

# IMED, INC.

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## Notice of Independent Review Decision

### **[Date notice sent to all parties]:**

**07/21/2014**

### **IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: Exalgo ER 8mg one tablet #30**

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

Board Certified Anesthesiology

### **REVIEW OUTCOME:**

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

Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

### **INFORMATION PROVIDED TO THE IRO FOR REVIEW:**

Clinical report dated 04/02/13  
Clinical report dated 05/22/14  
Appeal letter dated 05/29/14  
Prospective review response dated 06/30/14  
Prior utilization review reports dated 05/28/14 & 06/06/14

### **PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is a male who sustained an injury on xx/xx/xx. The patient has been followed for complaints of persistent left upper extremity pain following a left shoulder arthroplasty performed in November of 2012. The clinical report on 04/02/13 indicated the patient had done well with time-released Hydromorphone. The patient was still pending surgical intervention per the report. Hydromorphone was being prescribed at 16mg extended release as well as Clonazepam, Lidoderm

patches, Nuvigil, Zanaflex, and Neurontin. The patient was instructed to utilize Exalgo 16mg once daily at this evaluation. Hydrocodone 10/325mg utilized every 4 hours as needed for breakthrough pain was also prescribed. The patient was seen on 05/22/14. The patient reported continuing severe pain, 10/10 on the VAS. At this visit, the patient's physical examination noted a shiny and purple coloration of the left arm and hand as compared to the right side with a lower temperature. Allodynia was present and there was lack of range of motion with stiffness of the left hand. The patient was prescribed Exalgo ER 8mg tablets taken once daily at this evaluation. The patient is noted to have had prior stellate ganglion blocks that were beneficial. The patient did report some benefits from narcotic medications. There were further recommendations for stellate ganglion blocks at this evaluation. The letter of medical necessity on 05/29/14 indicated that the patient did reasonably require time-released Dilaudid in between stellate ganglion blocks. Per her report, Exalgo was 1 of the only medications that had addressed his acute exacerbations of CRPS.

The requested Exalgo ER 8mg, quantity 30 was denied by utilization review on 05/28/14 as this medication was not a recommended 1<sup>st</sup> line medication for pain. There had been no indication that other medications had provided relief or that the current medication was providing any relief.

The request was again denied by utilization review on 06/06/14 as the patient had no substantial benefit from the use of opioid medications and that there was no indication for a long acting prescription for Hydromorphone versus a short acting prescription such as Dilaudid. There was a peer to peer conversation per the report in which stated that the patient would be taking pills too often with an immediate release Dilaudid and that long acting medications were better for the patient. again stated that the primary pain reduction procedure for this patient was stellate ganglion blocks.

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

The patient has been followed for a history of chronic regional pain syndrome affecting the left upper extremity. Per the reports the patient had substantial benefit from stellate ganglion blocks and was utilizing Exalgo as a method of reducing pain in between stellate ganglion blocks. argued that the patient would be utilizing immediate release Dilaudid too frequently to control his symptoms and that an extended release Exalgo was more beneficial for the patient. The clinical documentation provided for review failed to identify any specific functional improvement obtained with the use of Exalgo even as a time-released narcotic. Per guidelines, 1 of the essential requirements for continuation of narcotic medications is documentation regarding functional benefit and pain reduction. This has not been documented in the clinical reports provided for review. The patient's primary method of obtaining pain relief is from stellate ganglion blocks and not narcotic medications. There is no indication that the patient could not reasonably utilize other short acting narcotics for control of exacerbations of his CRPS symptoms.

The clinical documentation provided for review does not address the prior reviewer's concerns and as such, the opinion of this reviewer is that the request is not medically necessary.

## IRO REVIEWER REPORT TEMPLATE -WC

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

**MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**

**ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

Official Disability Guidelines, Online Version, Pain Chapter

#### Opioids, criteria for use

##### 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) Is there likelihood of abuse or an adverse outcome? See Substance abuse (tolerance, dependence, addiction).
- (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 had a psychological evaluation and has been given a diagnosis of somatoform disorder. (3) 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).
- (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.

(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.

(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.

**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

(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)