

# Medical Treatment Guidelines

**Non-Acute Pain** 

# Effective May 2, 2022

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## **Contributors**

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## New York State Workers' Compensation Board Medical Advisory Committee

## Joseph Canovas, Esq.

Special Counsel New York State AFL-CIO

## Linda L. Clark, MD, MS (FACOEM, FACPM)

Senior Health Advisor, Common Ground Health, Rochester, NY

## Kenneth B. Chapman, MD

Director Pain Medicine, SIUH Northwell Health Systems Assistant Clinical Professor, NYU Langone Medical Center Adjunct Assistant Professor, Hofstra Medical School

## Cristina Demian, MD, MPH, FACOEM

Medical Director, Finger Lakes Occupational Health Services Associate Professor, University of Rochester Medical Center Department of Environmental Medicine

## Tildabeth Dorscher, MD

Fellowship Director, Addiction Medicine Fellowship, Jacob's School of Medicine Medical Director, Phoenix House of NYC and LI Clinical Assistant Professor, Department of Family Medicine, University at Buffalo

## Robert Goldberg, DO

Senior Attending Physician, Department of Rehabilitation, Beth Israel Hospital and Medical Center of NYC Faculty Institute for Family Health at the Icahn School of Medicine at Mount Sinai

Clinical Professor of Rehabilitation Medicine, Philadelphia College of Osteopathic Medicine

Member Council on Medical Education of the American Medical Association

Former Dean and Professor of Physical Medicine and Rehabilitation and Health Policy Touro College of Osteopathic Medicine and

Former Clinical Associate Professor of Rehabilitation Medicine, New York Medical College

## Hemant Kalia, MD MPH FIPP

Program Director, Interventional Spine & Pain Fellowship. Rochester Regional Health System, Rochester, NY

Clinical Assistant Professor, Physical Medicine & Rehabilitation, University of Rochester, NY

Clinical Assistant Professor: Department of Internal Medicine, Physical Medicine & Rehabilitation and Pain Management. Lake Erie College of Osteopathic Medicine

Board of Directors, Monroe County Medical Society

Editor-in-Chief, Advances in Clinical Medical Research & Healthcare Delivery

## Frank Kerbein, SPHR

Director, Center for Human Resources The Business Council of New York State, Inc.

## Winston C. Kwa, MD MPH

Medical Director, Mount Sinai Selikoff Centers for Occupational Health-Mid-Hudson Valley Associate Professor, Mount Sinai School of Medicine

## Jade Malcho, MD

Instructor of Clinical Emergency Medicine Addiction Medicine Physician Department of Emergency Medicine University of Rochester Medical Center

## Scott Matthews, MD

Fellow, Addiction Medicine Fellowship, Jacob's School of Medicine State University of New York at Buffalo

## Jacqueline M Moline, MD, MSc

Professor and Chair, Occupational Medicine, Epidemiology and Prevention At Zucker School of Medicine at Hofstra/Northwell Director, Occupational and Environmental Medicine of Long Island Director, Northwell Queens WTC Clinical Center

## Nicholas E. Nacca, MD, FAACT

Assistant Professor of Emergency Medicine Department of Emergency Medicine University of Rochester Medical Center

## Joseph Pachman, MD, PhD, MBA, MPH

Licensed Psychologist and Physician Board Certified in Occupational Medicine Fellow in ACOEM Vice President and National Medical Director, Liberty Mutual

## James A. Tacci, MD, JD, MPH

Medical Director and Executive Medical Policy Director. New York State Workers' Compensation Board

## Edward C. Tanner, MD

Chair, Department of Orthopaedics at Rochester General Hospital Past President, New York State Society of Orthopaedic Surgeons (NYSSOS) Member, American Academy of Orthopaedic Surgeons (AAOS) Member, American Association of Hip and Knee Surgeons (AAHKS)

## **Timothy Wiegand, MD**

Associate Professor, Emergency Medicine, Addiction Medicine and Medical Toxicology University of Rochester Medical Center

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## **General Guideline Principles** Α.

The principles summarized in this section are key to the intended application of the New York State Medical Treatment Guidelines (MTG) and are applicable to all Workers' Compensation Medical Treatment Guidelines.

#### **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 with a focus on a 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 may be considered and given relative weight when the pain has anatomic and physiologic correlation in proportion to the injury.

#### **A.4 Re-Evaluate Treatment**

If a given treatment or modality is not producing positive results within a well-defined timeframe, 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. These timeframes may be slightly longer in the context of conditions that are inherently mental health issues, and shorter for other nonmusculoskeletal medical conditions (e.g. pulmonary, dermatologic etc.). Recognition that treatment failure is at times attributable to an incorrect diagnosis a failure to respond should prompt the clinician to reconsider the diagnosis in the event of an unexpected poor response to an otherwise rational intervention.

#### **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** Acuity

Acute, Subacute and Chronic are generally defined as timeframes for disease stages:

- Acute Less than one month
- Subacute One to three month, and
- · Chronic greater than three months.

#### **Initial Evaluation A.7**

Initial evaluation refers to the acute timeframe following an injury and is not used to define when a given physician first evaluates an injured worker (initial encounter) in an office or clinical setting.

#### **A.8 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.

#### **Treatment Time Frames A.9**

Treatment time frames for specific interventions commence once treatments have been initiated, not on the date of injury. It is recognized that treatment 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.10 Delayed Recovery

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 and re-evaluation of the treatment program should be performed. When addressing a clinical issue that is not inherently a mental health issue, assessment for potential barriers to recovery (yellow flags/psychological issues) should be ongoing throughout the care of the patient. At 6-12 weeks, alternate treatment programs, including formal psychological or psychosocial evaluation should be considered. Clinicians must be vigilant for any pre-existing mental health issues or subsequent, consequential mental health issues that may be impacting recovery. For issues that are clearly and inherently mental health issues from the outset (i.e. when it is evident that there is an underlying, work-related, mental health disorder as part of the claim at issue), referral to a mental health provider can and should occur much sooner. Referrals to mental health providers 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.11 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.12 Active Therapeutic Exercise Program

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

# A.13 Diagnostic Imaging And Testing Procedures

Clinical information obtained by history taking and physical examination should be the basis for selection of imaging procedures and interpretation of results. All diagnostic procedures have characteristic specificities and sensitivities for various diagnoses. Usually, selection of one procedure over others depends upon various factors, which may include: relative diagnostic value; risk/benefit profile of the procedure; availability of technology; a patient's tolerance; and/or the treating practitioner's familiarity with the procedure.

When a diagnostic procedure, in conjunction with clinical information, provides sufficient information to establish an accurate diagnosis, a second diagnostic procedure is not required. However, a subsequent diagnostic procedure including a repeat of the original (same) procedure can be performed, when the specialty physician (e.g. physiatrist, sports medicine physician or other appropriate specialist) radiologist or surgeon documents that the initial study was of inadequate quality to make a diagnosis. Therefore, in such circumstances, a repeat or complementary diagnostic procedure is permissible under the MTG.

It is recognized that repeat imaging studies and other tests may be warranted by the clinical course and/or 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/or therapeutic injections when clinically indicated, and post-operatively to follow the healing process. Regarding serial imaging, (including x-rays, but particularly CT scans), it must be recognized that repeat procedures result in an increase in cumulative radiation dose and associated risks.

A given diagnostic imaging procedure may provide the same or distinctive information as obtained by other procedures. Therefore, prudent choice of procedures(s) for a single diagnostic procedure, a complementary procedure in combination with other procedures(s), or a proper sequential order in multiple procedures will ensure maximum diagnostic accuracy, minimize the likelihood of adverse effect on patients, and promote efficiency by avoiding duplication or redundancy.

# A.14 Surgical Interventions

Consideration 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 where applicable, evidence-based outcomes, and specific surgical experience.

# A.15 Pre-Authorization

All diagnostic imaging, testing procedures, non-surgical and surgical therapeutic procedures, and other therapeutics 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 procedures listed in section 324.3(1)(a) of Title 12 NYCRR. 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.16 Psychological/Psychiatric Evaluations

In select patients, mental health evaluations are essential to make, secure or confirm a diagnosis. Of course, the extent and duration of evaluations and/or interventions by mental health professionals may vary, particularly based on whether: the underlying clinical issue in the claim is inherently a mental health issue; or there is a mental health issue that is secondary or consequential to the medical injury or illness that is at issue in the claim in question; or there is a pre-existing, unrelated mental health issue that has been made worse by, or is impeding the recovery from (or both) the medical injury or illness that is at issue in the claim in question.

Tests of psychological function or psychometric testing, when indicated, can be a valuable component of the psychological evaluation in identifying associated psychological, personality and psychosocial issues. Although these instruments may suggest a diagnosis, neither screening nor psychometric tests are capable of making a diagnosis. The diagnosis should only be made after careful analysis of all available data, including from a thorough history and clinical interview.

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: When assessing for a pre-existing, unrelated mental health issue that has been made worse by, or is impeding the recovery from (or both) a work-related, medical injury or illness, then a one-time visit for initial psychiatric/psychological encounter should be sufficient, as care would normally be continued by the prior treating provider. If psychometric testing is indicated by findings in the initial encounter, time for such testing should not exceed an additional three hours of professional time. For conditions in which a mental health issue is a central part of the initial claim, or in which there is a mental health issue that is secondary or consequential to the work-related, medical injury or illness, that is part of the claim in question, then more extensive diagnostic and therapeutic interventions may be clinically indicated, and are discussed in detail in the Medical Treatment Guidelines for such mental health conditions.

# A.17 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. For all psychological/psychiatric interventions, there must be an assessment and treatment plan with measurable behavioral goals, time frames and specific interventions planned.

- Time to produce effect: two to eight weeks.
- Optimum duration: six weeks to three months.
- Maximum duration: three to six months.
- Counseling is not intended to delay but rather to enhance functional recovery.

## For PTSD Psychological Intervention:

- Optimum duration three to six months.
- Maximum duration: nine to twelve months.

For select patients, longer supervision and treatment may be required, and if further treatment 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 four weeks during the first six months of treatment. For treatment expected to last six to twelve months, such documentation should be provided every four to eight weeks. For long-term treatment beyond twelve months, such documentation should be provided every eight to twelve weeks. All parties should strive for ongoing and continuous communications, in order to facilitate seamless, continuous and uninterrupted treatment.

# A.18 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 and behavioral; (j) visual; and (k) sensory perceptual factors.

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

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. An FCE is not indicated early during a treatment regime for any reason including one to support a therapeutic plan.

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.

## A.19 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 the 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 of returning an injured worker to work drops progressively the longer the worker has been out of work.

## A.20 Job Site Evaluation

The treating physician may communicate with the employer or employer's designee, either in person, by video conference, or by telephone, to obtain information regarding the individual or specific demands of the patient's pre-injury job. This may include a description of the exertional demands of the job, the need for repetitive activities, load lifting, static or awkward postures, environmental exposures, psychological stressors and other factors that would pose a barrier to re-entry, risk of re-injury or disrupt convalescence. When returning to work at the patient's previous job tasks or setting is not feasible, given the clinically determined restrictions on the patient's activities, inquiry should be made about modified duty work settings that align with, the patient's condition in view of proposed work activities/demands in modified duty jobs. It should be noted, that under certain circumstances, more than one job site evaluation may be indicated.

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, as can video conferences, conducted from the worksite and ideally workstation or work area.

Frequency: one or two contacts

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

The physician shall document the conversation.

## Other

## A.21 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.22 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.23 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.24 Scope Of Practice

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

# **Non-Acute Pain**

# Effective date will coincide with the launch of OnBoard: Limited Release

## **Definition** B

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 despite 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 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 table 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 versus 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 their 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 Intervention**

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**

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]).
- List of activities: Such as gait, weight bearing, or resistance, which D.1.a.vi 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 history of psychological problems.
- D.1.a.xvi Other confounding psychosocial issues should be explored, including the presence of psychosocial, psychiatric, or social factors.
- D.1.a.xvii 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.
- Work History/Occupation: To include both impact of injury on job duties D.1.b.ii 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.v 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.vi Review of Systems Check List: Determine if there is any interplay between the pain complaint and other medical conditions. A review of systems should be conducted, the elements of which may include signs or symptoms related to the following systems: constitutional symptoms; eyes: ear, nose, mouth, and throat; cardiovascular; respiratory; gastrointestinal; genitourinary; musculoskeletal; integumentary/breast; neurological; psychiatric; endocrine; hematologic/lymphatic; allergic/immunologic. Based on the underlying condition being addressed, and clinical judgement, the breadth and focus of the review of systems can be tailored on a case by case basis.
- D.1.b.vii 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.viii 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.ix Alcohol Use: Quantify, i.e., drinks per week.
- D.1.b.x Smoking History: Include use of nicotine substitutes.
- D.1.b.xi 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:
  - If applicable, Waddell Signs, which include 5 categories of D.1.c.ix.a 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 three out of five of these categories, but not to isolated findings. Waddell Signs cannot be used to predict or diagnose malingering.

The presence of three out of five 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:

- History of Injury. The history of the injury should be reported in the D.2.a.i 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.

#### **Health History** D.2.a.ii

- 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 nonacute 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 Studies, 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.13 for quidelines on the performance of diagnostic or repeat diagnostic procedures.)

## **Non-Pharmacological Approaches** Ε.

## 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 sixth-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, selfmanagement 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-Pharmacological 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 nonacute pain, the standard of care for that injury should be observed.

For those instances in the New York Non-Acute Pain Medical Treatment Guidelines in which durations of treatment are given in terms of either a time duration or a specific number of sessions, the longer of the two durations of treatment should be utilized, in order to maximize the likelihood of adequacy of treatment.

## Non-Acute Pain Management Programs (Interdisciplinary or E.4 **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) with appropriate training or experience (which may include, for example, but not necessarily be limited to physicians board certified in Physical Medicine & Rehabilitation, Pain Medicine, Psychiatry, or Occupational Medicine).

# 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 and/or group communications 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 selfmanagement, 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: three to eight 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 three hours of professional time.

## E.8.d Psychological Intervention

Optimum duration: six weeks to three months.

Maximum duration: three to six 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 four weeks during treatment. For longterm, non-acute and clinically stable patients, clinical follow-up and corresponding documentation may be expanded to two to three-month intervals.

## E.8.e Biofeedback

Biofeedback is a form of behavioral medicine that helps patients learn selfawareness 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 using home training tapes. The 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: three to four sessions.
- Frequency: one or two times per week.
- Optimum Duration: five to six sessions.
- Maximum Duration: ten 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**

Note: It is vitally important that prescribers appreciate the potential for drug-drug interactions and the potential for one prescription to significantly increase the likelihood that a patient will experience adverse side-effects when multiple medications are being prescribed. This particularly true for any medication that is potentially sedating, a respiratory depressant, habit forming or addictive. Therefore, extreme caution should be exercised whenever one is considering prescribing more than one medication with these properties.

**Note:** For patients with non-acute pain, or certain long-term psychiatric illnesses, who are on stable doses of ongoing pharmacologic therapy, stable and uninterrupted dosing can be critical. Therefore, when clinically appropriate, prescribers may consider writing prescriptions with two to six monthly refills, in order to reduce the likelihood of prescriptions expiring in-between monthly to tri-monthly follow-up appointments.

Note: This guideline uses the nomenclature MED (Morphine Equivalent Dose). While this has historically been the standard terminology, some authoritative guidelines have moved to the term MME (Morphine Milligram Equivalent).

# 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 overthe-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, 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 selfmanagement 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-thecounter medications must 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 opioid 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.

#### F.1.e.i Alpha-Acting Agents (e.g. clonidine)

**Not Recommended** - 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.ii **Anticonvulsants**

**Not Recommended** - as 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.

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.ii.a Carbamazepine

**Recommended** - 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.ii.b Gabapentin

**Recommended** - 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 (for example nortriptyline), gabapentin provides more effective pain relief than monotherapy with either drug. Gabapentin given with opioids (for example 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 four to eight weeks for titration. Maximum dosage to 1800 mg and in rare instances up to 2400 mg per day.

For guidance on tapering of gabapentin, refer to Appendix J.

#### F.1.e.ii.c Pregabalin

**Recommended** - 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 six to eight weeks.

For guidance on tapering of pregabalin, refer to Appendix J.

#### F.1.e.ii.d **Topiramate**

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.ii.e Lamotrigine

**Not Recommended** - for most patients.

## F.1.e.iii Antidepressants

Antidepressants are classified into several 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.

Tricyclic Antidepressants (TCAs) (e.g. amitriptyline, F.1.e.iii.a desipramine, nortriptyline, doxepin, imipramine, trimipramine)

> **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 anticholinergic side effects when TCAs are prescribed always needs to be considered, particularly with older patients.

## F.1.e.iii.b Selective Serotonin Reuptake Inhibitors (SSRIs) (e.g., citalopram, fluoxetine, paroxetine, sertraline, fluvoxamine, escitalopram)

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.iii.c Selective Serotonin Norepinephrine Reuptake Inhibitors (SSNRI)/Serotonin Norepinephrine Reuptake Inhibitors (SNRI) (e.g., venlafaxine, duloxetine and milnacipran).

Not Recommended - as a first- or second-line treatment and are reserved for patients who fail other regimes due to side effects.

Duloxetine has been FDA approved for treatment of diabetic neuropathic pain, fibromyalgia and chronic musculoskeletal pain.

Milnacipran has been FDA approved for treatment of fibromyalgia and has a success rate like imipramine.

## F.1.e.iii.d Atypical Antidepressants/Other Agents (e.g., bupropion, mirtazapine, nefazodone)

**Recommended** - for depression.

**Not Recommended** - for neuropathic pain.

### F.1.e.iii.e Compound Medications

**Not Recommended** – topical, oral and/or system medications.

#### F.1.e.iii.f Glucosamine/Chondroitin

Not Recommended

### F.1.e.iii.g Hypnotics and Sedatives

(e.g., benzodiazepines, zaleplon, eszopiclone, zolpidem)

**Not Recommended** – 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.

For guidance on tapering Benzodiazepines and/or benzodiazepines with concurrent opioids, refer to Appendix I.

## F.1.e.iv Non-Steroidal Anti-inflammatory Drugs (NSAIDs) for Treatment of Non-Acute Pain

For most patients, ibuprofen, naproxen, or other older generation NSAIDs are recommended as first-line medications. Acetaminophen (or the analog paracetamol) may be a reasonable alternative to NSAIDs for patients who are not candidates for NSAIDs, although most evidence suggests acetaminophen is modestly less effective. There is evidence that NSAIDs are as effective for relief of pain as opioids (including tramadol) and less impairing.

**Recommended** - for treatment of nonacute pain.

*Indications* – For non-acute pain, NSAIDs are recommended for treatment. Over-the-counter (OTC) agents may suffice and should be tried first.

Frequency/Duration: As needed use may be reasonable for many patients.

Indications for Discontinuation: Resolution of symptoms, lack of efficacy, or development of adverse effects, that necessitate discontinuation.

#### F.1.e.v **NSAIDs for Patients at High Risk of Gastrointestinal Bleeding**

**Recommended** – for concurrent use of cytoprotective classes of drugs: misoprostol, sucralfate, histamine Type 2 receptor blockers, and proton pump inhibitors for patients at high risk of gastrointestinal bleeding.

Indications: For patients with a high-risk factor profile who also have indications for NSAIDs, cytoprotective medications should be considered, particularly if longer term treatment is contemplated. At-risk patients include those with a history of prior gastrointestinal bleeding, elderly, diabetics, and cigarette smokers.

Frequency/Dose/Duration: Proton pump inhibitors, misoprostol, sucralfate, H2 blockers recommended. Dose and frequency per manufacturer. There is not generally believed to be substantial differences in efficacy for prevention of gastrointestinal bleeding.

Indications for Discontinuation: Intolerance, development of adverse effects, or discontinuation of NSAID. Celecoxib should be only be used with extreme caution in patients who are concurrently taking Aspirin, with strict adherence to dosing recommendations of both medications to assure that patients allow ample time between self-administration of these medications.

### F.1.e.vi NSAIDs for Patients at Risk for Cardiovascular Adverse Effects

Patients with known cardiovascular disease or multiple risk factors for cardiovascular disease should have the risks and benefits of NSAID therapy for pain discussed.

**Recommended** - Acetaminophen or aspirin as the first-line therapy appear to be the safest regarding cardiovascular adverse effects.

**Recommended** - If needed, NSAIDs that are non-selective are preferred over COX-2 specific drugs. 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, the NSAID should be taken at least 30 minutes after or 8 hours before the daily aspirin.

## F.1.e.vii Acetaminophen for Treatment of Non-Acute Pain

**Recommended** - for treatment of non-acute pain, particularly in patients with contraindications for NSAIDs.

*Indications*: All patients with non-acute pain.

Dose/Frequency: Per manufacturer's recommendations; may be utilized on an as-needed basis. There is evidence of hepatic toxicity when exceeding four gm/day.

Indications for Discontinuation: Resolution of pain, adverse effects or intolerance.

## F.1.e.viii Topical Medications

**Recommended** – in select patients for treatment of non-acute pain, including topical creams, ointments, and lidocaine patches

Rationale for Recommendation - TOPICAL DRUG DELIVERY (e.g., capsaicin, topical lidocaine, topical NSAIDs and topical salicylates and nonsalicylates) 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. Prescribers should consider that topical medication can result in toxic blood levels.

**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.

**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.

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).

**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.1.e.ix N-Methyl-D-Aspartic Acid Receptor Antagonists (e.g., ketamine)

Not Recommended - either via oral or dermal routes.

#### F.1.e.x Selective Cyclo-oxygenase-2 (COX-2) Inhibitors

**Recommended** – 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.

Celecoxib should be only be used with extreme caution in patients who are concurrently taking Aspirin, with strict adherence to dosing recommendations of both medications to assure that patients allow ample time between self-administration of these medications.

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.xi **Skeletal Muscle Relaxants** (e.g., baclofen, cyclobenzaprine, metaxalone, tizanidine)

> **Recommended** - for acute musculoskeletal injury or exacerbation of iniurv.

**Not Recommended** - chronic use of any centrally acting muscle relaxant 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.

### **Opioids: Initiating Transitioning and Managing Long-Term Oral** F.2 **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, 1 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
- 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.

#### Risk Assessment/Stratification F2aiii

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 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)

Opioid Risk Tool		Mark each box that applies	Item score if female	Item score if male
Family history of substance abuse	<ul><li> Alcohol</li><li> Illegal drugs</li><li> Prescription drugs</li></ul>		1 2 3	3 3 4
2.Personal History of substance abuse	<ul><li> Alcohol</li><li> Illegal drugs</li><li> Prescription drugs</li></ul>		3 4 5	3 4 5
3.Age (mark box if 16-45)			1	1
4.History of preadolescent sexual abuse			3	0
5.Psychological disease	<ul> <li>Attention-deficit disorder, obsessive- compulsive disorder, bipolar disorder,</li> </ul>		2	2
	schizophrenia • Depression		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. <i>Pain Med.</i> 25: 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 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 seven to ten days is advised to titrate dosage and assess clinical efficacy.
- During dosage titration, advise the patient to avoid engaging in safety-sensitive occupational and nonoccupational 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 based on 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 reinstitution of previously successful treatment plans.
- Continuing review of overall therapy plan regarding nonopioid 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 selfmanagement.
- Several parts of these guidelines recommend consideration of referral to specialists in Pain Medicine and/or Addiction Medicine. These recommendations should not be considered synonymous with a recommendation to taper, deprescribe or discontinue any specific medication. Rather, they are a recommendation to enlist additional expertise.
- 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 comanagement 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).
- o 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, or if patients are requiring > 50

MED/24hrs, 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.
- o 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

Common Initial Side Effects	<ul> <li>Nausea</li> <li>Vomiting</li> <li>Drowsiness / sedation</li> <li>Unsteadiness</li> <li>Confusion</li> </ul>
Occasional Side Effects	<ul> <li>Dry mouth</li> <li>Sweating</li> <li>Pruritus</li> <li>Hallucinations</li> <li>Myoclonus</li> </ul>
Other Side Effects	Respiratory depression     Psychological dependence
Long Term Side Effects	<ul> <li>Constipation – should be anticipated and treated prophylactically with stool softeners, laxatives and increased fluids as clinically indicated.</li> <li>Nausea</li> <li>Vomiting</li> <li>Sexual dysfunctions</li> </ul>
Drug Metabolism Interactions	<ul> <li>Adverse effects if taken with mixed opioid agonist-antagonists</li> <li>Adverse effects if taken with sedating medications         (Benzodiazepines, antihistamines, diphenhydramine and prescription medications such as hydroxyzine, hypnotics)</li> <li>Adverse effects if taken with alcohol</li> </ul>
Hyperalgesia	An exaggerated pain response from usually painful stimulation
Allodynia	Pain due to a non-noxious stimulus that does not normally provoke pain

### Tolerance Dependence Addiction

- Tolerance occurs when higher and higher doses of an opioid are required to maintain the same degree of analgesia
- Dependence appropriate use with withdrawal symptoms if the drug is stopped
- Addiction escalating, uncontrolled use
- 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 newborn 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 (or NP/PA) who signs the form, or during his/her absence, by the covering physician (or NP/PA).
  - Requirement to continue active therapy.
  - Understanding of the need to pursue other pain management techniques in order to function with nonacute 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 nonprescribed 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.

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 (≥ 8 or opioid dose >100 mg/MED/day	Frequent (At least 3-4/year)

<sup>&</sup>lt;sup>2</sup> APS-AAPM Opioid Treatment Guidelines

Aberrant Behavior	At time of visit  Note: address aberrant behavior in person, not by phone
	not by phone

- 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] and Table 4 above.)
- Conducting UDTs with a frequency greater than those recommended in Table 4 should include an articulated medical justification for the increased frequency by the ordering provider.
- The specific drugs tested for in the UDT may be determined on a case specific basis based on the clinical judgement of the ordering provider. If excessively large test panels are ordered, providers may be requested to explain their medical rationale.
- 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 opioid medication as a consequence of the refusal. Prescription of opioid pain medications remains at the discretion of the provider throughout the clinical course of treatment, and a patient's refusal to participate in even a single UDT may be the basis for a provider's decision to not initiate (or to discontinue) opioid therapy.
- 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 (but not necessarily be limited to) evidence that patient is taking any non-prescribed drug(s) or not taking those drugs prescribed as part of treatment. Noncompliance can also be a refusal to undergo UDT, as noted above.
- The frequency of UDT is based on the clinical judgement of the treating provider, applying the guidelines set forth herein (see Tables 2 and 4 above). Providers need not feel compelled to

perform UDTs at the request of an external third party, if such request is not consistent with these guidelines.

- Employers cannot use test results to fire or discipline a worker in any discriminatory or retaliatory 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 nonprescribed 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 typically not to exceed more than one month (unless clearly articulated medical contraindications exist) or in a manner as articulated elsewhere in this guideline or its Appendices.
- As an alternative, a three to five day inpatient medically assisted withdrawal (detox) program can be considered, typically under the supervision of a physician who is appropriately trained and/or board certified in addiction medicine, and 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 opioid 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 opioidnaïve 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, and not causing any discernable adverse side effects, it may be appropriate to continue the 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.

**Recommended** - after calculating the appropriate conversion dose, the dose should be reduced by 50% to ensure 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 30mg

**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
Meperidine*	300 mg	10
Methadone, Tramadol and Tapenade	Dose equivalents unreliable	

<sup>\*</sup>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)

Current Morphine Equivalence (mg/day)	Recommended Transdermal Fentanyl Patch Dose <i>(72-hour</i> <i>patch)</i>
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 three days after the initial dose and every six 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 overdosage.
- 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 greater than or equal to 100mg/MED
    - In general, the total daily dose of opioid should not exceed 100 mg/oral MED and for longer term, low-dose therapy, the total daily dose should generally not exceed 50 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 and without adverse side effects 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

Prescribing Opioid Doses		
Less than 50 mg MED/day	Greater than or equal to 50 mg MED/day	
No assistance from a paint management consultant needed if the prescriber is documenting sustained improvement in both function and pain.	When considering doses greater or equal to 50 mg MED/day, consultation with a physician who is board certified in Pain Medicine or Physiatry is strongly recommended	
Consider getting consultative assistance if frequent adverse effects or lack of response is evident in order to address: <ul> <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>	In general, the total daily dose of opioid should not exceed 100mg Oral MED.  Risks substantially increase at doses at or above 100mg, so early attention to this benchmark dose is worthwhile.	
	Seek assistance from a pain management consultant to address:  O Potential alternative treatments to opioids; O Risk and benefit of a possible trail with opioid dose above 50 MED/day; O Most appropriate way to document improvement in function and pain; and O Possible need for consultation from other specialists, e.g. Addiction Medicine or Pain Psychologist.	

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	0.1

<sup>\*</sup> See Example below

Note: The US CDC recommends providers consult the manufacturer's full prescribing information for any dosage calculations and for any clinical decision making.

<sup>\*\*</sup> Meperidine is <u>not</u> 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 30mg	Opioid dose / 24 hours for each drug	To convert to oral morphine equivalent multiple by:	MED
Hydrocodone	5mg x 6 tablets = 30mg / day	1	30mg
Oxycodone	20mg x 2 tablets = 40mg / day	1.5	60mg
		Cumulative MED:	90mg

### Reasons to Discontinue Opioids and/or Refer to a Physician specializing F.3.e.iii 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.
  - o 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.
  - o Injecting oral/topical opioids.

- o 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

For more detailed guidance, please see Appendix H: Detailed Guidance on Opioid Tapering.

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 six to eight 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 six 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.
    - o Moderate risk patients, referral or comanagement.
    - Tapering/discontinuation of opioids.
    - o 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 > 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 and 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.
- May cause serotonin syndrome with concomitant use of other serotonergic agents like SSRI's, SNRI's, SSNRI's, TCA's etc.

### 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. Certain formulations of buprenorphine (buccal film and transdermal patch) are FDA approved for severe chronic pain management. 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 buccal film and tablet formulations, as well as transdermal patch preparations. Only the buccal film and transdermal patch are approved for the treatment of pain. The tablet form is FDA approved only 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. However, it should be noted that buprenorphine, when prescribed properly, can serve as a useful adjunct to tapering opioid dosage in patients, and ultimately potentially as a substitute (please see Appendix I)

In order to prescribe buprenorphine for purposes including but not necessarily limited to maintenance or detoxification in the treatment of OUDs providers should familiarize themselves with the necessary training and registration requirements at: https://www.samhsa.gov/

## 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.

### **Spinal Cord Stimulator and Intrathecal Drug Delivery** G.

# **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 a reasonably exhaustive number of attempts at 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.
  - SCS systems may also be indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: CRPS Types I and II, persistent phantom limb pain, spinal cord injury dysesthesias and chronic limb ischemia.
- Chronic Critical Limb Ischemia (CLI) A short-term trial (3-7 days) of a non high-frequency dorsal column spinal cord stimulator (SCS) can be considered for the treatment of chronic, intractable pain secondary to chronic critical limb ischemia (CLI) when BOTH of the following criteria are met:
  - Failure of available conventional multidisciplinary medical (e.g., pharmacological, physical therapy) and surgical management (e.g. revascularization)
  - An evaluation by a mental health provider (e.g. a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g. alcohol or drug dependence, depression, psychosis) that would impact perception of pain and/or negatively impact the success of a SCS or contraindicate placement of the device.
- 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
- 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), PCS (Pain Catastrophizing scale) 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 the pre-requisites are met, conditional pre-authorization must be obtained from the payor for a SCS screening trial of device effectiveness. There are multiple types of SCS devices, and the selection of a specific type or device may be case specific. If a specific SCS type or device is being requested, then the medical rationale for the selection of that specific type or device should be included with the request for prior authorization.

## **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.
- o 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.

- o A screening test is considered successful if the patient meets the following criteria:
  - Stimulation covers the patient's pain areas if using paresthesias based system
  - Patient is comfortable with the sensation of stimulation if using paresthesia based system
  - o Patient experiences a minimum of 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 preauthorization from the carrier to implant a permanent SCS.

# **G.2** Peripheral Nerve Stimulation (PNS)

A provider who wants to perform this procedure must request pre-authorization before performing the procedure.

- To be pre-authorized, the patient must be evaluated by a physician (MD or DO) appropriately trained or experienced in the use of such devices (typically a specialist in Physical Medicine, Pain Management or Spine Surgery) in consultation with the primary treating physician/surgeon.
- The procedure must be performed by a physician with the documented training or experience as noted above.

Indication: Similar to spinal cord stimulation, a short-term trial or a diagnostic block of the affected nerve may be required prior to implantation of the device.

NOTE: This guideline does not apply to cranial nerves (e.g. vagus nerve, trigeminal nerve), gastric, sacral nerve and/or posterior tibial nerve.

PNS can be considered when there is:

- a) Documentation of severe and unremitting focal nerve pain, in a defined neuronal distribution, for at least three months; and
- b) Documented failure of multiple other treatment modalities, as clinically indicated, including but not necessarily limited to: e.g. physical therapy, braces, medications or surgery; and
- c) Lack of surgical contraindications including infections and medical risks; and
- d) Appropriate patient education, discussion and disclosure of risks and benefits; and
- e) No active substance use issues or use disorders; and

f) Formal psychological screening by a mental health professional has been completed, and determined that the patient is an appropriate candidate for this procedure.

# **G.3** 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 preauthorization 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.3.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. Intrathecal pump can be considered as a treatment of last resort in conditions such as:

- Severe, chronic, intractable pain recalcitrant to all conservative treatment options in conditions like but not limited to:
  - Failed back surgery syndrome with low back pain and/or radicular pain
  - Chronic arachnoiditis
  - Visceral pain syndromes
  - o Complex regional pain syndrome
  - Phantom limb pain
  - Peripheral neuropathies
  - Spinal cord injuries
- Severe spasticity of cerebral or spinal cord origin in patients who are unresponsive to or who cannot tolerate oral baclofen therapy

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

- A diagnosis of a specific physical condition known to be chronically painful has been made based on 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.3.b Pain Pump Screening Trial

- A successful trial of continuous infusion by a percutaneous spinal infusion pump for a minimum of 24 hours or a bolus trial as an outpatient is required to ascertain effectiveness and make sure there are no side effects.
- A screening test is considered successful if the patient:
  - o 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.3.c** Pain Pump Implantation

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

#### **Functional Maintenance Care** Н.

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-thecounter 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 selfdirected pain management plan should be developed that can be initiated by the patient in the event 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/selfdirected 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, homebased, self-management program, and/or the need for modifications to that program; and
  - Determine the value, if any, of reinstituting 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.
  - o 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 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 ten 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.

<sup>&</sup>lt;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

Name:				Date: _			
Here are some of the things which other patients h							-
from 0 to 6 to say how much physical activities suc			lking or dr			affect <u>yo</u>	
	COMPLE DISAGE			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 norm	nal work affec	ts or wou	ld affect yo	our pain.			
	COMPLE <sup>-</sup> DISAGI			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
<ol><li>I do not think that I will ever be able to go back to that work</li></ol>	0	1	2	3	4	5	6

### Appendix B: Frequently Used Tests of Psychological Functioning

### 1. Comprehensive Inventories of 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 Million Behavioral Health Inventory (MBHI). Provides information on coping styles (introversive, inhibited, dejected, cooperative, sociable, etc.), health habits (smoking, drinking, eating, etc.), psychiatric indications (anxiety, depression, etc.), stress moderators (illness apprehension vs. illness tolerance, etc.), treatment prognostics (interventional fragility vs. interventional resilience, medication abuse vs. medication competence, etc.) and other factors.

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

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

### 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 status.

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 text 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 ten-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: Assessment Date:	Record #:					
	Current Ana	algesic 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			
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?  1. What was your pain level on average during the past week? (Please circle the appropriate number)	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.)			
No Pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can	1. Physical functioning  Better Same Worse   2. Family relationships			
be	3. Social relationships			
2. What was your pain level at its worst during the past week?	4. Mood			
No Pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can	5. Sleep patterns 6. Overall functioning			
be	o. Overall full clothing			
3. What percentage of your pain has been relieved during the past week? (Write in a percentage between 0% and 100 %.)	*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.			
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? Yes_No				
Query to clinician: Is the patient's pain relief clinically significant? YesNoUnsure				

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

		<u>,                                      </u>			
	Adverse Events	Potential Aberrant Drug-Related Behavior			
		This section must be completed by the physician			
1.	Is patient experiencing any side effects from	Please check any of the following items that you			
	current pain reliever?YesNo	discovered during your interactions with the patient.			
		Please note that some of these are directly			
Asl	k patient about potential side effects:	observable (e.g., appears intoxicated), while others			
	None Mild Moderate	may require more active listening and/or probing.			
Sev	/ere	Use the "Assessment" section below to note			
a.	Nausea	additional details.			
b.	Vomiting	Purposeful over-sedation			
	<u> </u>	Negative mood change			
_	Constipation	Appears intoxicated			
C.	Constipation				
	Makiba a	Increasingly unkempt or impaired			
d.	Itching	Involvement in car or other accident			
		Requests frequent early renewals			
e.	Mental	Increased dose without authorization			
	cloudiness	Reports lost or stolen prescriptions			
		Attempts to obtain prescriptions from other			
f.	Sweating	doctors			
		Changes route of administration			
g.	Fatigue	Uses pain medication in response to			
•	· — — —	situational stressor			
h.	Drowsiness	Insists on certain medications by name			
		Contact with street drug culture			
i.	Other	Abusing alcohol or illicit drugs			
l "-	Other	_			
		Hoarding (i.e., stockpiling) of medication			
١.	Other	Arrested by police			
j.	Other	Victim of abuse			
		Other:			
2.	Patients overall severity of side effects?				
	NoneMildModerateSe	evere			
Ass	sessment: (This section must be completed by the	e physician.)			
		ing (e.g., benefits, such as pain relief, outweigh side			
	ects) from opioid therapy?YesNo	Unsure			
	mments:				
Spe	ecific Analgesic Plan:	Comments:			
Spe	Continue present regimen				
	Adjust dose of present analgesic	-			
	_ Switch analgesics				
l —	_ Add/Adjust concomitant therapy				
1	Discontinue/taper off opioid therapy				

Date:	Physician's Signature:

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 C.1: Pain Catastrophizing Scale (> 30 Abnormal)

	Not at All	To a Slight Degree	To a Moderate Degree	To a Great Degree	All the Time
I worry all the time about whether the shock will end.	0	1	2	3	4
I feel I can't go on.	0	1	2	3	4
It's terrible and I think it's never going to get any better.	0	1	2	3	4
It's awful and I feel that it overwhelms me.					
I feel I can't stand it anymore.	0	1	2	3	4
I become afraid that the shocks will get worse.	0	1	2	3	4
I keep thinking of other painful events.	0	1	2	3	4
I anxiously want the shocks to go away.	0	1	2	3	4
I can't seem to keep it out of my mind.	0	1	2	3	4
I keep thinking about how much it hurts.	0	1	2	3	4
I keep thinking about how badly I want the shocks to stop.	0	1	2	3	4
There's nothing I can do to reduce the intensity of the shocks.	0	1	2	3	4
I wonder whether something serious may happen.	0	1	2	3	4

The table above showing the Pain Catastrophizing Scale is provided as an illustrative example only and is not intended to be a comprehensive instruction on the use of this tool. The actual tool, as well as the detailed instructions on its application and validity, are all copyrighted materials. Providers utilizing this tool are expected to be trained and knowledgeable in the details and application of these more extensive materials.

# **Appendix D: Dosing Thresholds for Selected Opioids**

Opioid	Recommended Dose Threshold for Pain Consult (not equianalgesic)	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)
Hydromorphone	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 longacting (LA) opioids. (See Section F.4.b)

Morphine	100mg per 24 hours	Immediate- release: 15mg q4-6 hours Sustained-release: 15mg q12 hours	Adjust dose for renal impairment.
Oxycodone	70mg per 24 hours	Immediate-release: 5mg q4-6 hours Sustained-release: 10mg q12hours	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).
Oxymorphone	30mg per 24 hours	Immediate- release: 5-10mg q4-6 hours Sustained-release: 10mg q12 hours	Use with extreme caution due to potentially fatal interaction with alcohol or medications containing alcohol.

<sup>\*</sup>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			
Opioids or "opiates" – Natural (from opium)							
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			
Morphine  (Avanza, 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	quantities to hydrocodone, these drugs may be found in the urine. Also, morphine may metabolize to produce a small amount (<10%) of hydromorphone.			

Drugs or Drug Classes	Detection Time in Urine	Test to Order	Expected Results	Consideration				
Opioids – Semisynthetic (derived from opium)								
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				
Hydromorphone (Dilaudid, Exalgo)	1-3 days	Opiates Immunoassay + GC/MS or LC/MS Opiates	Opiates Immunoassay  – positive  GC/MS or LC/MS  – hydromorphone	semisynthetic opioid(s).  Since hydrocodone is metabolized in small amounts to hydromorphone, both may be found in the urine.				
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	Likewise, oxycodone is metabolized to oxymorphone, so these may both be present in the urine of oxycodone users.  However, the reverse is not true. In other words, hydromorphone and oxymorphone use does not result in positive screens for hydrocodone and oxycodone, respectively.				
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					

Drugs or Drug Classes	Detection Time in Urine	Test to Order	Expected Results	Consideration			
Opioids – Synthetic (man-made)							
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			
Meperidine (Demerol)	1-3 days	GC/MS or LC/MS Meperidine	GC/MS or LC/MS  - normeperidine, possibly meperidine	(GC/MS) or LC/MS) is needed to identify these drugs. If the purpose is to document compliance with treatment, the			
Methadone (Methadose)	3-7 days	Methadone Immunoassay + GC/MS or LC/MS Methadone	Methadone Immunoassay – positive  GC/MS or LC/MS – methadone & EDDP	laboratory can be instructed to remove the cutoff concentration so that the presence of lower concentrations can be identified.			

Drugs or Drug Classes	Detection Time in Urine	Test to Order	Expected Results	Consideration
Others				
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 to 3 days with short- acting; up to 30 days with 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 to 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.
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 with 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 patient reason for use and adjust monitoring plan accordingly.

### **Appendix F: Patient Informed Consent for Opioid Treatment** Form

Patient Name	PATIENT INFORMED CONSENT FOR OPIOID TREATMENT FORM				
may also cause some serious problems. The problems may be worse if I mix the pain medicine with alcohol or other drugs.  I understand that the pain medicine I will be taking may cause serious problems including:  Confusion.  Poor judgment.  Nausea (a stomachache).  Vomiting.  Constipation (hard stools that may be painful to push out).  Sleepy or drowsy feeling.  Poor coordination and balance (such as feeling unsteady, tripping, and falling).  Slow reaction time.  Slow breathing or I can stop breathing - which could cause me to die.  More depression (such as feeling sad, hopeless, or unable to do anything).  Dry mouth.  Increased feeling of pain (hyperalgesia).  Addiction (it may be very hard to stop taking the pain medicine when I'm ready to quit).  For men: the pain medicine may lead to less interest in sex and poor sexual performance.  For pregnant women, the pain medicine may hurt my unborn child and may cause my child to be born addicted to the pain medicine may hurt my unborn child and may cause my child to be born addicted to the pain medicine scaused by the pain medicine, in addition to the problems listed here.  I understand that these problems may get better when I stop taking the pain medicine.  My doctor has reviewed the serious problems that this pain medicine may cause. My doctor has					
<ul> <li>⇒ Confusion.</li> <li>⇒ Poor judgment.</li> <li>⇒ Nausea (a stomachache).</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> <li>I will tell my doctor if I have any of the problems listed here.</li> <li>I understand there may be other problems caused by the pain medicine, in addition to the problems listed here.</li> <li>I understand that these problems may get better when I stop taking the pain medicine.</li> <li>My doctor has reviewed the serious problems that this pain medicine may cause. My doctor has</li> </ul>	may also cause some serious problems. The problems may be worse if I mix the pain medicine with				
<ul> <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> <li>I will tell my doctor if I have any of the problems listed here.</li> <li>I understand there may be other problems caused by the pain medicine, in addition to the problems listed here.</li> <li>I understand that these problems may get better when I stop taking the pain medicine.</li> <li>My doctor has reviewed the serious problems that this pain medicine may cause. My doctor has</li> </ul>	<ul> <li>⇒ Confusion.</li> <li>⇒ Poor judgment.</li> <li>⇒ Nausea (a stomachache).</li> <li>⇒ Vomiting.</li> <li>⇒ Constipation (hard stools that may be painful to push out).</li> </ul>				
<ul> <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> <li>I will tell my doctor if I have any of the problems listed here.</li> <li>I understand there may be other problems caused by the pain medicine, in addition to the problems listed here.</li> <li>I understand that these problems may get better when I stop taking the pain medicine.</li> <li>My doctor has reviewed the serious problems that this pain medicine may cause. My doctor has</li> </ul>	<ul> <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> </ul>				
I understand there may be other problems caused by the pain medicine, in addition to the problems listed here.  I understand that these problems may get better when I stop taking the pain medicine.  My doctor has reviewed the serious problems that this pain medicine may cause. My doctor has	<ul> <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>				
My doctor has reviewed the serious problems that this pain medicine may cause. My doctor has	I understand there may be other problems caused by the pain medicine, in addition to the problems				
	My doctor has reviewed the serious problems that this pain medicine may cause. My doctor has				
Patient Signature: Date:	Patient Signature: Date:				
I attest that this form was reviewed by me with the patient and all questions were answered.	I attest that this form was reviewed by me with the patient and all questions were answered.				

Date:

Doctor Signature:

### **Appendix G: Patient Understanding for Opioid Treatment** Form

Patient Understanding for Opioid Treatment Form						
Patient Name:		WCB Claim #:				
Doctor Name:						
	taking a pain medication called <b>OPIOIDS</b> to ree (patient must initial each box to show agree	•	•	my pain.		
Initial	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.		Initial	When I am asked, I will get lab tests to see if I am taking my medicines the right way.		
Initial	I will tell my doctor about any new medical problems.		Initial	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 take care of me.		
Initial	I will tell my doctor about all medicine I take and will tell my doctor if I am given any new medicines.		Initial	I will store my pain medicine in a safe place where other people cannot take it.		
Initial	I will tell my doctor if I see another doctor, or if I go to the Emergency Room.		Initial	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.		
Initial	I will only get my pain medicine prescription from this doctor. My doctor's name is listed on the top of this page.		Initial	My doctor may stop giving me pain medicine if:  I do not follow this agreement.		
Initial	If my doctor is away, I will only get medicine form the doctor who is in charge while my doctor is away.			<ul> <li>The pain medicine is not helping me.</li> <li>I am not meeting my goals in active therapy.</li> </ul>		
Initial	I will only get my pain medicine from one pharmacy (drug store).			<ul> <li>My pain or my functions do not improve.</li> </ul>		
Initial				<ul> <li>I have bad side effects from the pain medicine.</li> <li>I become addicted to the pain</li> </ul>		
Initial	I will do what I can to get back to work.			<ul> <li>medicine.</li> <li>I give or sell the pain medicine to someone else.</li> </ul>		
Initial	I will not drink alcohol or use any other drugs unless I am told to do so by my doctor		Initial	I am not pregnant and will call my doctor as soon as possible if I think I may be pregnant.		
Patient	Signature:			Date:		
l attest	I attest that this form was reviewed by me with the doctor and all questions were answered.					

### Appendix H: Guide for Clinicians on the Appropriate Dosage **Reduction or Discontinuation of Long-Term Opioid Analgesics**

#### A-H1 Introduction

Judicious opioid analgesic prescribing in acute situations can benefit individual patients when use is limited to short term where benefits are likely to outweigh risks. Per CDC guidelines, opioid prescribing should be used rarely, and optimal duration is three days or less, with further guidelines to definitely avoid prescriptions of seven days or more. Recent research shows that there is rarely benefit in long-term opioid treatment, and that other analgesics can be effective or more effective treatment for pain management.

As a result of these changing prescribing recommendations involving opioid analgesics, many providers face newfound challenges posed by attempting to taper off opioid analgesic while continuing to manage chronic pain.

Changes in opioid prescriptions, such as dose escalation, dose reduction or discontinuation of long-term opioid analgesics, have potential to harm or put patients at risk if not made in a thoughtful, deliberative, collaborative, and measured manner.

Safe and effective nonopioid treatments should be integrated into patients' pain management plans based on an individualized assessment of benefits and risks considering the patient's diagnosis, circumstances, and unique needs. Once tapered, it is frequently found that the experience of pain is diminished.

Coordination across the health care team is critical. In working with people who are experiencing continued pain, clinicians have a responsibility to provide or arrange for coordinated management of patients' pain and opioid-related problems, and they should never abandon patients. Consideration of an opioid taper should also give the provider an opportunity to review all of the patient's medications for appropriateness, adverse effects and the potential for dose reduction or elimination.

Note: This guideline uses the nomenclature MED (Morphine Equivalent Dose). While this has historically been the standard terminology, some authoritative guidelines have moved to the term MME (Morphine Milligram Equivalent).

#### A-H2 Definition

**DSM-5 Opioid Use Disorder:** A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following occurring within a 12-month period:

- 1. Opioids often taken in larger amounts over a longer period than was intended.
- 2. A persistent desire or unsuccessful efforts to cut down or control opioid use.
- 3. A great deal of time is spent in activities necessary to obtain, use or recover from the effects of opioids.
- 4. Craving, or a strong desire or urge to use opioids

- 5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school or home.
- 6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
- 7. Important social, occupational or recreational activities given up or reduced because of opioid use.
- 8. Recurrent opioid use in situations in which it is physically hazardous.
- 9. Continued opioid use in continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
- 10. Tolerance, as defined by either of the following:
  - a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect, or
  - b. Markedly diminished effect with continued use of the same amount of an opioid

NOTE: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.

- 11. Withdrawal, as manifested by either of the following:
  - a. The characteristic opioid withdrawal syndrome, or
  - b. Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.

NOTE: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.

Mild:	Presence of 2 to 3 symptoms
Moderate:	Presence of 4 to 5 symptoms
Severe:	Presence of 6 or more symptoms

### A-H3 Considerations for Tapering and Discontinuing Opioid Therapy

- Pain improves;
- The patient requests dosage reduction or discontinuation:
- Pain and function are not meaningfully improved with opioid treatment:
- The patient is receiving higher (for example, >90MME/24hrs) opioid doses without evidence of benefit from the higher dose, or with evidence of adverse side-effects from the opioid;
- The patient has current evidence of opioid misuse or diversion:
- The patient has current evidence of opioid use disorder which may require referral to an addiction medicine specialist;
- The patient experiences side effects that diminish quality of life or impair function;
- The patient is using illicit substances or misusing prescribed medications (e.g., benzodiazepines, sedative-hypnotics, muscle relaxants or gabapentin) that increase the risk of adverse outcomes;
- The patient experiences an overdose or other serious event (e.g., hospitalization, injury) or has warning signs for an impending event such as confusion, sedation, or slurred speech, falls, or motor vehicle accidents;

- The patient is receiving medications (e.g., benzodiazepines) or has medical conditions (e.g., lung disease, sleep apnea, liver disease, kidney disease, fall risk, advanced age) that increase risk for adverse outcomes; and or
- o The patient has been treated with opioids for a prolonged period (e.g., years), and current benefit-harm balance is unclear.
- Some of the situations described above may require referral to an emergency department, or urgent referral to addiction medicine specialist.
- Establishing a team to support the patient, which may include but not necessarily be limited to: a specialist in addiction medicine; the primary care provider; a case manager; therapists; group facilitators and pharmacists.

### A-H4 Considerations Prior to Taper Decision

Decisions to continue or reduce opioids for pain should be based on individual patient needs. Consider whether opioids continue to meet treatment goals. whether opioids are exposing the patient to an increased risk for serious adverse events or opioid use disorder, and whether benefits continue to outweigh risks of opioids.

The majority of patients report improvements in function, sleep, anxiety, and mood following reduction of long-term opioid dosages without worsening pain. Other patients report increased pain, insomnia, anxiety, and depression. The duration of increased pain related to hyperalgesia or opioid withdrawal is unpredictable and may be prolonged in some patients. It is important for the physician to distinguish between patients who have been adhering to prescribed doses of opioids, and those who have not, as this will affect the approach to treatment. In general, tapering is successful when physicians are mindful of the following:

- Avoid insisting on opioid tapering or discontinuation when opioid use may be warranted (e.g., treatment of cancer pain, pain at the end of life, or other circumstances in which benefits outweigh risks of opioid therapy).
- Avoid misinterpreting cautionary dosage thresholds as mandates for dose reduction. While, for example, the guidelines recommend avoiding or carefully justifying increasing dosages above 90 MME/day, they do not recommend abrupt reductions for patients on high dose opioids. Consider individual patient situations.
- Some patients using both benzodiazepines and opioids may require tapering one or both medications to reduce risk for respiratory depression. Tapering decisions and plans need to be coordinated with prescribers of both medications. If benzodiazepines are tapered, they should be tapered gradually due to risks of benzodiazepine withdrawal, which include anxiety, hallucinations, seizures, delirium tremens, and, in rare cases, death.
- Avoid dismissing patients from care. This practice puts patients at high risk and sacrifices opportunities to provide life-saving interventions, such as medicationassisted treatment for opioid use disorder. Ensure that patients continue to receive coordinated care.

- Tapering in physically dependent patients should be informed by close collaboration among all members of the healthcare team, with the goal of reducing taper-associated risks including acute withdrawal, pain exacerbation, anxiety, depression, suicidal ideation, self-harm, ruptured trust, and patients seeking opioids from high-risk sources.
- Particularly for more complex cases, consider consultation with a pain psychologist to incorporate appropriate behaviorally focused interventions

### A-H5 Important Steps Prior to Taper Initiation

- Commit to working with your patient to improve function and decrease pain.
   Use accessible, affordable <u>nonpharmacologic</u> and <u>nonopioid pharmacologic</u>
   treatments. Integrating behavioral and nonopioid pain therapies before and
   during a taper can help manage pain and strengthen the therapeutic
   relationship.
- Depression, anxiety, and post-traumatic stress disorder (PTSD) can be common in patients with painful conditions, especially in patients receiving longterm opioid therapy. Depressive symptoms predict taper dropout. Treating comorbid mental disorders can improve the likelihood of opioid tapering success.
- If your patient has serious mental illness, is at high suicide risk, or has suicidal ideation, offer or arrange for consultation with a behavioral health provider before initiating a taper.
- If a patient exhibits opioid misuse behavior or other signs of opioid use disorder, <u>assess for opioid use disorder using DSM-5 criteria</u>. If criteria for opioid use disorder are met (especially if moderate or severe), offer or arrange for medication-assisted treatment, typically involving referral to and/or collaboration with an addiction medicine specialist.
- Access appropriate expertise if considering opioid tapering or managing opioid use disorder during pregnancy. Opioid withdrawal risks include spontaneous abortion and premature labor. For pregnant women with opioid use disorder, medication for opioid use disorder (MOUD, formerly referred to as medication assisted treatment or MAT) is preferred over detoxification. Pregnant patients should also receive education on breast-feeding while on MOUD.
- Advise patients that there is an increased risk for overdose on abrupt return to a previously prescribed higher dose. Strongly caution that it takes as little as a week to lose tolerance and that there is a risk of overdose if they return to their original dose. Provide opioid overdose education and strongly consider offering a prescription for naloxone, accompanied by the recommendation that family members and other close associates receive naloxone training.

#### A-H6 Patient Shared Decision-Making

Discuss with patients their perceptions of risks, benefits, and adverse effects of continued opioid therapy, and include patient concerns in taper planning. For patients at higher risk of overdose based on opioid dosages, review benefits and

risks of continued high-dose opioid therapy. If the current opioid regimen does not put the patient at imminent risk, tapering does not need to occur immediately, but should still be pursued if deemed appropriate, based on the considerations noted above. Take the time to obtain patient buy-in. Tapering is more likely to be successful when patients collaborate in the taper. Include patients in decisions, such as which medication will be decreased first and how quickly tapering will occur.

### A-H7 Taper Rate Individualization

When opioid dosage is reduced, a taper slow enough to minimize opioid withdrawal symptoms and signs should be used. Tapering plans should be individualized based on patient goals and concerns. The length of the taper may be impacted by: the type of opioid prescribed; the dose of the opioid; and the duration of the prior opioid therapy. Common tapers involve dose reduction of 5% to 20% every four weeks.

- **Slower tapers** (e.g., 5-10% per month) are often better tolerated than more rapid tapers, especially following opioid use for more than a year. Longer intervals between dose reductions allow patients to adjust to a new dose before the next reduction. Tapers can typically be completed over three to 18 months, but in select circumstances may take longer, depending on the opioid dose, type of opioid, and other case-specific factors.
- Faster tapers can be appropriate for some patients. A decrease of five to ten percent of the original dose per week (until 30% of the original dose is reached, followed by a weekly decrease of ten percent of the remaining dose) is less likely to trigger withdrawal and can be successful for some patients, particularly after opioid use for weeks to months rather than years.
- Pauses: At times, tapers might have to be paused and restarted again when the
  patient is ready. Pauses may allow the patient time to acquire new skills for
  management of pain and emotional distress, introduction of new medications, or
  initiation of other treatments, while allowing for physical adjustment to a new
  dosage. Pauses should be time-limited and of a planned duration, and typically not
  exceed one to two months. Dosage increases should not be done during a taper or
  pauses.
- Progress: Tapers may be considered successful as long as the patient is making progress, however slowly, towards a goal of reaching a safer dose, whether that be ultimate discontinuation of the medication, or in rare instances, dose reduction to the minimal dose needed.
- **Discontinuation:** Once the smallest available dose is reached, the interval between doses can be extended. Opioids may be stopped, if appropriate, when taken less often than once a day.
- **More rapid tapers** (e.g., over two to three weeks) might be needed for patient safety when the risks of continuing the opioid outweigh the risks of a rapid taper (e.g., in the case of a severe adverse event such as overdose).

- **Ultra-rapid detoxification** under anesthesia is associated with substantial risks and **should not be used**.
- Buprenorphine may also be used in tapering. Buprenorphine should only be
  prescribed by appropriately trained and authorized prescribers. In order to
  maximize pain control, the medication should be given in a three or four times a
  day manner. This medication provides analgesia and facilitates gradual reduction in
  dosing.
- Providers might also consider serial urine drug and alcohol screening during the taper

### A-H8 Treatment of Opioid Withdrawal Symptoms

If tapering is done gradually, withdrawal symptoms should be minimized and manageable. Expectation management is an important aspect of counseling patients through withdrawal. Significant opioid withdrawal symptoms may indicate a need to pause or slow the taper rate. Onset of withdrawal symptoms depends on the duration of action of the opioid medication used by the patient. Symptoms can begin as early as a few hours after the last medication dose or as long as a few days, depending on the duration of action. Early withdrawal symptoms (e.g., anxiety, restlessness, sweating, yawning, muscle aches, diarrhea and cramping) usually resolve after five to ten days but can take longer. Some symptoms (e.g., dysphoria, insomnia, irritability) can take weeks to months to resolve.

Short-term oral medications can help manage withdrawal symptoms, especially when prescribing faster tapers. These include alpha-2 agonists for the management of autonomic signs and symptoms (sweating, tachycardia), and symptomatic medications for muscle aches, insomnia, nausea, abdominal cramping, or diarrhea. Commonly used short-term medications include clonidine and hydroxyzine for anxiety and loperamide for diarrhea.

### A-H9 Behavioral Health Support

Make sure patients receive appropriate psychosocial support. Ask how you can support the patient. Acknowledge patient fears about tapering. While motives for tapering vary widely, fear is a common theme. Many patients fear stigma, withdrawal symptoms, pain, and/or abandonment. Make yourself or a team member available to the patient to provide support, if needed. Let patients know that while pain might get worse at first, many people have improved function without worse pain after tapering opioids. Follow up frequently, for example, at least weekly. Watch closely for signs of anxiety, depression, suicidal ideation, and opioid use disorder and offer support or referral as needed. Collaborate with mental health providers and with other specialists as needed to optimize psychosocial support for anxiety related to the taper.

### A-H10 Special Populations

If patients experience unanticipated challenges to tapering, such as inability to make progress despite intention to taper or opioid-related harm, assess for opioid use disorder using DSM-5 criteria. If patients meet criteria for opioid use disorder (especially if moderate or severe), offer or arrange MOUD, and/or referral to an appropriate specialist, such as an addiction medicine specialist. In many cases,

tapering may be done by primary care providers in consultation with addiction medicine mentoring programs.

If patients on high opioid dosages are unable to taper despite worsening pain and/or function with opioids, whether or not opioid use disorder criteria are met, consider transitioning to buprenorphine. Buprenorphine is a partial opioid agonist that can treat pain as well as opioid use disorder, and has other properties that may be helpful, including less opioid-induced hyperalgesia and easier withdrawal than full mu-agonist opioids, and less respiratory depression than other long-acting opioids. Buprenorphine can then be continued or tapered gradually. Transitioning from full-agonist opioids requires attention to timing of the initial buprenorphine dose to avoid precipitating withdrawal. With the exception of long-acting preparations, a 24-hour "washout" is typically effective for transition to buprenorphine. Notable exceptions to this are methadone and long-acting oxycodone/oxymorphone preparations, which typically require 48-72-hour washout period. The initiation of buprenorphine is made on a case specific basis, based on the presence and type of withdrawal symptoms and/or provider judgement.

### **Appendix I: Guidance on Tapering Benzodiazepines**

#### A-I1 Introduction

When prescribed at a low dosage for no more than 30 days, benzodiazepines can effectively treat several conditions, including but not necessarily limited to: generalized and social anxiety; panic disorder; and sleep disorders. Long-term use for anxiety and sleep disorders is generally not indicated, because it is associated with the development of physiologic and psychological dependence characterized by tolerance, withdrawal, and reluctance to reduce or discontinue use despite the objective lack of effectiveness. For short-acting benzodiazepines, rebound symptoms may appear between doses, which typically leads to dose escalation with temporary relief of these symptoms. Additionally, use of supratherapeutic doses poses a safety concern. When risks of continued use outweigh any potential benefits, tapering down and off the medication should be discussed.

### A-I2 Approach to the Patient

For many patients, education about the adverse effects of long-term benzodiazepine use can be a good starting point when discussing tapering. The physician can build rapport and increase patient motivation by suggesting a trial dosage reduction that would not require the patient's commitment to completely taper off of the medication. This strategy may allow the patient to develop selfefficacy to manage a small dose reduction without significant adverse effects and ease anxiety about further dose reductions. Providing anticipatory guidance about potential withdrawal symptoms, as well as encouraging the patient and reinforcing alternative strategies for stress management, are supportive interventions to incorporate before and during benzodiazepine tapers. Some patients may also benefit from directed psychotherapy focused on addressing any underlying psychiatric symptoms unmasked by tapering. Consideration of a benzodiazepine taper gives the provider an opportunity to review all the patient's medications for appropriateness, adverse effects, and potential for dose reduction or elimination. Predictive factors associated with difficult tapers include, but are not necessarily limited to: previous failed attempts; comorbid chronic psychiatric or physical illness; personality disorders; a history of alcohol or drug use; lack of family or social support; older age; and an unsympathetic primary care provider.

### A-I3 When to Taper Benzodiazepines

Any patient taking benzodiazepines daily for longer than one month should be considered for a taper/discontinuation of their benzodiazepine. This is especially true for persons at particularly high risk of adverse outcomes with prolonged benzodiazepine use. Such persons include, but are not necessarily limited to patients: older than 65 years (because of the risk of injury from falls and other cognitive adverse effects); taking multiple benzodiazepines, benzodiazepines combined with prescribed opioids, gabapentinoids, or amphetamines, or supratherapeutic dosages; with a cognitive disorder, history of traumatic brain injury, or current or history of substance use disorder or dependence, especially sedative-hypnotic or alcohol use disorder.

### A-I4 Before Initiating a Taper

A team-based approach will be most effective in efforts to taper a patient from benzodiazepines. Build a stable relationship with your patient. Evaluate and treat

any co-occurring conditions. Obtain complete drug and alcohol history and random drug screen. Review recent medical notes (ER visits) and coordinate care with other providers. If available, query prescription drug monitoring database.

### A-I5 Approach to Tapering

Abruptly discontinuing benzodiazepines after a patient has been taking them daily for more than one month is potentially dangerous; withdrawal can be severe or even life-threatening. Taper schedules should be individualized, informed by factors such as lifestyle, personality, environmental stressors, reasons for taking benzodiazepines, and amount of available personal and clinical support. Because anticipatory anxiety is often related to withdrawal, benzodiazepines are commonly tapered slowly, with psychological support emphasized during the process to help patients learn alternative coping skills.

The length of the taper may be determined on a case-specific basis. Although some patients may prefer a quicker taper, this must be balanced with the severity of potential withdrawal symptoms. In some patients, it may be appropriate to use a faster tapering schedule (eight to 12 weeks), with the option to slow down if withdrawal symptoms become unmanageable. In some patients, it may be appropriate to utilize a prolonged schedule with the patient exerting some control over pacing. It is worth noting in this context that even benzodiazepine tapers lasting one to two years have been successful.

Fundamentally, there are three approaches to a benzodiazepine taper: (1) use the same medication for tapering, (2) switch to a longer-acting equivalent, and (3) use adjunctive medications to help mitigate potential withdrawal symptoms. The dosage reduction mainly depends on the starting dose and whether the patient is tapering as an inpatient or outpatient. For safety reasons, outpatient tapers usually need to be slower than inpatient tapers. Patients taking higher dosages of benzodiazepines can usually tolerate larger initial reductions than those taking lower dosages. The initial reduction typically ranges between 5% and 25% of the starting dose, with further reductions of 5% to 25% every one to four weeks as tolerated. Supratherapeutic doses can initially be reduced by 25% to 30%, then further reduced by 5% to 10% daily, weekly, or monthly as appropriate, based on how well the patient tolerates withdrawal symptoms during the taper.

Addition of an anticonvulsant should be considered for high-dosage withdrawal. Adjunctive medications, such as carbamazepine, imipramine, and divalproex, can mitigate some of the withdrawal discomfort. Clonidine may also be used at bedtime when patients complain of sleep disturbance. Use of antidepressants, such as duloxetine or amitriptyline, may help patients with chronic pain. Switching to a longer-acting benzodiazepine equivalent may allow for a smoother taper experience.

For complex cases, stabilizing the dose at a 50% reduction for several months before resuming the taper may improve tolerability. At the end of the taper, some patients may need to reduce the pace with much smaller dosage reductions to tolerate the withdrawal.

### A-I6 Additional Tapering Considerations

Patients with benzodiazepine use disorder will have more difficulty reducing or stopping the dosage because of cravings. They may report intolerable withdrawal symptoms, request early refills, use benzodiazepines for reasons other than why they were prescribed, or report a need for benzodiazepines to perform normal daily activities. These patients may not be able to taper off without more intensive follow-up and intervention. A taper may be a litmus test for addiction; these patients may benefit from a referral to an addiction medicine specialist. Providers might also consider serial urine drug and alcohol screening during the taper. This is useful for detecting use of other substances and can also confirm tapering and discontinuation of benzodiazepine from all sources. Such screening should include an expanded benzodiazepine panel in order to capture the wide number of medications in this class. When reviewing screening results is important to bear in mind that sertraline, a commonly prescribed antidepressant, has the potential for producing false positives.

### A-I7 Specific Patient Subgroup Recommendations

### A-I7-a Supratherapeutic Doses

Consider inpatient admission, due to greater medical risks; consider switching to a longer half-life drug (e.g. diazepam or clonazepam); reduce dose initially by 25-30%; then reduce dose by approximately 5-10% daily to weekly; consider an anticonvulsant for high dose withdrawal. For high dose (or illicit) benzodiazepine use, physicians should strongly consider referral to inpatient detoxification.

### A-I7-b Therapeutic Bedtime Dosing (e.g. qHS)

Reduce by approximately 25% weekly; anticipate and educate regarding rebound insomnia which can occur as early as one day; provide reassurance and sleep hygiene information; initiate alternate treatment options, such as cognitive behavioral therapy and non-benzodiazepine agents.

### A-I7-c Therapeutic Daytime Dosing (e.g. generally one to four times a day)

Anticipate and provide education regarding rebound anxiety and recurrence of initial anxiety symptoms; plan additional psychological support during taper; the last phase of withdrawal is likely to be difficult; points of dosing schedule changes (e.g. three times a day to two times a day) can be psychologically challenging; encourage patient to actively participate in developing the withdrawal schedule when possible; initial dose taper typically between 10-25%, with observation for signs of withdrawal, anticipation of early withdrawal for benzodiazepines with a short half-life, and individualization of subsequent reductions based on initial response. Generally, further reductions of 10-25% every 1-2 weeks are well tolerated pharmacologically. Taper may need to be slowed, and/or additional psychological support may need to be offered, as patients learn new ways to cope with their anxiety.

#### A-I7-c Concurrent Opioids

Co-prescribing of benzodiazepines and opioids can lead to pain related behavioral management problems and put patients at higher risk for fatal and non-fatal overdose. Often prescriptions for these medications are given by different prescribers, so collaboration and coordination with patients and their other care providers may be necessary to determine best treatment options. Consider tapering both. Patients with increased anxiety may have a more difficult time with the benzodiazepine taper. Patients with PTSD/anxiety and pain due to trauma may have a more difficult time with the opioid taper. Generally, any decrease in either of these medication classes is desirable. Collaboration with the patient and other providers may provide insights as to how to start the taper, and with which medication(s). Generally speaking, the benzodiazepine should be tapered and discontinued prior to the opioid taper, given that there will typically not be an indication for long term benzodiazepine prescribing. Prescription of gabapentinoids should be avoided in this patient population, given their tendency to potentiate the effects of both benzodiazepine and opioids. Given the distinct possibility of overdose in this patient population, physicians should also strongly consider providing a naloxone prescription to these patients, and their family members or close personal contacts should be appropriately trained in naloxone use.

### A-I7-d Additional Strategies

- While it can be helpful to be flexible with the tapering schedule, prolonged tapers (e.g. greater than 6 months) have the potential to worsen long-term outcomes.
- Consider stabilizing on 50% dose for several months before proceeding with the taper.
- Switching to a long-acting benzodiazepine such as Diazepam, may also be helpful in cases involving long-term use, supratherapeutic doses, or short half-life benzodiazepines.
- Establishing a team to support the patient, which may include but not necessarily be limited to: a specialist in addiction medicine; the primary care provider; a case manager; therapists; group facilitators and pharmacists.
- Residential treatment if indicated, etc.

### A-I7-e Adjunctive Medication Options

Adjunctive medications may be useful to support the last phase of the taper. For example, duloxetine or amitriptyline may be considered for pain.

### A-I7-f Cognitive Behavioral Therapy (CBT)

**CBT maybe** particularly for insomnia or panic disorder, concurrent with the taper, improves outcomes.

### A-18 Benzodiazepine Equivalent Doses and Suggested Tapers\*

# A-I8-a Option 1: Benzodiazepine Taper Using Currently Prescribed Medication

Begin taper using current benzodiazepine at the current dose and decrease this dose by five to ten percent every one to two weeks. If the taper is being tolerated well, continue at this rate. Tapers can be held at any time in order for the body to adjust. Do not raise the dose in order to counter the withdrawal side-effects which often manifest as an increase in anxiety and sleeping difficulties.

If the patient is expressing discomfort on the taper, then consider transition to a longer acting benzodiazepine. When switching benzodiazepines, unless familiar with this process, one might consider consultation with a Pain Medicine or Addiction Medicine specialist, or a pharmacist, in order to avoid inadvertent dosing errors.

### A-I8-b Option 2: Benzodiazepine Taper Utilizing Transition to a Long-Acting Benzodiazepine

This option may be considered initially, or in the context of the patient not tolerating a continued taper of their existing benzodiazepine prescription (as discussed above in Option # 1).

Switch to a longer acting benzodiazepine. After transitioning to a longer acting benzodiazepine, reduce dose by 50% the first two to four weeks then maintain on that dose for one to two months then reduce dose by 25% every two weeks. When switching benzodiazepines, unless familiar with this process, one might consider consultation with a Pain Medicine or Addiction Medicine specialist, or a pharmacist, in order to avoid inadvertent dosing errors.

#### **A-I9 Benzodiazepine Relative Half-Lives**

Approximate Dosage Equiv	Elimination Half-Life	
Chlordiazepoxide	25mg	>100 Hours
Diazepam	10mg	>100 hours
Clonazepam	1mg	20 to 50 hours
Lorazepam	2mg	10 to 20 hours
Alprazolam	1mg	12 to 15 hours
Temazepam	30mg	10 to 20 hours.

### A-I10 Tapering Strategies and Schedules (Examples)

The following are provided for illustrative purposes only. Individual tapering strategies will vary on a case-by-case basis.

### A-I10-a Example 1

Withdrawal from high-dose alprazolam with diazepam substitution. NOTE: 6mg alprazolam is approximately equivalent to 120mg diazepam.

Schedule 1	Morning	Midday/Afternoon	Evening/Night	Daily Diazepam Equivalent
Starting Dosage	alprazolam 2mg	alprazolam 2mg alprazolam 2mg		120mg
Stage 1 (one week)	alprazolam 2mg	alprazolam 2mg	alprazolam 1.5mg diazepam 10mg	120mg
Stage 2 (one week)	alprazolam 2mg	alprazolam 2mg	alprazolam 1mg diazepam 20mg	120mg
Stage 3 (one week)	alprazolam 1.5mg diazepam 10mg	alprazolam 2mg	alprazolam 1mg diazepam 20mg	120mg
Stage 4 (one week)	alprazolam 1mg diazepam 20mg	alprazolam 2mg	alprazolam 1mg diazepam 20mg	120mg
Stage 5 (one to two weeks)	alprazolam 1mg diazepam 20mg	alprazolam 1mg diazepam 10mg	alprazolam 1mg diazepam 20mg	110mg
Stage 6 (one to two weeks)	alprazolam 1mg diazepam 20mg	alprazolam 1mg diazepam 10mg	alprazolam 0.5mg diazepam 20mg	100mg
Stage 7 (one to two weeks)	alprazolam 1mg diazepam 20mg	alprazolam 1mg diazepam 10mg	Stop alprazolam diazepam 20mg	90mg
Stage 8 (one to two weeks)	alprazolam 0.5mg diazepam 20mg	alprazolam 1mg diazepam 10mg	diazepam 20mg	80mg
Stage 9 (one to two weeks)	alprazolam 0.5mg diazepam 20mg	alprazolam 0.5mg diazepam 10mg	diazepam 20mg	80mg
Stage 10 (one to two weeks)	alprazolam 0.5mg diazepam 20mg	Stop alprazolam diazepam 10mg	diazepam 20mg	60mg
Stage 11 (one to two weeks)	Stop alprazolam diazepam 20mg	diazepam 10mg	diazepam 20mg	50mg
Stage 12 (one to two weeks)	diazepam 25mg	Stop midday dose; divert 5mg to each morning and night doses	diazepam 25mg	50mg
Stage 13 (one to two weeks)	diazepam 20mg	-0-	diazepam 25mg	45mg
Stage 14 (one to two weeks)	diazepam 20mg	-0-	diazepam 20mg	40mg

After Stage 14, continue taper as tolerated as noted above. When transitioning to once daily dosing, typically the evening/night dose is the last to be removed.

A-I10-b Example 2 - Simple withdrawal from diazepam 4mg daily (follow this schedule to complete Schedule 1 above) **NOTE:** Each Stage is one to two weeks.

Schedule 2	Morning	Night	Total Daily Dosage
Starting dosage	diazepam 20mg	diazepam 20mg	40mg
Stage 1	diazepam 18mg	diazepam 20mg	38mg
Stage 2	diazepam 18mg	diazepam 18mg	36mg
Stage 3	diazepam 16mg	diazepam 18mg	34mg
Stage 4	diazepam 16mg	diazepam 16mg	32mg
Stage 5	diazepam 14mg	diazepam 16mg	30mg
Stage 6	diazepam 14mg	diazepam 14mg	28mg
Stage 7	diazepam 12mg	diazepam 14mg	26mg
Stage 8	diazepam 12mg	diazepam 12mg	24mg
Stage 9	diazepam 10mg	diazepam 12mg	22mg
Stage 10	diazepam 10mg	diazepam 10mg	20mg
Stage 11	diazepam 8mg	diazepam 10mg	18mg
Stage 12	diazepam 8mg	diazepam 8mg	16mg
Stage 13	diazepam 6mg	diazepam 8mg	14mg
Stage 14	diazepam 5mg	diazepam 8mg	13mg
Stage 15	diazepam 4mg	diazepam 8mg	12mg
Stage 16	diazepam 3mg	diazepam 8mg	11mg
Stage 17	diazepam 2mg	diazepam 8mg	10mg
Stage 18	diazepam 1mg	diazepam 8mg	9mg
Stage 19		diazepam 8mg	8mg
Stage 20		diazepam 7mg	7mg
Stage 21		diazepam 6mg	6mg
Stage 22		diazepam 5mg	5mg
Stage 23		diazepam 4mg	4mg
Stage 24		diazepam 3mg	3mg
Stage 25		diazepam 2mg	2mg
Stage 26		diazepam 1mg	1mg

After stage 26 continue tapering to discontinue medication as tolerated, as noted above.

# A-I10-c Example 3

Alprazolam 2mg two times a day, converted to diazepam 40mg daily

	Alprazolam	Diazepam
Week 1		35mg / day
Week 2	Total dose decrease by 25%	30mg/ day
Week 3		25mg / day
Week 4	Total dose decrease by 50%	20mg / day (50%)
Week 5-8	Pause Taper: Hold dose steady for four weeks	Continue at 20mg / day for one month
Week 9-10	Current dose reduction of 25% every two weeks	15mg / day
Week 11-12		10mg / day
Week 13-14		5mg / day
Week 15		Discontinue

# **Appendix J: Gabapentinoids Tapering**

#### **A-J1** Introduction

Gabapentinoids are FDA-approved to treat a variety of conditions including partial seizures and nerve pain from spinal cord injury, shingles, and diabetes. Other approved uses include fibromyalgia and restless legs syndrome. Gabapentin was first approved in 1993 and pregabalin was first approved in 2004.

The U.S. Food and Drug Administration (FDA) has warned that serious breathing difficulties may occur in patients using gabapentin or pregabalin who have respiratory risk factors. These include the use of opioid pain medicines and other drugs that depress the central nervous system, and conditions such as chronic obstructive pulmonary disease (COPD) that reduce lung function. The elderly are also at higher risk.

The use of gabapentinoids has been growing through prescribed medical use, as well as misuse and abuse. Gabapentinoids are often being combined with CNS depressants, which increases the risk of respiratory depression. CNS depressants include opioids, anti-anxiety medicines, antidepressants, and antihistamines.

Gabapentin has been found to increase the risk of fatal opioid overdose and adverse opioid effects. This medication is sedating and has addictive qualities. The increased implication of gabapentin as a contributing substance in opioid-related adverse events over the last ten years has been attributed to a rise in off-label prescribing of gabapentin.

#### A-J2 Recommendation

Any health care provider considering using these medications in patients with nonacute pain explore alternative evidence-based approaches to pain management.

#### A-J3 Gabapentinoid Tapering

For patients for whom it is determined that the risk of gabapentinoids outweighs the clinical benefits, it is advised that tapering of gabapentinoids in patients with nonacute pain be initiated at the earliest opportunity. Sudden discontinuation should be avoided due to the risk of rebound anxiety and seizures, similar to that seen with discontinuation of benzodiazepines.

A-J3-a Example recommended schedule for tapering gabapentin

Generally, one will initially decrease the dose by approximately 25 percent (of the initial dose) per week over approximately four weeks, then decrease the daily frequency over 3-4 weeks.

For example, for a patient taking 800 mg, three times per day (2400

- Decrease by 200 mg per dose, and sequentially decrease each week, e.g.,
  - o 800 mg tid x 7 days, then
  - o 600 mg tid x 7 days, then
  - o 400 mg tid x 7 days, then

- o 200 mg tid x 7 days, then
- o proceed to 100 mg tid x 7 days, then
- o eliminate the middle dose, and proceed to 100 mg q 12 hours x 7 days, then
- o eliminate the early dose (bedtime dose should be last one stopped) and proceed to 100 mg per day, qhs x 7 days,
- o then discontinue (some providers include a week of every-other-day bedtime dosing prior to discontinuation).

Schedule 1	Morning	Midday/Afternoon	Evening/Night	Total
Starting Dose	800mg	800mg	800mg	2400mg
Week One	600mg	600mg	600mg	1800mg
Week Two	400mg	400mg	400mg	1200mg
Week Three	200mg	200mg	200mg	600mg
Week Four	100mg	100mg	100mg	300mg
Week Five	100mg	-0-	100mg	200mg
Week Six	-0-	-0-	100mg	100mg
Week Seven	Discontinue – some providers include a week of every-other day bedtime dosing prior to discontinuation			

# A-J3-a Example recommended schedule for tapering pregabalin.

The following protocol is an example of recommended schedule for tapering pregabalin. The daily dose of pregabalin can be safely reduced at a maximum of 50-100mg/wk.

For example weaning schedule for patient previously maintained on pregabalin 150mg twice daily.

	Week 1	Week 2	Week 3	Week 4	Stop and
Morning	150mg	75mg	50mg	25mg	Review
Evening	75mg	75mg	50mg	25mg	Patient

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This Treatment Guideline is adopted, with modifications, from the State of Colorado's Chronic Pain Disorder Medical Treatment Guidelines (effective February 2012) with supplementation from Part I, Introduction, of the State of California's Chronic Pain Medical Treatment Guidelines (effective July 2009) and the State of Washington Medical Directors' Group Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain.

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