

CASEREVIEW

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Notice of Independent Review Decision

DATE OF REVIEW: AUGUST 9, 2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Pharmacy: MS Contin 100 mg po qid #120

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION

This physician is Board Certified in Physical Medicine and Rehabilitation with over 15 year of experience.

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

August 19, 2009: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD who noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, muscle spasms. He recommended an MRI LS for the evaluation of slowly worsening LBP/LE radiculopathy, MRI CS for the evaluation of worsening neck pain/LUE radiculopathy/parasthesias and EMG BUE/BLE. He prescribed him MS Contin (increase to 100 mg tid), MSIR 30 mg (decrease to tid prn btp), Soma 350 mg tid, Lyrica 100 mg and Peri Colace 50/8.6 mg.

September 17, 2009: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD who noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, muscle spasms. He recommended an MRI LS for the evaluation of slowly worsening LBP/LE radiculopathy, MRI CS for the evaluation of worsening neck pain/LUE radiculopathy/parasthesias and EMG BUE/BLE. He prescribed him MS Contin (increase to 100 mg tid), MSIR 30 mg (decrease to tid prn btp), Soma 350 mg tid, Lyrica 100 mg and Peri Colace 50/8.6 mg.

October 15, 2009: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD who noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, muscle spasms. He recommended an MRI LS for the evaluation of slowly worsening LBP/LE radiculopathy, MRI CS for the evaluation of worsening neck pain/LUE radiculopathy/parasthesias and EMG BUE/BLE. He prescribed him MS Contin (increase to 100 mg tid), MSIR 30 mg (decrease to tid prn btp), Soma 350 mg tid, Lyrica 100 mg and Peri Colace 50/8.6 mg. He also recommended repeat LESIs, Dx worsening LBP/LE radicular symptoMr.

November 4, 2009: MRI Spine Lumbar W/WO contrast (read by: RT) Impression: There is mild multilevel lumbar spondylosis. This causes mild foraminal narrowing at multiple levels, though without demonstrable intraforaminal nerve root compression. At L2-L3 there is borderline deflection of the right-sided posterior L3 nerve root due to asymmetric disc bulge. Minor disc bulges are seen elsewhere but with no canal stenosis.

MRI Spine Cervical W/WO Contrast (read by: RT) Impression: Multilevel cervical spondylosis partially accentuated by reversal cervical curvature. At C3-C4 there is partial effacement of the ventral thecal sac with borderline compression of the midline cord and slight left foraminal narrowing. At C4-C5 there is mild compression of the midline ventral cord. At C5-C6 partial effacement of ventral thecal sac is noted. There is minimal right foraminal narrowing. At C6-C7 partial effacement of the thecal sac with no cord compression.

November 12, 2009: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD who noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy.

December 10, 2009: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD who noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He also recommended surgery and scheduled a surgical evaluation for CS/LS.

January 7, 2010: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD who noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He also recommended surgery and scheduled a surgical evaluation for CS/LS.

February 4, 2010: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD who noted Mr.'s symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended surgery and scheduled a surgical evaluation for CS/LS.

March 4, 2010: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD who noted Mr.'s symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms. He also noted that they received surgery recommendation but did not receive surgery.

April 1, 2010: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD who noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that

they repeat CESI for worsened typical symptoms. He also noted that they received surgery recommendation but did not receive surgery.

April 29, 2010: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD who noted Mr.'s symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms. He also noted that they received surgery recommendation but did not receive surgery.

May 27, 2010: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD who noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms. He also noted that they received surgery recommendation but did not receive surgery.

June 24, 2010: Mr. was examined by Dr. MD who noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms. He also noted that they received surgery recommendation but did not receive surgery. He noted that the repeat surgical evaluation (CS/LS) was approved and pending appointment with surgeon.

July 22, 2010: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD noted that Mr. underwent evaluation with Mr., Clinic, 7/10 with recommendations of CT/Myelo LS pending. He also noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms.

August 19, 2010: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD noted that Mr. underwent evaluation with Mr. Clinic, 7/10 with recommendations of CT/Myelo LS pending. He also noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the

LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms.

September 16, 2010: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD noted that Mr. underwent evaluation with Mr. Clinic, 7/10 with recommendations of CT/Myelo LS pending. He also noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms.

October 14, 2010: Mr (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr., MD noted that Mr. underwent evaluation with Mr. Clinic, 7/10 with recommendations of CT/Myelo LS pending. He also noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms.

November 11, 2010: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD noted that Mr. underwent evaluation with Mr. Clinic, 7/10 with recommendations of CT/Myelo LS. He noted that they are attempting to appeal the denial of CT/Myelo. He also noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms.

December 9, 2010: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD noted that Mr. underwent evaluation with Mr. Clinic, 7/10 with recommendations of CT/Myelo LS. He noted that they are attempting to appeal the denial of CT/Myelo. He also noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms.

January 3, 2011: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD noted that Mr. underwent evaluation with Mr. Clinic, 7/10 with recommendations of CT/Myelo LS. He noted that they are attempting to appeal the denial of CT/Myelo. He also noted Mr. symptoms to be consistent with significant

CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms.

February 3, 2011: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD noted that Mr. underwent evaluation with Mr. Clinic, 7/10 with recommendations of CT/Myelo LS. He noted that they are attempting to appeal the denial of CT/Myelo. He also noted Mr.'s symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms.

March 3, 2011: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD noted that Mr. underwent evaluation with Mr. Clinic, 7/10 with recommendations of CT/Myelo LS. He noted that they are attempting to appeal the denial of CT/Myelo. He also noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms. Medications: Duragesic – Significantly effective, MS Contin – Significantly effective, MSIR – Significantly effective, HCD – Minimally effective, Opana 5 mg – Ineffective, Soma 350 tid – Significantly effective, Skelaxin – Unable to recall effectiveness, Flexeril – Ineffective, Zanaflex – Minimally effective, Robaxin – Ineffective, Restoril – Moderately effective, Lyrica – Significantly effective, and Elavil/Paxil – Moderately effective.

March 31, 2011: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD noted that Mr. underwent evaluation with Mr. Clinic, 7/10 with recommendations of CT/Myelo LS. He noted that they are attempting to appeal the denial of CT/Myelo. He also noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms.

April 28, 2011: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr., MD noted that Mr. underwent evaluation with Mr. Clinic, 7/10 with recommendations of CT/Myelo LS. He noted that they are attempting to appeal the denial of CT/Myelo. He also noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and

muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms.

May 11, 2011: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD noted that Mr. underwent evaluation with Mr. Clinic, 7/10 with recommendations of CT/Myelo LS. He noted that they are attempting to appeal the denial of CT/Myelo. He also noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms.

May 26, 2011: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr., MD noted that Mr. underwent evaluation with Mr. Clinic, 7/10 with recommendations of CT/Myelo LS. He noted that they are attempting to appeal the denial of CT/Myelo. He also noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms.

June 23, 2011: Mr. (who reported worsening pain in his neck and by any activity including sitting, standing, bending, twisting, and riding in a car) was examined by Dr. MD noted that Mr. underwent evaluation with Mr. Clinic, 7/10 with recommendations of CT/Myelo LS. The appeal of the CT/Myelo was denied again. He also noted Mr. symptoms to be consistent with significant CS/LS disc disruptions resulting in persistent/worsening radiculopathy, parasthesias, subjective weakness, and muscle spasms. He also recommended repeat LESIs, Dx worsening LBP/LE radiculopathy. He noted that the LESIs were denied twice. He also recommended that they repeat CESI for worsened typical symptoms. Medications: Duragesic – Significantly effective, MS Contin – Significantly effective, MSIR – Significantly effective, HCD – Minimally effective, Opana 5mg – Ineffective, Soma 350 mg tid – Significantly effective, Skelaxin – unable to recall effectiveness, Flexeril – Ineffective, Zanaflex – Minimally effective, Robaxin – Ineffective, Restoril – Moderately effective, Lyrica (100mg) – Significantly effective, Cymbalta – Significantly effective, and Elavil/Paxil – Moderately effective.

June 27, 2011: M.D. performed a UR on the claimant. Rationale for Denial: “The most recent note dated 5/26/11 notes increasing pain despite escalating opiate dosages requiring addition of Percocet to the current regimen of long and short acting Morphine and request for repeated cervical and lumbar ESIs. The claimant is utilizing over 520 Morphine equivalents of opioid per day. As such narcotic decency is likely. Even at this high dosage, pain is poorly controlled and therefore opioid hyperalgesia should be considered along with a weaning schedule.”

July 8, 2011: M.D. performed a UR on the claimant. Rationale for Denial: The clinical documentation submitted in support of the appeal request does not provide a clear rationale and medical decision-making to establish the medical necessity of this dosing schedule; therefore, the prior non-certification is upheld.

PATIENT CLINICAL HISTORY:

The worker sustained an un-described industrial injury more than 15 years ago.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.

Decision to deny MS Contin is upheld upon. Per the ODG Pain Chapter Recommendation opioid dosing should not exceed 120 mg oral morphine per day and recommendation to discontinue opioids if “persistent pain and lack of improved function despite high doses of opiates of > 120 mg per day.” This claimant has persistent pain despite escalating dosage of opioids with a morphine equivalent dose on MS Contin 100 mg qid. MSIR 30 mg, Percocet 10/325 mg is at a minimum of 490 mg per day to a maximum of 580 mg per day. Also submitted clinicals do not note monitoring for adverse side effects or abhorrent behavior with no notation of urine drug screens despite ever increasing amounts of opioids prescribed.

Per the ODG:

Opioids

This topic is covered under multiple headings. See more specific entries, as follows: [Opioids, criteria for use](#); [Opioids for chronic pain](#); [Opioids for neuropathic pain](#); [Opioids for osteoarthritis](#); [Opioids, cancer pain vs. nonmalignant pain](#); [Opioids, dealing with misuse & addiction](#); [Opioids, differentiation: dependence & addiction](#); [Opioids, dosing](#); [Opioids, indicators for addiction](#); [Opioids, long-term assessment](#); [Opioids, pain treatment agreement](#); [Opioids, psychological intervention](#); [Opioids, specific drug list](#); [Opioids, screening for risk of addiction \(tests\)](#); [Opioids, state medical boards guidelines](#); [Opioids, steps to avoid misuse/addiction](#); [Detoxification](#); [Substance abuse](#) (tolerance, dependence, addiction); [Urine Drug Testing](#) (UDT) in patient-centered clinical situations; [Weaning of medications](#); [Implantable drug-delivery systems](#) (IDDSs); [Methadone](#); [Rapid detox](#); [Testosterone replacement for hypogonadism](#) (related to opioids); [Opioid hyperalgesia](#) & [Opioids, specific drug list](#). Opioid drugs are also referred to as opiate analgesics, narcotic analgesics, or schedule C (II -IV) controlled substances. Opioid analgesics are a class of drugs (e.g., morphine, codeine, and methadone) that have a primary indication to relieve symptoms related to pain. Opioid drugs are available in various dosage forms and strengths. They are considered the most powerful class of analgesics that may be used to manage both acute and chronic pain. These medications are generally classified according to potency and duration of dosage duration.

Overall Classification:

Pure-agonists: include natural and synthetic opioids such as morphine sulfate (MS Contin®), hydromorphone (Dilaudid®), oxymorphone (Numorphan®), levorphanol (Levo-Dromoran®), codeine (Tylenol w/Codeine 3®), hydrocodone (Vicodin®), oxycodone (OxyContin®), methadone (Dolophine HCl®), and fentanyl (Duragesic®). This group of opioids does not have a ceiling effect for their analgesic efficacy nor do they antagonize (reverse) the effects of other pure opioids. (Baumann, 2002) Morphine is the most widely used type of opioid analgesic for the treatment of moderate to severe pain due to its availability, the range of doses offered, and its low cost.

Partial agonists-antagonists: agents that stimulate the analgesic portion of opioid receptors while blocking or having little or no effect on toxicity. This group of opiates includes buprenorphine (Suboxone®). Partial agonists-antagonists have lower abuse potential than pure-agonists, however the side effects of this class of analgesics include hallucinations and dysphoria. *Opioid antagonists* such as naloxone are included in this class. They are most often used to reverse the effects of agonists and agonist-antagonist derived opioids. (Baumann, 2002)

Mixed agonists-antagonists: another type of opiate analgesics that may be used to treat pain. They include such drugs as butorphanol (Stadol®), dezocine (Dalgan®), nalbuphine (Nubain®) and pentazocine (Talwin®). (Baumann, 2002) Mixed agonists-antagonists have limited use among chronic pain patients because of their ceiling effect for analgesia that results in the analgesic effect not increasing with dose escalation.

Central acting analgesics: an emerging fourth class of opiate analgesic that may be used to treat chronic pain. This small class of synthetic opioids (e.g., Tramadol) exhibits opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Central analgesics drugs such as Tramadol (Ultram®) are reported to be effective in managing neuropathic pain. (Kumar, 2003) Side effects are similar to traditional opioids.

Opioid Classifications: Short-acting/Long-acting opioids:

Short-acting opioids: also known as “normal-release” or “immediate-release” opioids are seen as an effective method in controlling both acute and chronic pain. They are often used for intermittent or breakthrough pain. These agents are often combined with other analgesics such as acetaminophen and aspirin. These adjunct agents may limit the upper range of dosing of short-acting agents due to their adverse effects. The duration of action is generally 3-4 hours. Short-acting opioids include Morphine (Roxanol®), Oxycodone (OxyIR®, Oxyfast®), Endocodone®, Oxycodone with acetaminophen, (Roxilox®, Roxicet®, Percocet®, Tylox®, Endocet®), Hydrocodone with acetaminophen, (Vicodin®, Lorcet®, Lortab®, Zydone®, Hydrocet®, Norco®), Hydromorphone (Dilaudid®, Hydrostat®). (Baumann, 2002)

Long-acting opioids: also known as “controlled-release”, “extended-release”, “sustained-release” or “long-acting” opioids, are a highly potent form of opiate analgesic. The proposed advantage of long-acting opioids is that they stabilize medication levels, and provide around-the-clock analgesia. Long-acting opioids include: Morphine (MSContin®, Oramorph SR®, Kadian®, Avinza®), Oxycodone (Oxycontin®), Fentanyl (Duragesic Patch®), Hydromorphone (Palladone®). Note: On 01/26/10 Purdue Pharma suspended Palladone® from the US market due to adverse effects with alcohol. (FDA, 2010)

CRITERIA FOR USE OF OPIOIDS

Therapeutic Trial of Opioids

1) Establish a Treatment Plan. The use of opioids should be part of a treatment plan that is tailored to the patient. Questions to ask prior to starting therapy:

- (a) Are there reasonable alternatives to treatment, and have these been tried?
- (b) Is the patient likely to improve? Examples: Was there improvement on opioid treatment in the acute and subacute phases? Were there trials of other treatment, including non-opioid medications?
- (c) Has the patient received a screen for the risk of addiction? Is there likelihood of abuse or an adverse outcome? See [Substance abuse \(tolerance, dependence, addiction\)](#). See [Opioids, screening for risk of addiction](#). ([Webster, 2008](#)) ([Ballyantyne, 2007](#))
- (d) Ask about Red Flags indicating that opioids may not be helpful in the chronic phase: (1) Little or no relief with opioid therapy in the acute and subacute phases. (2) The patient has been given a diagnosis in one of the particular diagnostic categories that have not been shown to have good success with opioid therapy: conversion disorder; somatization disorder; pain disorder associated with psychological factors (such as anxiety or depression, or a previous history of substance abuse). Patients may misuse opioids prescribed for pain to obtain relief from depressed feelings, anxiety, insomnia, or discomforting memories. There are better treatments for this. ([Sullivan, 2006](#)) ([Sullivan, 2005](#)) ([Wilsey, 2008](#)) ([Savage, 2008](#))
- (e) When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

2) Steps to Take Before a Therapeutic Trial of Opioids:

- (a) Attempt to determine if the pain is nociceptive or neuropathic. Also attempt to determine if there are underlying contributing psychological issues. Neuropathic pain may require higher doses of opioids, and opioids are not generally recommended as a first-line therapy for some neuropathic pain.
- (b) A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics.
- (c) Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals.
- (d) Baseline pain and functional assessments should be made. Function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale. See Function Measures.
- (e) Pain related assessment should include history of pain treatment and effect of pain and function.
- (f) Assess the likelihood that the patient could be weaned from opioids if there is no improvement in pain and function.
- (g) The patient should have at least one physical and psychosocial assessment by the treating doctor (and a possible second opinion by a specialist) to assess whether a trial of opioids should occur. When subjective complaints do not correlate with imaging studies and/or physical findings and/or when psychosocial issue concerns exist, a second opinion with a pain specialist and a psychological assessment should be obtained. ([Sullivan, 2006](#)) ([Sullivan, 2005](#)) ([Wilsey, 2008](#)) ([Savage, 2008](#)) ([Ballyantyne, 2007](#))
- (h) The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian.
- (i) A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient's use of medications for relief from pain. See [Guidelines for Pain Treatment Agreement](#). This should include the consequences of non-adherence.

(j) Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs.

3) Initiating Therapy

(a) Intermittent pain: Start with a short-acting opioid trying one medication at a time.

(b) Continuous pain: extended-release opioids are recommended. Patients on this modality may require a dose of "rescue" opioids. The need for extra opioid can be a guide to determine the sustained release dose required.

(c) Only change 1 drug at a time.

(d) Prophylactic treatment of constipation should be initiated.

(e) If partial analgesia is not obtained, opioids should be discontinued.

4) On-Going Management. Actions Should Include:

(a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.

(b) The lowest possible dose should be prescribed to improve pain and function.

(c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of [function](#), or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. *The 4 A's for Ongoing Monitoring*: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. ([Passik, 2000](#))

(d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.

(e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. ([Webster, 2008](#))

(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).

(g) Continuing review of overall situation with regard to nonopioid means of pain control.

(h) Consideration of a consultation with a [multidisciplinary pain clinic](#) if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. ([Sullivan, 2006](#)) ([Sullivan, 2005](#)) ([Wilsey, 2008](#)) ([Savage, 2008](#)) ([Ballyantyne, 2007](#))

5) Recommended Frequency of Visits While in the Trial Phase (first 6 months):

(a) Every 2 weeks for the first 2 to 4 months

(b) Then at approximate 1 ½ to 2-month intervals

Note: According to the California Medical Board Guidelines for Prescribing Controlled Substances for Pain, patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care. ([California, 1994](#))

6) When to Discontinue Opioids: See [Opioid hyperalgesia](#). Also see [Weaning of Medications](#). Prior to discontinuing, it should be determined that the patient has not had treatment failure due to causes that can be corrected such as under-dosing or inappropriate dosing schedule.

Weaning should occur under direct ongoing medical supervision as a slow taper except for the

below mentioned possible indications for immediate discontinuation. The patient should not be abandoned.

- (a) If there is no overall improvement in function, unless there are extenuating circumstances
- (b) Continuing pain with the evidence of intolerable adverse effects; lack of significant benefit (persistent pain and lack of improved function despite high doses of opiates- e.g. > 120 mg/day morphine equivalents)
- (c) Decrease in functioning
- (d) Resolution of pain
- (e) If serious non-adherence is occurring
- (f) The patient requests discontinuing
- (g) Immediate discontinuation has been suggested for: evidence of illegal activity including diversion, prescription forgery, or stealing; the patient is involved in a motor vehicle accident and/or arrest related to opioids, illicit drugs and/or alcohol; intentional suicide attempt; aggressive or threatening behavior in the clinic. It is suggested that a patient be given a 30-day supply of medications (to facilitate finding other treatment) or be started on a slow weaning schedule if a decision is made by the physician to terminate prescribing of opioids/controlled substances.
- (h) Many physicians will allow one "slip" from a medication contract without immediate termination of opioids/controlled substances, with the consequences being a re-discussion of the clinic policy on controlled substances, including the consequences of repeat violations.
- (i) If there are repeated violations from the medication contract or any other evidence of abuse, addiction, or possible diversion it has been suggested that a patient show evidence of a consult with a physician that is trained in addiction to assess the ongoing situation and recommend possible detoxification. ([Weaver, 2002](#))
- (j) When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

7) When to Continue Opioids

- (a) If the patient has returned to work
- (b) If the patient has improved functioning and pain ([Washington, 2002](#)) ([Colorado, 2002](#)) ([Ontario, 2000](#)) ([VA/DoD, 2003](#)) ([Maddox-AAPM/APS, 1997](#)) ([Wisconsin, 2004](#)) ([Warfield, 2004](#))

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**

- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)