COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF INDUSTRIAL ACCIDENTS

Opioid/Controlled Substance Protocol

REVISED OCTOBER 2024

INTRODUCTION

This Protocol is intended to

- Promote the delivery of safe, quality health care to injured workers;
- Ensure patient pain relief and functional improvement;
- Be used in conjunction with other treatment guidelines, not in lieu of other recommended treatment;
- Prevent and reduce the number of complications caused by prescription medication, including addiction; and
- Recommend opioid prescribing practices that promote functional restoration.

The protocol does not apply to patients with cancer, end of life/hospice patients, or inpatients of hospitals, nursing homes, and skilled nursing facilities. The protocol is not intended to be a substitute for appropriate medical judgment and should allow for philosophical and practice differences among health care practitioners who provide care to injured workers. On a rare occasion, a case may fall outside of this protocol and may be reviewed, and prescription medication approved, on an individual basis. Ongoing use of medication, as with all other interventions, should be guided by objective evidence of functional improvement and include an active treatment program. Before prescribing opioids, the prescribing practitioner must be cognizant of synergism and drug interactions which affect the respiratory and central nervous systems; as well as the patient's age, metabolic capacity, and any potentially co-morbid medical conditions. Generic medication should be used if possible.

In May, 2024 the Massachusetts Department of Public Health (MDPH) released a report by the MDPH's Occupational Health Surveillance Program titled "Opioid-Related Overdose Deaths Among Injured Workers: Findings from the Public Health Data Warehouse." The report underscored the strong link between work-related injury and fatal opioid-related overdoses among Massachusetts workers. Working-age Massachusetts residents who died between 2011 and 2020 were 35% more likely to have died of an opioid-related overdose if they had previously been injured at work. This report highlights the need for safe workplaces that practice effective injury prevention strategies, as well as work environments that remove the stigma surrounding substance use disorders and employ harm-reduction strategies such as naloxone training. The DIA's Opioid/Controlled Substance Protocol should be viewed within the larger context of the link between work-related injuries, substance use disorders and opioid-related overdoses and the need for primary prevention of work-related injuries, removal of stigma for substance use disorders and use of harm-reduction strategies.

TIME FRAMES

Acute Pain: Up to 4 weeks from onset
Subacute Pain: 4-12 weeks from onset
Post-operative Pain: Up to 4 weeks from date of surgery
Chronic Pain: Greater than 12 weeks from onset

RECOMMENDATION FOR ACUTE, SUBACUTE, AND POST-OPERATIVE PAIN

1. Opioid medication should only be used when the severity of the pain warrants that choice, and after determining that other non-opioid pain medication or non-pharmacological therapies, including but not limited to home exercise, chiropractic treatment, physical therapy, and psychological treatment, will not provide adequate pain relief. Increased activity should be encouraged if medically indicated. This recommendation is not intended to mandate a trial of non-opioid medication and/or complementary therapies prior to prescribing opioids when opioids are necessary for relief of severe pain or non-opioid medication is contraindicated.

2. When opioid medications, including other controlled substances, are prescribed:
   - Assess for risk factors including current and past addiction or misuse, and factors affecting patient adherence. Presence of these risk factors should not prohibit initiation of opioid therapy for acute/postoperative pain if deemed appropriate, but these risk factors should be taken into consideration if need for opioid therapy extends beyond the anticipated time period. POTENTIAL RISK FACTORS – Medical and psychiatric co-morbidities, emotional/physical trauma, declines other adjunctive treatments, inconsistency in prescription monitoring, personal or family history of substance abuse, positive score on screening questionnaires, conflicting or non-specific medical diagnoses, patient deception, complex pain conditions, and smoking. No single risk factor is predictive of a problematic course, and decisions about patient care should be balanced with a thorough assessment of patient strengths and coping skills.
   - Adhere to federal and state laws and regulations regarding prescription of medication, including but not limited to state Prescription Monitoring Program regulations.
   - Start with the lowest possible effective dose.
   - Prescribe no more than the number of doses needed based on usual duration of pain severe enough to require opioids for that condition.
   - Counsel the patient on risks of overdose, dependence, addiction, the importance of using medications as prescribed for effective pain relief, as well as safe storage and proper disposal of unused medication.
   - The use of opioids can present serious safety concerns. Review job requirements and provide guidance regarding safe use of medication while performing safety sensitive activities such as operating machinery and driving. Discuss possible dangers associated with psychomotor effects related to dosage and timing.
   - Consider psychological assessment when risk factors are present.

3. Do not initiate treatment of acute pain, including post-operative pain, with long acting opioid analgesics.

4. The use of opioids, including controlled substances, should be re-evaluated if persistence of pain suggests the need to continue these medications beyond the anticipated time period of pain treatment for the condition.

5. When issuing a prescription for an opiate to an adult patient for outpatient use for the first time, a practitioner shall not issue a prescription for more than a 7-day supply. A practitioner shall not issue an opiate prescription to a minor for more than a 7-day supply at any time and shall discuss with the parent or guardian of the minor the risks associated with opiate use and the reasons why the prescription is necessary. Notwithstanding the aforesaid, if, in the professional medical judgment of a practitioner, more than a 7-day supply of an opiate is required to treat the adult or minor patient's acute medical condition or is necessary for the treatment of chronic pain management, then the practitioner may issue a prescription for the quantity needed to treat such acute medical condition or chronic pain. The condition triggering the prescription of an opiate for more than a 7-day supply shall be documented in the patient's medical record and the practitioner shall indicate that a non-opiate alterative was not appropriate to address the medical condition. See M.G.L. Chapter 94C Section 19D.

6. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day. If the patient's dosage is increased to 90 MME/day without substantial improvement in function and pain, seek a consultation with a pain specialist. A consult may be considered at an earlier time period if there are risk factors related to opioid treatment.

7. Exercise caution when prescribing opioid analgesics to patients currently taking benzodiazepines, barbiturates, centrally acting muscle relaxants, other central nervous system depressants, and/or other opioids; and consider conferring with co-treating health care provider to coordinate care and formulate a treatment plan which minimizes the effects of polypharmacy. Treatment with a combination of opioids and scheduled sedatives should be discouraged.

8. Medical record should document evaluation, current medication list, and the clinical rationale for prescribing opioids and other controlled substances if any, along with the functional benefit from continued use. Documentation should include a discussion regarding a safe return to work plan and safety issues pertaining to change of medication dose.

9. The use of an opioid treatment agreement is recommended after 4 weeks, or when risk factors for opioid misuse are present, in order to document patient understanding, acknowledgement of potential adverse effects, agreement with the expectations of opioid use, and conditions for termination of opioid prescribing.

RECOMMENDATION FOR CHRONIC PAIN

MA Chronic Pain Treatment Guideline Section IV. D. MEDICATIONS

Before initiating or maintaining a patient on opioid therapy for chronic pain, a formal risk assessment should occur, addressing risks and benefits of this treatment. Studies support a potential pain reduction benefit for a small subset of patients, although empirical data supporting gains lasting longer than one year are lacking. Studies do not demonstrate objective improvements in function. Especially at higher doses, serious risks of chronic opioid therapy can include development of opioid use disorder, death from overdose, breathing problems during sleep, hypogonadism, immunosuppression, chronic constipation, bowel obstruction, and hyperalgesia, i.e., increased sensitivity to feeling pain. Risks for any poor outcome including overdose are significantly increased with the patient who is also being managed on multiple other medications for pain, i.e., polypharmacy. Presence of multiple medical and psychiatric comorbidities also potentiate risk. It should be noted, however, in the absence of empirical data supporting long-term opioid therapy (LTOT), a small number of patients have fared well with LTOT. This highlights the importance of treating each chronic pain patient through an individualized treatment plan, which may include LTOT for certain patients.

All patients who are on opioid therapy for chronic pain should be provided with education about risk, complete a written treatment agreement, and be assessed by a pain physician or pain psychologist with experience in opioid risk stratification. Formal validated screening measures also are available, as well as use of the state prescription drug monitoring program and urine toxicology assessment. All patients also should receive naloxone, and household members should receive education, to mitigate overdose risk.

As with other forms of pain treatment, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks associated with LTOT. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

It is recommended that use of opioid analgesics and sedative hypnotic medications in chronic pain patients be used in a very limited manner, with total avoidance desirable whenever clinically feasible and/or resolution of the underlying cause of the pain. However, comorbid chronic pain and refractory anxiety often exist, and co-prescription of these types of agents require more careful patient monitoring rather than complete preclusion.

On-Going, Long-Term Opioid Management – Actions should include:

A) Prescriptions from a single practitioner, and one pharmacy when possible. Clinicians should review the patient's history of controlled substance prescriptions using state Prescription Drug Monitoring Program (PDMP) data to determine whether the patient is receiving opioids from multiple sources or dangerous combinations that put the patient at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and at every prescribing visit during opioid therapy for chronic pain. The Massachusetts Prescription Monitoring Program may be accessed at **www.mass.gov/dph/dcp/onlinepmp**.

B) Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Visits initially at least every 2-4 weeks for the first 2-4 months of the trial, then at least once every 6-8 weeks while receiving opioids.

C) Patient Physician Agreement – All patients on long term opioids must have a written, informed agreement. The agreement should discuss side effects of opioids, results of use in pregnancy, inability to refill lost or missing medication/prescription, withdrawal symptoms, requirement for random drug testing and pill counts, necessity of tapering, and reasons for termination of prescription. The agreement should NOT be unilateral, i.e., physician responsibilities within the relationship should be delineated as well as those of the patient. Abandonment must not be a consequence of agreement violation.

D) A baseline initial drug screen should be performed before starting opioid therapy, and the use of random drug screening at least twice and up to 4 times per year, or more if clinically indicated, for the purpose of improving patient care. Based on the empirical literature, the higher the individual patient's risk, the more frequently the patient should undergo screening.

E) If more than two opioids are prescribed for long-term use**;** and/or the total daily dose of opioids is above 90 MME/day; and/or opioids and other central nervous system depressants are prescribed, then a second opinion from a Pain Medicine Specialist is strongly recommended.

F) Inpatient treatment may be appropriate in complex cases as well as referral to a Pain Specialist.

G) Laboratory monitoring as indicated.

H) The total daily dose of opioids should not be increased above 90 MME/day. In some instances, the patient may benefit from a higher dose if there is documented objective improvement in function and pain, a lack of significant opioid side effects, and a lack of signs of opioid misuse or abuse, all of which should be assessed on each visit.

I) Multidisciplinary treatment including non-opioid pain medication and non-pharmacological therapies, including but not limited to home exercise, chiropractic treatment, physical therapy, and psychological treatment may be beneficial. "Multidisciplinary" should be defined as coordinated treatment by multiple disciplines in which the providers communicate with each other in order to develop and implement treatment that takes into consideration the patient's complex biopsychosocial needs.

J) Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate these risk factors into the management plan strategies to mitigate risk, including offering naloxone especially when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

K) Clinicians should, if possible, offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder. Prescribing practitioners should be mindful of the impact of prescribing opioids relative to safety sensitive positions; and provide a prescription for naloxone and overdose education to patient and household members.

GENERAL GUIDELINES FOR OPIOID DISCONTINUATION AND TAPERING

Patients should not be abandoned

Tapering may be necessary. Medical management ideally should be part of an overall interdisciplinary treatment plan and return to work must be a treatment goal if medically possible. Multidisciplinary treatment including non-opioid pain medication and non-pharmacological therapies, including but not limited to home exercise, chiropractic treatment, physical therapy, acupuncture, and psychological treatment may be beneficial during the tapering process. If a patient meets criteria for a diagnosis of Substance Use Disorder (SUD), admission to a formal substance use treatment facility should take precedence over other components of care.

Tapering to a reduced dosage or discontinuing opioid therapy should be considered if:

- Resolution of the painful condition.
- The patient received other treatment(s) resulting in pain reduction and thus no longer requires the same opioid dose.
- The patient requests a dosage reduction and/or there are significant side effects that are refractory to management.
- The patient fails to achieve or maintain significant pain relief or functional improvement despite reasonable dose escalation.
- The patient is on a dosage of ≥ 50 MME per day without clear evidence of benefit outweighing risk.
- Evidence of opioid misuse (e.g. challenges with adherence to prescribed schedule, repeated dose increases, problematic urine toxicology screening or PDMP results, evidence of diversion, using for reasons other than prescribed).
- The patient shows warning signs of overdose risk.
- The patient has had an overdose or other serious event.
- The effects of opioids are resulting in serious medical or psychiatric comorbidities.
- The patient is receiving medications (e.g. benzodiazepines) or has medical conditions (e.g. sleep apnea, pulmonary disease, liver disease, kidney disease, fall risk, or mental health conditions) that increase risk for adverse outcomes.
- Additionally: The patient is on a dosage of ≥ 90 MME per day unless there is clear evidence tapering is harmful.

Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

Tapering long-term opioid analgesics remains a practice area for which there are few well-designed studies. Nonetheless, practical guidance is available from resources that promote best practices. The most widely used guideline is the HHS Guide for Clinicians on the Appropriate Dose Reduction or Discontinuation of Long Term Opioids.

https://www.hhs.gov/system/files/Dosage_Reduction_Discontinuation.pdf

Immediate discontinuation of opioids is always discouraged and can place the patient at great risk for overdose and other morbidities as well as mortality. For the patient on opioids for over one year and/or on high doses (≥ 90 MME), a structured taper is recommended. Medically assisted tapers may be considered and unless contraindicated, offered to the patient. Frequent follow-up during tapering period is recommended. Assessments should illicit information to develop a treatment plan that addresses the taper, pain, function, and co-morbidities. Assessments should include those related to mood changes and other psychiatric comorbidities. Chronic medical conditions can increase the risk of continued opioid use and should be managed in tandem. If the patient is pregnant, consider postponing the taper and ensure the patient will deliver at a facility that is equipped for treatment of neonatal opioid withdrawal syndrome. For pregnant patients, tapering may cause adverse antenatal outcomes such as premature labor or spontaneous abortion.

Fear of withdrawal and fear of increased pain are common. Anxiety can be reduced, and a successful taper is more likely with high frequency clinician contact, e.g., weekly visits, or regular communication by virtual visited or other electronic means. Interdisciplinary care, including behavioral management of anxiety, is always recommended for patients with psychiatric comorbidities common to chronic pain. “Crises” commonly occur during tapering, typically involving an increase in pain, and efforts to continue the course of care should be encouraged. A pain increase may not be related to inadequate dosing or “too rapid” of a taper. Although successful tapering may reduce the patient’s pain, all tapering protocols should include other pain management interventions that focus on reducing the patient’s distress and improving overall function. A harm reduction framework and approach may be applicable to patients on long-term opioid therapy to prevent opioid related deaths. Not all patients are immediately ready to begin a taper. A motivational interviewing approach with high frequency patient contact should be used to engage the patient and shared decision-making increases the success of tapers. If the patient is resistant to referral or change in opioid use, continue to work with them, provide information, and continue to encourage appropriate referral. There are serious risks for continuing a patient on opioids when opioids are contraindicated, and decision-making should occur within a clear time period e.g. one month time frame.

- Recommendations for tapering schedules vary and should always be individualized. The rate of opioid taper should be adjusted based on patient-specific factors such as the severity of withdrawal symptoms. Tapering may be based on duration of opioid use:
  - Less than or equal to 3 days of scheduled use or as needed: no taper required
  - > 3 days but < 7 days of scheduled use: 50% reduction over two days
  - 7 days but less than or equal to 1 month: 20% reduction every 2 days
  - More than or equal to 1 month but less than or equal to 1 year: 10% reduction every week
  - More than or equal to 1 year: 10% reduction each month

  Ref: Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. Cdc clinical practice guideline for prescribing opioids for pain - united states, 2022. *MMWR Recomm Rep.* 2022;71(3):1-95.
- Consultation with an addiction/pain medicine specialist or behavioral health specialist with expertise in pain management is recommended for complex patients.

- Multidisciplinary treatment including non-opioid pain medication and non-pharmacological therapies, including but not limited to home exercise, chiropractic treatment, physical therapy, acupuncture, and psychological treatment may be beneficial during the tapering process.
- Prescribe naloxone and instruct the patient and family/household members in overdose prevention.
- The potential impacts of tapering and discontinuation include opioid withdrawal and unmasking or exacerbation of previous medical and psychosocial conditions. These symptoms are treatable and involvement of other specialists may be considered before the taper is started. Considerations for delayed or slow tapering may be appropriate. Tapering may also increase overdose risk as tolerance to a higher dose is lost in less than one week.

Injured workers on long term opioids may benefit from the Department of Industrial Accidents Opioid Alternative Treatment Program (OAP) – Section 19A Medical Mediation Agreement.

LINKS:
https://www.hhs.gov/system/files/Dosage_Reduction_Discontinuation.pdf
www.massmed.org/opioid-guidelines/
www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm
https://www.hss.edu/conditions_patient-guide-opioid-tapering.asp#:~:text=Fast%20tapering%20is%20the%20process,usually%20cause%20severe%20withdrawal%20symptoms.