIDs. It may be used as a fourth-line drug for neuropathic pain. It may be useful for patients who cannot tolerate tricyclic antidepressants.

- May cause impaired alertness or nausea.
- This medication has physically addictive properties and withdrawal may follow abrupt discontinuation.
- Use cautiously in patients who have a history of seizures or who are taking medication that may lower the seizure threshold, such as MAO inhibitors, SSRIs, and TCAs.
- Not recommended in those with prior opioid addiction.
- Has been associated with deaths in those with an emotional disturbance or concurrent use of alcohol or other opioids.

- Significant renal and hepatic dysfunction requires dosage adjustment.

#### **F.4.b Methadone**

Methadone is an opioid analgesic with complicated pharmacokinetic and pharmacodynamic interactions and side effects. Experience in the use of methadone demonstrates that methadone is far more potent as an analgesic than has been suggested by equianalgesic tables derived from single-dose studies. With repetitive dosing, methadone is approximately ten times more potent than indicated in these standard tables. The main reason for this is the long elimination half-life of methadone (24 to 36 hours), which allows for much higher drug levels to be reached than could be predicted from single-dose studies.

This long and unpredictable half-life and associated risk for accumulating toxic levels of methadone can result in severe respiratory depression; multiple interactions with other drugs, including frequently abused drugs such as antianxiety agents; and ability to cause major disturbances of cardiac rhythm. As such, methadone should be used with extreme caution, if at all, in the setting of pre-existing cardiac, psychiatric, or respiratory dysfunction.

Prescribers must be knowledgeable that doses and dosing schedules used for analgesic purposes are different from those used in addiction management. Therefore, the use of methadone as an analgesic agent requires the same pain assessment skills as for any opioid drug but even greater scrutiny in patient monitoring and side effects. Methadone should not be prescribed for opioid-naïve patients. Methadone prescribers must be aware of safety precautions and have adequate training and experience when prescribing this medication. The axiom “start low, go slow” is particularly applicable in the case of methadone.

#### **F.4.c Buprenorphine**

Buprenorphine is approved for the treatment of opioid addiction and can be considered, off-label, for the treatment of non-acute pain in limited instances. It is a partial opioid agonist and has a ceiling effect, so that respiratory depression and death are uncommon. It attaches to the mu receptor so other opioids cannot attach. This makes it a drug for consideration in an individual with a history of opioid addiction.

Buprenorphine is available orally in 2 mg and 8 mg tablets and as a transdermal patch. Only the transdermal patch is approved for the treatment of pain. The tablet form is FDA approved for the treatment

of opioid addiction. Tablets may be considered in patients who have both a history of addiction and pain. When used for the treatment of pain, the dose employed is typically lower than the dose used in the treatment of addiction.

Advantages of buprenorphine in treatment of pain include reduced potential for inappropriate use and subsequent addiction. In patients who are physically dependent on opioids, appropriate caution should be exercised to avoid the potential for withdrawal due to the antagonistic effect of buprenorphine.

To prescribe buprenorphine, a physician needs to take an 8-hour online course and get a special DEA number. For more information go to: [www.buprenorphine.samhsa.gov](http://www.buprenorphine.samhsa.gov). To take the 8-hour course online go to: [www.BupPractice.com](http://www.BupPractice.com).

#### **F.4.d Tapentadol**

Tapentadol is an opioid agonist indicated for the management of moderate to severe acute pain in adults. Tapentadol extended release (ER) is indicated for the management of moderate to severe non-acute pain in adults, as well as neuropathic pain associated with diabetic peripheral neuropathy in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

Tapentadol should not be considered a first line medication. Side effects similar to opioids may limit its use. It is not recommended for use in patients with severe renal impairment. Tapentadol should be used with caution and reduced dosage in patients with moderate hepatic impairment and is not recommended for use in severe hepatic impairment. It is advisable to start at lower doses and adjust according to patient response.

There is no equianalgesic dose conversion guidance for tapentadol or tapentadol extended release to oral morphine.

## **G SPINAL CORD STIMULATOR AND INTRATHECAL DRUG DELIVERY**

### **G.1 IMPLANTABLE SPINAL CORD STIMULATOR (SCS)**

Spinal Cord Stimulators are not included on the list of pre-authorized procedures. Providers who want to perform one of these procedures must request pre-authorization from the carrier before performing the procedure.

Spinal cord stimulators are also known as dorsal column stimulators. The system uses implanted electrical leads and a battery powered implanted pulse generator.

Before considering SCS, the patient may consider enrolling in an authorized Functional Restoration Program (See sections C.1.e, Functional Restoration Approach to Non-Acute Pain Management, and E.4, Non-Acute Pain Management Programs [Interdisciplinary or Functional Restoration Pain Management Program]). Declining this option does not preclude SCS implantation.

#### **G.1.a Indications**

- SCS is prescribed for treatment of select patients with chronic back or neck radicular pain, specifically patients with failed neck or back surgery syndrome who have:
  - Persistent severe and functionally disabling radicular neck or back pain (cannot be used for axial neck pain or for low back pain primarily axial in origin).
  - Been provided with conservative non-surgical treatments (e.g., active/passive therapy, medications, and injections).
  - Undergone surgical treatment that failed to relieve symptoms and improve function and for whom further surgery has been considered but is not being pursued at this time.
- Other indications for SCS include: complex regional pain syndrome (CRPS), phantom limb and spinal cord injury dysesthesias.
- Proper patient selection: One of the most important aspects to the successful treatment with a spinal cord stimulator is proper patient selection. In addition to a treating physician's detailed history, physical exam and complete diagnostic work-up, no patient can undergo insertion of a spinal cord stimulator before a thorough psychological evaluation

demonstrates that there are no significant psychological-behavioral factors that would predict poor response to a SCS.

- Psychological evaluation: A comprehensive psychological evaluation should include a clinical interview and complete review of the medical records, a standardized detailed personality inventory (See Section D.2, Personality/Psychological/Psychosocial Clinical Evaluation for Pain Management) and pain inventory. The goal of the required comprehensive psychological evaluation is to assist in determining the suitability of a patient for SCS implantation. Patient expectations need to be realistic and patients should understand that SCS intervention is not a cure for pain, but rather a masking of their symptoms which might regress over time.

Before proceeding to a spinal stimulator trial, the required psychological evaluation should demonstrate the following:

- No primary psychiatric risk factors or red flags (i.e., severe psychiatric disorders such as severe psychosis, active suicidal ideation, severe depression, or addiction/concurrent substance abuse)
- and
- The patient has a demonstrated history of motivation and adherence to prescribed treatments.

Note: tolerance and dependence are not addictive behaviors and do not preclude implantation.

All the evaluation criteria must be successfully met before the SCS screening trial test is scheduled. If all of the pre-requisites are met, conditional pre-authorization must be obtained from the payor for a SCS screening trial of device effectiveness.

#### **G.1.b SCS Neurostimulation Screening Trial**

- During a SCS neurostimulation screening trial, the patient receives a temporary, external neurostimulation system for 3 to 7 days, and uses the external system while completing daily activities.
- After the screening test ends, results are evaluated to determine if the patient is a candidate for a permanent SCS implantation. The patient should maintain a pain and activity diary during the screening trial.

- A screening test is considered successful if the patient meets the following criteria:
  - Stimulation covers the patient's pain areas
  - Patient is comfortable with the sensation of stimulation
  - Patient experiences a 50% decrease in pain, which must be confirmed by a validated pain measure such as the Visual Analog Scale (VAS) or Numerical Rating Scale (NRS), and
  - Demonstrates objective functional gains or decreased use of pain medications. Objective, measurable functional gains should be evaluated and documented prior to and before discontinuation of the trial.

**G.1.c Permanent SCS Implantation**

If the screening trial is successful, the treating physician must request pre-authorization from the carrier to implant a permanent SCS.

**G.1.d Special Circumstances**

In limited situations, i.e., the presence of extreme comorbidities, a spinal cord stimulator may be considered in a patient without previous low back or neck surgery. The physician may contact the Medical Director's Office for an expedited determination in these circumstances.

**G.2 INTRATHECAL DRUG DELIVERY (Pain Pumps)**

Intrathecal drug delivery (Pain Pumps) is not included on the list of pre-authorized procedures.

- Providers who want to perform this procedure must request pre-authorization from the carrier before performing the procedure.
- To be pre-authorized, the patient must be evaluated and have the recommendation of at least one physician certified in chronic pain management in consultation with the primary treating physician.
- The procedure must be performed by a physician with documented experience in the performance of this procedure.

### **G.2.a Indications**

Clinical studies are conflicting regarding long-term, effective pain relief in patients with non-malignant pain. Due to the complication rate for long-term use, it may be considered only in very rare occasions.

The small eligible sub-group of patients must meet all of the following indications:

- A diagnosis of a specific physical condition known to be chronically painful has been made on the basis of objective findings; and
- All reasonable surgical and non-surgical treatment has been exhausted including failure of conservative therapy including active and/or passive therapy, medication management, or therapeutic injections; and
- No practical issues that might interfere with device placement, maintenance, or assessment (e.g., morbid obesity, body size insufficient to support the size and weight of the implanted device, severe cognitive impairment); and
- Pre-trial psychiatric or psychological evaluation has been performed (as for SCS) and should demonstrate the following:
  - No primary psychiatric risk factors or red flags;
  - Motivation and adherence to prescribed treatments;
  - There is no evidence of current addictive behavior (Tolerance and dependence to opioid analgesics are not addictive behaviors and do not preclude implantation).
- Recommend that before a pain pump trial is considered, the patient be offered treatment at a functional restoration program if available.

All the evaluation criteria must be successfully met before a screening trial is scheduled.

### **G.2.b Pain Pump Screening Trial**

- A successful trial of continuous infusion by a percutaneous spinal infusion pump for a minimum of 24 hours.
- A screening test is considered successful if the patient :

- Experiences a 50% decrease in pain, which may be confirmed by VAS, and
- Demonstrates objective functional gains or decreased utilization of pain medications, and
- Objective functional gains should be evaluated and documented prior to and before discontinuation of the trial.

### **G.2.c Pain Pump Implantation**

If the screening trial is successful, the treating physician must request pre-authorization from the carrier to implant a permanent pain pump.

## **H FUNCTIONAL MAINTENANCE CARE**

Maximum Medical Improvement (MMI) shall not preclude the provision of medically necessary care. While patients at MMI typically do not require ongoing maintenance medical care, there may be clinical flare-ups/fluctuations that require episodic care. Such care shall be medically necessary to maintain function at maximum medical improvement level. In rare cases, a regular, ongoing and minimal level of clinical intervention may be necessary to prevent or minimize deterioration in function that has been clearly and objectively documented in the absence of such care.

Exacerbations have been addressed by a Board Panel decision and by MDO Bulletin, 2012 #1.

### **H.1 General Recommendations for Functional Maintenance Care**

#### **H.1.a Ongoing, Independent, Self-Management Plan**

- As patients progress/plateau in their response to treatment, the physician (MD/DO) and the patient should work to develop clinically appropriate, independent, self-management programs that encourage physical activity and/or work activities despite residual pain, with the goal of preserving functional status.
- Such independent programs may include active techniques such as strengthening, stretching and range of motion physical exercise, which are typically home-based and self-directed.
- One-time or short-term counseling or support may be of value to avoid dependence on physicians and other healthcare providers. Such counseling should include education on the

appropriate use of pain medications, including over-the-counter medications.

- Referral to community support/self-help groups, programs and/or networks is encouraged.

#### **H.1.b Self-Directed Pain Management Plan**

- In addition to an ongoing active self-management program, a self-directed pain management plan should be developed that can be initiated by the patient in the event that symptoms worsen and function decreases.
- This self-directed plan should include short-term interventions and/or medication use.
- The MD/DO must be highly cognizant of the potential for adverse clinical and functional outcomes with the long-term use of pain medications, and must take appropriate steps early in the course of care to avoid or minimize the risk of such adverse outcomes.

#### **H.1.c Review of Self-Management and Self-Directed Treatment Programs**

- The MD/DO should periodically review the self-management/self-directed treatment plan and any new clinical information especially in relation to possible alternative causes of deterioration of function.
- Continuation or modification of the treatment plan depend upon the medical provider's evaluation of the patient's symptoms and documentation of objective findings.

#### **H.1.d Ongoing Care**

- As the condition becomes more stable, progressively longer trials of therapeutic withdrawal should be attempted to ascertain whether therapeutic gains can be maintained in the absence of active clinical interventions.
- When a patient's condition no longer shows functional improvement from therapy, a decision must be made on whether the patient will need to continue treatment, or can maintain his/her functional status with a self-management program, without additional medical intervention(s).

- Therapy modalities should be discontinued and the patient should return to an independent, home-based, self-directed program.
- For patients who demonstrate a documented functional decline, a clinical reassessment should be undertaken to:
  - Rule out comorbid conditions;
  - Assess the adequacy of the current independent, home-based, self-management program, and/or the need for modifications to that program; and
  - Determine the value, if any, of reinstating clinical interventions as part of an ongoing maintenance program (in addition to a self-management program) tailored to the specific needs of the patient.

#### **H.1.e Ongoing Maintenance Care**

A maintenance program of physical therapy, occupational therapy or spinal manipulation (by a physician (MD/DO), chiropractor or physical therapist) may be indicated in certain situations after the determination of MMI, when tied to maintenance of functional status.

- Although the current body of scientific evidence as reviewed does not support the routine use of this intervention, maintenance therapy modalities may be indicated in certain situations in order to maintain functional status, without which an objective deterioration of function has been previously observed and documented in the medical record.
- Specific objective goals should be identified and measured in order to support the need for ongoing maintenance care.
- Progressively longer trials of therapeutic withdrawal are to be attempted to ascertain whether therapeutic goals can be maintained in the absence of clinical interventions.
- Within a year and annually thereafter, a trial without maintenance treatment should be instituted.
- The care of non-acute pain symptoms should include an ongoing patient self-management plan performed by the patient regularly and a self-directed pain management plan initiated as indicated:

- An ongoing clinically appropriate self-management plan, typically independent, home-based and self-directed, developed jointly by the provider and patient should be implemented to encourage physical activity and/or work activities despite residual pain, with goal of preserving function.
  - In addition to the self-management plan, a self-directed pain management plan should be developed which can be initiated by the patient in the event that symptoms worsen and function decreases.
  - If deterioration of ability to maintain function is documented, reinstatement of ongoing maintenance may be acceptable.
- Frequency
    - Maximum up to 10 visits/year, after the determination of MMI, according to objectively documented maintenance of functional status.
    - No variance from the maximum frequency is permitted.

## **APPENDIX A: FEAR-AVOIDANCE BELIEFS QUESTIONNAIRE (FABQ)**

**Purpose:** The FABQ<sup>3</sup> was developed to investigate fear-avoidance beliefs. The FABQ consists of 2 sections. The first section (items 1-5) is the Physical Activity section (FABQPA), and the second (items 6-16) is the Work section (FABQW).

**Scoring:** Not all items contribute to the final score; however the patient should still complete all items as these were included when the reliability and validity of the scale was initially established.

Each section is graded separately by adding the responses from the respective scale items (0 – 6 for each item). For scoring purposes, only 4 of the physical activity section items are scored (24 possible points) and only 7 of the work items (42 possible points). The method for scoring each section is outlined below.

### **Scoring the Physical Activity subscale (FABQPA)**

Add items 2, 3, 4, and 5 (the score circled by the patient for these items).

### **Scoring the Work subscale (FABQW)**

Add items 6, 7, 9, 10, 11, 12, and 15 (the score circled by the patient for these items).

### **Interpretation**

The higher the total score, the greater the degree of fear and avoidance beliefs shown by the patient.

**Note:** It is important to ensure that all items are completed, as there is no procedure to adjust for incomplete items.

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<sup>3</sup> Wadell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain*, 1993; 52: 157-168

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 New York Non-Acute Pain Medical Treatment Guidelines

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Name: \_\_\_\_\_

Date: \_\_\_\_\_

Here are some of the things which other patients have told us about their pain. For each statement please circle any number from 0 to 6 to say how much physical activities such as bending, lifting, walking or driving affect or would affect your pain.

	COMPLETELY DISAGREE			UNSURE			COMPLETELY AGREE	
1. My pain is caused by physical activity	0	1	2	3	4	5	6	
2. Physical activity makes my pain worse	0	1	2	3	4	5	6	
3. Physical activity might harm me	0	1	2	3	4	5	6	
4. I should not do physical activities which (might) make my pain worse	0	1	2	3	4	5	6	
5. I cannot do physical activities which (might) make my pain worse	0	1	2	3	4	5	6	

The following statements are about how your normal work affects or would affect your pain.

	COMPLETELY DISAGREE			UNSURE			COMPLETELY AGREE	
6. My pain was caused by my work or by an accident at work	0	1	2	3	4	5	6	
7. My work aggravated my pain	0	1	2	3	4	5	6	
8. I have a claim for compensation for my pain	0	1	2	3	4	5	6	
9. My work is too heavy for me	0	1	2	3	4	5	6	
10. My work makes or would make my pain worse	0	1	2	3	4	5	6	
11. My work might harm me	0	1	2	3	4	5	6	
12. I should not do my normal work with my present pain	0	1	2	3	4	5	6	
13. I cannot do my normal work with my present pain	0	1	2	3	4	5	6	
14. I cannot do my normal work until my pain is treated	0	1	2	3	4	5	6	
15. I do not think that I will be back to my normal work within 3 months	0	1	2	3	4	5	6	
16. I do not think that I will ever be able to go back to that work	0	1	2	3	4	5	6	

## **APPENDIX B: FREQUENTLY USED TESTS OF PSYCHOLOGICAL FUNCTIONING**

### **1. Comprehensive Inventories for Medical Patients**

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

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

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

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

#### **B. Millon™ Behavioral Medical Diagnostic (MBMD™)**

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

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

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

### **2. Comprehensive Psychological Inventories**

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

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

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

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

*Characteristics* – Standardized test normalized on psychiatric patients.

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

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

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

*Characteristics* – Standardized test normalized on community members.

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

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

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

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

**D. Personality Assessment Inventory™ (PAI)**

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

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

*Characteristics* – Standardized test normalized on community members.

### **3. Brief Multidimensional Screens for Medical Patients**

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

#### **A. Brief Battery for Health Improvement, 2nd Edition (BBHI-2™)**

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

*Benefits* – Can identify patients needing treatment for depression and anxiety, and identify patients prone to somatization, pain magnification and self-perception of disability. Can compare the level of factors above to other pain patients and community members. Serial administrations can track changes in measured variables during the course of treatment, and assess outcome.

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

#### **B. Pain Patient Profile (P3®)**

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

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

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

**C. SF-36®**

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

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

*Characteristics* – Non-standardized test without norms.

**D. McGill Pain Questionnaire (MPQ)**

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

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

*Characteristics* – Non-standardized test without norms.

**E. Oswestry Disability Questionnaire (ODQ)**

*What it measures* – Disability secondary to low back pain.

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

*Characteristics* – Non-standardized test without norms.

**F. Visual Analog Scales (VAS)**

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

*Benefits* – Quantifies the patient's pain report, most commonly using a 10 centimeter horizontal line. Serial administrations could be used to track changes in pain reports during the course of treatment and assess outcome.

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

## **G. Numerical Rating Scales (NRS)**

*What it measures* – Numerical report of patients' pain.

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

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

## **4. Brief Multidimensional Screens for Psychiatric Patients**

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

### **A. Brief Symptom Inventory (BSI®)**

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

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

*Characteristics* – Standardized test normalized on community members.

### **B. Brief Symptom Inventory – 18 (BSI-18®)**

*What it measures* – Depression, anxiety, somatization.

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

*Characteristics* – Standardized test normalized on patients with chronic pain associated with cancer.

### **C. Symptom Check List 90 (SCL 90)**

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

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

*Characteristics* – Standardized test normalized on community members.

## **5. Brief Specialized Psychiatric Screening Measures**

### **A. Beck Depression Inventory® (BDI)**

*What it measures* – Depression.

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

*Characteristics* – Standardized test without norms, uses cutoff scores.

### **B. Post Traumatic Stress Diagnostic Scale (PDS®)**

*What it measures* – Post Traumatic Stress Disorder (PTSD).

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

*Characteristics* – Standardized test normalized on community members.

### **C. Center of Epidemiologic Studies – Depression Questionnaire**

*What it measures* – Depression.

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

*Characteristics* – Non-standardized test without norms.

**D. Brief Patient Health Questionnaire™ from PRIME - MD®**

*What it measures* – Depression, panic disorder.

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

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

**E. Zung Questionnaire**

*What it measures* – Depression.

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

*Characteristics* – Non-standardized test without norms.

## APPENDIX C: PAIN ASSESSMENT AND DOCUMENTATION TOOL (PADT) Progress Note

### Pain Assessment and Documentation Tool (PADT™)

Patient Name: \_\_\_\_\_ Record #: \_\_\_\_\_

Assessment Date: \_\_\_\_\_

Current Analgesic Regimen			
Drug Name	Strength (e.g., mg)	Frequency	Maximum Total Daily Dose

The PADT is a clinician-directed interview; that is, the clinician asks the questions, and the clinician records the responses. The Analgesia, Activities of Daily Living, and Adverse Events sections may be completed by the physician, nurse practitioner, physician assistant, or nurse. The Potential Aberrant Drug-Related Behavior and Assessment sections must be completed by the physician. Ask the patient the questions below, except as noted.

Analgesia	Activities of Daily Living																												
<p>If zero indicates “no pain” and ten indicates “pain as bad as it can be,” on a scale of 0 to 10, what is your level of pain for the following questions?</p> <p>1. What was your pain level on average during the past week? (Please circle the appropriate number)</p> <p>No Pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can be</p> <p>2. What was your pain level at its worst during the past week?</p> <p>No Pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can be</p> <p>3. What percentage of your pain has been relieved during the past week? (Write in a percentage between 0% and 100 %.)</p> <hr/> <p>4. Is the amount of pain relief you are now obtaining from your current pain reliever(s) enough to make a real difference in your life?</p> <p>___ Yes ___ No</p>	<p>Please indicate whether the patient’s functioning with the current pain reliever(s) is Better, the Same, or Worse since the patient’s last assessment with the PADT.* (Please check the box for Better, Same, or Worse for each item below.)</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 70%;"></th> <th style="width: 10%; text-align: center;">Better</th> <th style="width: 10%; text-align: center;">Same</th> <th style="width: 10%; text-align: center;">Worse</th> </tr> </thead> <tbody> <tr> <td>1. Physical functioning</td> <td style="text-align: center;">___</td> <td style="text-align: center;">___</td> <td style="text-align: center;">___</td> </tr> <tr> <td>2. Family relationships</td> <td style="text-align: center;">___</td> <td style="text-align: center;">___</td> <td style="text-align: center;">___</td> </tr> <tr> <td>3. Social relationships</td> <td style="text-align: center;">___</td> <td style="text-align: center;">___</td> <td style="text-align: center;">___</td> </tr> <tr> <td>4. Mood</td> <td style="text-align: center;">___</td> <td style="text-align: center;">___</td> <td style="text-align: center;">___</td> </tr> <tr> <td>5. Sleep patterns</td> <td style="text-align: center;">___</td> <td style="text-align: center;">___</td> <td style="text-align: center;">___</td> </tr> <tr> <td>6. Overall functioning</td> <td style="text-align: center;">___</td> <td style="text-align: center;">___</td> <td style="text-align: center;">___</td> </tr> </tbody> </table> <p>*If the patient is receiving his or her first PADT assessment, the clinician should compare the patient’s functional status with other reports from the last office visit.</p>		Better	Same	Worse	1. Physical functioning	___	___	___	2. Family relationships	___	___	___	3. Social relationships	___	___	___	4. Mood	___	___	___	5. Sleep patterns	___	___	___	6. Overall functioning	___	___	___
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4. Mood	___	___	___																										
5. Sleep patterns	___	___	___																										
6. Overall functioning	___	___	___																										

<b>Query to clinician: Is the patient's pain relief clinically significant?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure	
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<b>Progress Note</b> <b>Pain Assessment and Documentation Tool (PADT™)</b>																																																																							
<p style="text-align: center;"><b>Adverse Events</b></p> <p>1. Is patient experiencing any side effects from current pain reliever?    <input type="checkbox"/> Yes    <input type="checkbox"/> No</p> <p>Ask patient about potential side effects:</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 15%;">None</th> <th style="width: 15%;">Mild</th> <th style="width: 15%;">Moderate</th> <th style="width: 5%;"></th> </tr> </thead> <tbody> <tr> <td><b>Severe</b></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>a. Nausea</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>b. 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Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p style="text-align: center;"><b>Potential Aberrant Drug-Related Behavior</b></p> <p style="text-align: center; font-size: small;">This section must be completed by the physician</p> <p><i>Please check any of the following items that you discovered during your interactions with the patient. Please note that some of these are directly observable (e.g., appears intoxicated), while others may require more active listening and/or probing. Use the "Assessment" section below to note additional details.</i></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Purposeful over-sedation</li> <li><input type="checkbox"/> Negative mood change</li> <li><input type="checkbox"/> Appears intoxicated</li> <li><input type="checkbox"/> Increasingly unkempt or impaired</li> <li><input type="checkbox"/> Involvement in car or other accident</li> <li><input type="checkbox"/> Requests frequent early renewals</li> <li><input type="checkbox"/> Increased dose without authorization</li> <li><input type="checkbox"/> Reports lost or stolen prescriptions</li> <li><input type="checkbox"/> Attempts to obtain prescriptions from other doctors</li> <li><input type="checkbox"/> Changes route of administration</li> <li><input type="checkbox"/> Uses pain medication in response to situational stressor</li> <li><input type="checkbox"/> Insists on certain medications by name</li> <li><input type="checkbox"/> Contact with street drug culture</li> <li><input type="checkbox"/> Abusing alcohol or illicit drugs</li> <li><input type="checkbox"/> Hoarding (i.e., stockpiling) of medication</li> <li><input type="checkbox"/> Arrested by police</li> <li><input type="checkbox"/> Victim of abuse</li> <li><input type="checkbox"/> Other: _____</li> <li>_____</li> <li>_____</li> </ul>
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f. Sweating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																																			
g. Fatigue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																																			
h. Drowsiness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																																			
i. Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																																			
_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																																			
j. Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																																			
_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																																			
<p>2. Patients overall severity of side effects?  <input type="checkbox"/> None    <input type="checkbox"/> Mild    <input type="checkbox"/> Moderate    <input type="checkbox"/> Severe</p> <p><b>Assessment: (This section must be completed by the physician.)</b></p> <p>Is your overall impression that this patient is benefiting (e.g., benefits, such as pain relief, outweigh side effects) from opioid therapy?    <input type="checkbox"/> Yes    <input type="checkbox"/> No    <input type="checkbox"/> Unsure</p> <p>Comments: _____</p> <p>_____</p>																																																																							
<p><b>Specific Analgesic Plan:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Continue present regimen</li> <li><input type="checkbox"/> Adjust dose of present analgesic</li> <li><input type="checkbox"/> Switch analgesics</li> <li><input type="checkbox"/> Add/Adjust concomitant therapy</li> <li><input type="checkbox"/> Discontinue/taper off opioid therapy</li> </ul>	<p><b>Comments:</b> _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>																																																																						

<b>Date:</b> _____	<b>Physician's Signature:</b> _____
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Adapted from Chou R, Fanciullo GJ, Fine PG, Adler JA, Ballantine JC, et al. Clinical Guidelines for Use of Chronic Opioid Therapy in Chronic Noncancer Pain. *J Pain*, 2009; 10(2): 113-130

### APPENDIX D: DOSING THRESHOLDS FOR SELECTED OPIOIDS

Opioid	Recommended Dose Threshold for Pain Consult <i>(not equianalgesic)</i>	Recommended Starting Dose for Opioid-Naive Patients	Considerations
Codeine	700mg per 24 hours	30mg q 4–6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient.
Fentanyl Transdermal	25mcg/hour (q 72 hr)		Use only in opioid-tolerant patients who have been taking ≥ 60mg MED daily for a week or longer.
Hydrocodone	100mg per 24 hours	5-10mg q 4–6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. (See acetaminophen warning, Section F.2.c.ii)

Opioid	Recommended Dose Threshold for Pain Consult <i>(not equianalgesic)</i>	Recommended Starting Dose for Opioid-Naive Patients	Considerations
Hydro-morphone	20mg per 24 hours	2mg q 4–6 hours	
Methadone	Special consideration, see Section F.4.b	Special consideration, see Section F.4.b	Methadone is difficult to titrate due to its half-life variability. It may take a long time to reach a stable level in the body. Methadone dose should not be increased more frequently than every 7 days. Do not use as PRN or combine with other long-acting (LA) opioids. (See Section F.4.b)
Morphine	100mg per 24 hours	Immediate-release: 15mg q 4-6 hours Sustained-release: 15mg q 12 hours	Adjust dose for renal impairment.
Oxycodone	70mg per 24 hours	Immediate-release: 5mg q 4-6 hours Sustained-release: 10mg q 12 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. (See acetaminophen warning Section F.2.c.ii).

Opioid	Recommended Dose Threshold for Pain Consult <i>(not equianalgesic)</i>	Recommended Starting Dose for Opioid-Naive Patients	Considerations
Oxymorphone	30mg per 24 hours	Immediate-release: 5-10mg q 4-6 hours  Sustained-release: 10mg q 12 hours	Use with extreme caution due to potential fatal interaction with alcohol or medications containing alcohol.

\*Meperidine and propoxyphene products should not be prescribed for non-acute pain.

## APPENDIX E: URINE DRUG TESTING

Drugs or Drug Classes	Detection Time in Urine	Test to Order	Expected Results	Consideration
<b><i>Opioids or “opiates” – Natural (from opium)</i></b>				
Codeine (Tylenol #2/3/4)	1-3 days	Opiates Immunoassay + GC/MS or LC/MS Opiates	Opiates Immunoassay –positive GC/MS or LC/MS–codeine, possibly morphine & hydrocodone	Immunoassays for “opiates” are responsive for morphine and codeine but do not distinguish which is present. Confirmatory testing is required to reliably identify drug(s) present. Since codeine is metabolized to morphine and small quantities to hydrocodone, these drugs may be found in the urine. Also, morphine may metabolize to produce a small amount (<10%) of hydromorphone.
Morphine (Avinza, Embeda, MS Contin, Kadian)	1-3 days	Opiates Immunoassay + GC/MS or LC/MS Opiates	Opiates Immunoassay –positive GC/MS or LC/MS–morphine, possibly hydromorphone	

Drugs or Drug Classes	Detection Time in Urine	Test to Order	Expected Results	Consideration
<b><i>Opioids – Semisynthetic (derived from opium)</i></b>				
Hydrocodone (Lorcet, Lortab, Norco, Vicodin)	1-3 days	Opiates Immunoassay + GC/MS or LC/MS Opiates	Opiates Immunoassay –positive GC/MS or LC/MS – hydrocodone, possibly hydromorphone	“Opiates” immunoassays may also detect semisynthetic opioids depending on their cross-reactivity pattern. However, a negative result does not exclude use of semisynthetic opioids. Confirmatory testing (GC/MS or LC/MS) is required to verify compliance with the prescribed semisynthetic opioid(s).  Since hydrocodone is metabolized in small amounts to hydromorphone, both may be found in the urine. Likewise, oxycodone is metabolized to oxymorphone, so these may both be present in the urine of oxycodone users. However, the reverse is not
Hydromorphone (Dilaudid, Exalgo)	1-3 days	Opiates Immunoassay + GC/MS or LC/MS Opiates	Opiates Immunoassay –positive GC/MS or LC/MS –hydromorphone	
Oxycodone (Roxicet, OxyContin)	1-3 days	Opiates Immunoassay + GC/MS or LC/MS Opiates	Opiates Immunoassay –positive GC/MS or LC/MS – oxycodone possibly oxymorphone	

Drugs or Drug Classes	Detection Time in Urine	Test to Order	Expected Results	Consideration
Oxymorphone (Opana)	1-3 days	Opiates or Oxycodone Immunoassay + GC/MS or LC/MS Opiates	Opiates or Oxycodone Immunoassay – positive  GC/MS or LC/MS  – oxymorphone	true. In other words, hydromorphone and oxymorphone use does not result in positive screens for hydrocodone and oxycodone, respectively.
<b><i>Opioids – Synthetic (man-made)</i></b>				
Fentanyl	1-3 days	GC/MS or LC/MS Fentanyl	GC/MS or LC/MS  –fentanyl & norfentanyl	Current “opiates” immunoassays do not detect synthetic opioids. Thus, confirmatory testing (GC/MS or LC/MS) is needed to identify these drugs. If the purpose is to document compliance with treatment, the laboratory can be instructed to remove the cutoff concentration so that the presence of lower concentrations can be identified.
Meperidine (Demerol)	1-3 days	GC/MS or LC/MS Meperidine	GC/MS or LC/MS  –normeperidine, possibly meperidine	
Methadone (Methadose)	3-7 days	Methadone Immunoassay + GC/MS or LC/MS Methadone	Methadone Immunoassay – positive  GC/MS or LC/MS  – methadone & EDDP	

Drugs or Drug Classes	Detection Time in Urine	Test to Order	Expected Results	Consideration
Propoxyphene (Darvon, Darvocet)	1-3 days	Propoxyphene Immunoassay + GC/MS or LC/MS Propoxyphene	Propoxyphene Immunoassay – positive  GC/MS or LC/MS  – propoxyphene & norpropoxyphene	
<b>Others</b>				
Alcohol	Up to 8 hours	Alcohol	Alcohol –see Consideration	Additional testing for alcohol metabolites, ethyl glucuronide (EtG) or ethyl sulfate (EtS) can identify alcohol up to 80 hours after consumption.
Amphetamines	2-3 days	Amphetamines, Methamphetamines or MDMA Immunoassay + GC/MS or LC/MS Amphetamines	Amphetamines, methamphetamines or MDMA Immunoassay – see Consideration  GC/MS or LC/MS  – amphetamine, methamphetamine or MDMA	Amphetamines immunoassays are highly cross-reactive so results should be interpreted cautiously, and may require consultation with the lab. They may detect other sympathomimetic amines, such as ephedrine, pseudoephedrine or selegiline. Confirmatory testing can identify which amphetamine is present.

Drugs or Drug Classes	Detection Time in Urine	Test to Order	Expected Results	Consideration
Barbiturates	1-3 days w/short-acting; up to 30 days w/long-acting	Barbiturates Immunoassay	Barbiturates Immunoassay –see Consideration	The clearance half-life of intermediate-acting barbiturates averages 24 hours. It takes about 5 to 7 half-lives to clear 98% of a drug dose. Thus, the presence of an intermediate-acting barbiturate indicates exposure within 5-7 days.
Benzodiazepines	1-3 days w/short-acting; up to 30 days w/long-acting	Benzodiazepines Immunoassay	Benzodiazepines Immunoassay –see Consideration  GC/MS or LC/MS  – alprazolam, diazepam, clonazepam, lorazepam, etc.	Immunoassays for benzodiazepines have a 28% overall false negative rate and vary in cross-reactivity. Certain benzodiazepines (clonazepam and alprazolam) have limited detectability by most available immunoassays. Confirmatory testing is needed when use is expected or suspected.

Drugs or Drug Classes	Detection Time in Urine	Test to Order	Expected Results	Consideration
Cocaine or benzoylecgonine	2-4 days	Cocaine Metabolites Immunoassay	Cocaine Metabolites Immunoassay –see Consideration	Cocaine immunoassays do not cross-react with other topical anesthetics that end in “caine” (e.g. lidocaine) and are highly specific for cocaine use.
Marijuana	2-4 days; up to 30 days w/chronic heavy use	Cannabinoids (THC) Immunoassay	Cannabinoids Immunoassay –see Consideration GC/MS or LC/MS – THC	THC may be an indicator of the patient’s risk category. Prescribers should have an office policy, discuss with the patients reason for use and adjust monitoring plan accordingly.

## APPENDIX F: PATIENT INFORMED CONSENT FOR OPIOID TREATMENT FORM

PATIENT INFORMED CONSENT FOR OPIOID TREATMENT FORM	
Patient Name _____	WCB Claim #: _____
Doctor Name _____	
<p>I plan to take a pain medicine called OPIOIDS. This pain medicine may help improve my pain but it may also cause some serious problems. The problems may be worse if I mix the pain medicine with alcohol or other drugs.</p> <p>I understand that the pain medicine I will be taking may cause serious problems including:</p> <ul style="list-style-type: none"><li>⇒ Confusion.</li><li>⇒ Poor judgment.</li><li>⇒ Nausea (a stomach ache).</li><li>⇒ Vomiting.</li><li>⇒ Constipation (hard stools that may be painful to push out).</li><li>⇒ Sleepy or drowsy feeling.</li><li>⇒ Poor coordination and balance (such as feeling unsteady, tripping, and falling).</li><li>⇒ Slow reaction time.</li><li>⇒ Slow breathing or I can stop breathing - which could cause me to die.</li><li>⇒ More depression (such as feeling sad, hopeless, or unable to do anything).</li><li>⇒ Dry mouth.</li><li>⇒ Increased feeling of pain (hyperalgesia).</li><li>⇒ Addiction (it may be very hard to stop taking the pain medicine when I'm ready to quit).</li><li>⇒ For men: the pain medicine may lead to less interest in sex and poor sexual performance.</li><li>⇒ For pregnant women, the pain medicine may hurt my unborn child and may cause my child to be born addicted to the pain medicine.</li></ul> <p>I will tell my doctor if I have any of the problems listed here.</p> <p>I understand there may be other problems caused by the pain medicine, in addition to the problems listed here.</p> <p>I understand that these problems may get better when I stop taking the pain medicine.</p> <p>My doctor has reviewed the serious problems that this pain medicine may cause. My doctor has answered all questions that I have about this pain medicine and the serious problems it may cause.</p> <p>Patient Signature: _____ Date: _____</p> <p><b><i>I attest that this form was reviewed by me with the patient and all questions were answered.</i></b></p> <p>Doctor Signature: _____ Date: _____</p>	

## APPENDIX G: PATIENT UNDERSTANDING FOR OPIOID TREATMENT FORM

PATIENT UNDERSTANDING FOR OPIOID TREATMENT FORM	
Patient Name _____	WCB Claim #: _____
Doctor Name _____	
I am taking a pain medicine called <b>OPIOIDS</b> to help improve my pain.	
<b>I agree</b> (the patient must initial each box to show agreement):	
<input type="checkbox"/> I will take my pain medicine exactly the way my doctor tells me to. That means I will take the right amount of pain medicine at the right time.  <input type="checkbox"/> I will tell my doctor about any new medical problems.  <input type="checkbox"/> I will tell my doctor about all medicine I take, and will tell my doctor if I am given any new medicines.  <input type="checkbox"/> I will tell my doctor if I see another doctor, or if I go to the Emergency Room.  <input type="checkbox"/> I will only get my pain medicine prescription from this doctor. My doctor's name is listed on the top of this page.  <input type="checkbox"/> If my doctor is away, I will only get medicine from the doctor who is in charge while my doctor is away.  <input type="checkbox"/> I will only get my pain medicine from one pharmacy (drug store).  <input type="checkbox"/> I will follow my doctor's directions about therapy, exercises and physical things to do so I can learn to live with my pain.  <input type="checkbox"/> I will do what I can to get back to work.  <input type="checkbox"/> I will not drink alcohol or use any other drugs unless I am told to do it by my doctor.	<input type="checkbox"/> When I am asked, I will get lab tests to see if I am taking my medicines the right way.  <input type="checkbox"/> If the lab tests show that I am not taking the medicines the way I should, my doctor may cut down or stop my medicine or send me to a specialist or special program to help care for me.  <input type="checkbox"/> I will store my pain medicine in a safe place where other people cannot take it.  <input type="checkbox"/> I will keep my scheduled appointments. If I must miss an appointment, I will call my doctor to cancel at least 24 hours before the appointment.  <input type="checkbox"/> My doctor may stop giving me pain medicine if: <ul style="list-style-type: none"> <li>• I do not follow this agreement.</li> <li>• The pain medicine is not helping me.</li> <li>• I'm not meeting my goals in active therapy.</li> <li>• My pain or my functions do not improve.</li> <li>• I have bad side effects from the pain medicine.</li> <li>• I become addicted to the pain medicine.</li> <li>• I give or sell the pain medicine to someone else.</li> </ul> <input type="checkbox"/> I am not pregnant and I will call my doctor as soon as possible if I think I may be pregnant.
Patient Signature: _____	Date: _____
<b><i>I attest that this form was reviewed by me with the patient and all questions were answered.</i></b>	

Doctor Signature:

Date:

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