

# Icon Medical Solutions, Inc.

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## Notice of Independent Review Decision

**DATE:** November 24, 2014

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

OxyContin 20 mg tablet, take 1 p.o. b.i.d. #60, No refills

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

The reviewer is certified by the American Board of Physical Medicine and Rehabilitation with over 16 years of experience.

**REVIEW OUTCOME:**

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

Overturned (Disagree)

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

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The claimant is a male who sustained a right ankle fracture when he fell while working on xx/xx/xx.

10/22/13: The claimant was evaluated for pain to the right ankle, right foot, and neck. It was noted that he had been out of medication due to non-coverage of OxyContin. On exam, positive findings included altered mental status, obese patient presents with a cane favoring the right lower extremity. He had diminished motion at the right ankle and hypersensitivity at the right lower extremity. Mild swelling was seen at the right ankle and foot area. The assessment was right ankle pain. The plan was to request prior authorization for OxyContin due to intolerance of current prescription. His medications were listed as Norco 325/10 mg 1 q.d., OxyContin 20 mg 1 p.o. b.i.d., Cymbalta 60 mg 1 p.o. q.d., Robaxin 500 mg 1 p.o. q.d., Celebrex 200 mg 1 p.o. q.d., and Cymbalta 30 mg 1 q.d. He was noted to have an allergy to Claritin and Darvocet-N 50. Also noted: Gabapentin – pm due to side effects. Meloxicam – pt no longer taking. BuTrans – pt is no longer taking. Cymbalta.

02/07/14: The claimant was evaluated for ankle pain. It was noted that he had chronic ankle pain, suspected sympathetically maintained pain, and chronic OCD lesion of the medial talar dome s/p work related injury xxxx. He was noted to have toe off brace on the right side. He stated that the brace was rubbing his lateral ankle and developed some plantar heel pain about 8 months prior. He complained of plantar heel pain on the left side. He was taking OxyContin, Norco, Celebrex, Cymbalta, and Robaxin. On exam, his gait was antalgic. On the right, diffuse allodynia and hyperpathia were noted over the ankle and foot. He had some focal tenderness at the plantar fascia as well. Moderate gastroc tightness bilaterally. Right ankle x-ray, weight bearing, showed spurring at the dorsal TN joint and posterior calcaneus. Left calcaneus x-ray, weight bearing, showed a normal study. The impression was right plantar fasc/fibromatosis, right pain ankle foot, right osteochondritis dissecans, right neuralgia/neuritis nos, and right contracture tendon. The plan was to see an orthotist for modification of his brace. He was notified of the importance of gastroc stretching exercises. It was noted that he would have to have a life-long bracing requirement.

03/14/14: The claimant was evaluated. He was requesting to go back to the orthopedic doctor that did his brace on his right leg as his leg was bruised and discolored and he wanted to have a second look on it. He wanted to see if it was due for a new insert in his boot. On exam, his gait demonstrated limping favoring the right lower extremity. The assessment was right ankle pain s/p right ankle fracture. His OxyContin and Norco were refilled.

05/13/14: The claimant was evaluated. The notes remained unchanged from prior visits, including the exam. It was noted that he underwent urine drug screen on 05/13/14, with the results as follows: Negative for amphetamines, ecstasy, methamphetamines, cocaine, barbiturates, marijuana, methadone, or phencyclidine, and positive for benzodiazepines, oxycodone, opiates/morphine, and tri-cyclic antidepressants.

06/20/14: The claimant was evaluated. He rated his pain at 10/10 at worst and 3/10 at least. He stated that he had not been able to get a hold of the orthopedic for padding for his boots. His exam remained unchanged from prior visits. His OxyContin, Norco, Robaxin, and Cymbalta were refilled.

07/18/14: The claimant was evaluated with no change since last visit. He rated his pain as 3/10 at least and 10/10 at worst. The severity/intensity level was rated 3/10 with pain medication. He was taking Norco 325/10 mg t.i.d. and OxyContin 20 mg b.i.d. as well as Cymbalta and Robaxin. His OxyContin was refilled, and he was to continue HC and Cymbalta. He was to follow up with brace company for adjustment and repair of his boots.

08/15/14: The claimant was evaluated. He stated that it took about an hour and a half for his medications to fully kick in. He had lost his balance and fell about two weeks prior. He stated that OxyContin was the only medication that worked for his pain. It was noted that he received new boots and was walking better. A random urine drug screen was collected and found to be negative for

amphetamine, ecstasy, methamphetamines, cocaine, barbiturates, marijuana, methadone, and phencyclidine and positive for benzodiazepine, oxycodone, opiates/morphine, and tri-cyclic antidepressants.

09/05/14: UR. It is noted in the comments that the claimant was evaluated with MRI and bone scan and was noted to have undergone surgeries and subsequently developed signs of reflex sympathetic dystrophy. Other treatments included activity restrictions, assistive device, orthotics, physical therapy, home exercise program, sympathetic block, and medications. Medications were reportedly effective. A peer review on 08/07/14 noted that the claimant was noted to have clinical benefit from OxyContin with significant pain relief for a longer duration compared to other first-line opioids. It had allowed him to resume his home exercises as well as increase his functional mobility. It was noted that he was certified 60 tablets of OxyContin 20 mg in 05/2014. It was also noted that a letter of medical necessity dated 08/29/14 stated that he had little to no distinguished relief of his pain with previous use of Opana 5 mg, Opana ER 10 mg, and BuTrans 10 mcg. His symptoms had been stable with OxyContin 20 mg b.i.d. An updated clinical assessment from the prescribing physician to provide objective evidence of ongoing pain reduction with the use of OxyContin had not been noted. Associated functional improvement in terms of facilitating activities of daily living as well as work activities had also not been documented. Per guidelines, continuation of opioids is recommended when the patient has improved functioning and pain, and has returned to work. Lastly, a plan to institute treatment for drug-related constipation had not been noted. With the above issues, the medical necessity of this request is not substantiated.

09/12/14: The claimant was evaluated. He described his pain as burning, sharp, stabbing, constant, deep, stabbing, and throbbing at a severity/intensity level of 7/10 with pain medication. The signs and symptoms were alleviated by medication and rest. He stated that his medications were working well but he had to pay for his OxyContin himself as it was denied. He stated that his inserts were working for him. He stated that when he was on Opana, it changed his personality and he had nausea and vomiting and he was nonfunctional. The Duragesic patches "would not stay on." He had "issues with pain control with oxycodone." It was noted that his pain level during the past week was 6. Comparing the average pain during the past week with the average pain before treated with current pain relievers, percentage of pain that had been relieved was 50. The amount of pain relief with the current pain relievers was noted to be enough to make a difference in his life. He had no drug-aberrant behavior. It was noted in his social history that he was smoking a pack a day. His medications included Norco 325/10 mg 1 q.d., OxyContin 20 mg b.i.d., Cymbalta and Robaxin. His exam remained unchanged. On FCE, his dysfunctions included limited right ankle plantar flexion ROM, right ankle dorsiflexion ROM, right ankle inversion ROM, right ankle eversion ROM. Decreased right ankle plantar flexion muscle strength, right ankle dorsiflexion muscle strength, right ankle inversion muscle strength when compared bilaterally. Decreased left hand grip muscle strength when compared bilaterally. 72.5% disability rating as determined by the Functional Rating Index. Patient reports pain is a 4/10 on the visual analog scale.

10/03/14: UR. RATIONALE: The ODG indicate that opiates are appropriate for the treatment of chronic pain. There should be documentation of an objective functional improvement and an objective decrease in pain and documentation that patient is being monitored for aberrant drug behavior and side effects. The clinical documentation submitted for review indicated the patient had a 50% pain relief and had better physical functioning with family and social relationships. The patient was noted to have undergone a urine drug screen and had no aberrant drug behavior. Although it was documented that the patient had better functioning, there was lack of documentation of objective functional improvement. There was a lack of documentation indicating whether the patient had side effects from the current medications. This request would not be supported. However, this medication should not be stopped abruptly and, as such, should be weaned. This is a case and cannot be partially certified without a peer to peer discussion and agreement. As such, it must be denied in its entirety.

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

As the IRO request was labeled as life threatening, the previous adverse decisions are overturned. The life-threatening nature of the request signals that abrupt discontinuance of a chronically consumed (at least by documentation over one year) and undoubtedly by now psychologically and physically dependent opioid may potentially lead to significant withdraw, prompting (and rightly so) further urgent medical care. The request for this medication partially satisfies recommended criteria for medical necessity given stable, effective (reported 50% relief) management of chronic (13 years), severe (up to 10/10) sympathetically mediated pain of the right foot and ankle with reports of improved function without aberrant behavior and failure of several Y ODG drug Formulary analgesics (Gabapentin, Meloxicam, BuTrans, Opana, Duragesic patches) for either ineffectiveness or intolerance.

However, in light of two recent UR denials for this medication and alluded un-numbered previous denials for this N ODG drug formulary medication, there are several issues that still need to be definitely addressed, documented, and, if need be, discussed in a telephone peer-to-peer call by the prescribing provider upon the next monthly (and each and every time) request for this medication:

1. How the medication and other opioid Norco 10 mg are actually taken as opposed to just how they are prescribed.
2. VAS pain score on and off the medication.
3. Specific examples of improved function attributed to the medication (eg. Improved ankle range of motion and strength, improved duration of standing and walking time, increased frequency of performance of home exercises, ease of performance of specific ADLs, ability to perform specific chores around the house, ability to return to work).
4. Activity/work status.
5. Side effects attributable to the medication and how they are addressed.

6. Explanation of urine drug screens positive for benzodiazepines and tricyclic antidepressants that are not listed in current medication regimen (OxyContin, Norco, Cymbalta, Robaxin). Other prescribers of medication, and the medications they prescribe.
7. Catalogue of other self-directed pain modulation techniques including compliance with home exercise program, modalities (such as ice, heat, electrical stimulation), desensitization techniques, over the counter medications and/or topical agents, and activity modification.
8. Other previous or considered potentially longer acting interventions such as Lower Extremity Sympathetic blocks, trial of Spinal Cord Stimulator, Intrathecal Morphine Pump, and Chronic Pain Management Program.
9. Consideration of weaning from opioid medication all together.

Again, as the request was marked life threatening and due to reasons stated above, the request for OxyContin 20 mg tablet, take 1 p.o. b.i.d. #60, No refills is medically necessary at this time.

ODG:

<p>OxyContin® (oxycodone)</p>	<p>OxyContin® is the brand name of a time-release formula of the analgesic chemical oxycodone, produced by the pharmaceutical company Purdue Pharma. See <a href="#">Opioids</a> for general guidelines, as well as specific <a href="#">Oxycodone</a> controlled release (OxyContin®) listing for more information and references. This drug was recently included in a list of 20 medications identified by the FDA's Adverse Event Reporting System, that are under FDA investigation. (<a href="#">FDA, 2008</a>) On April 2, 2010, the FDA approved a new formulation of Oxycontin designed to discourage abuse, but according to the manufacturer, there is no evidence that the reformulation is less subject to misuse, abuse, diversion, overdose or addiction. (<a href="#">FDA, 2010</a>) Due to issues of abuse and Black Box FDA warnings, Oxycontin is recommended as second line therapy for long acting opioids. [Oxycontin ranked #1 in amount billed for WC in 2011. (<a href="#">Coventry, 2012</a>)]</p>
<p>Opioids, criteria for use</p>	<p>CRITERIA FOR USE OF OPIOIDS 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</p>

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

	<p>(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. &gt; 120 mg/day morphine equivalents)</p> <p>(c) Decrease in functioning</p> <p>(d) Resolution of pain</p> <p>(e) If serious non-adherence is occurring</p> <p>(f) The patient requests discontinuing</p> <p>(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.</p> <p>(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.</p> <p>(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. (<a href="#">Weaver, 2002</a>)</p> <p>(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.</p> <p>(k) Routine long-term opioid therapy is not recommended, and ODG recommends consideration of a one-month limit on opioids for new chronic non-malignant pain patients in most cases, as there is little research to support use. The research available does not support overall general effectiveness and indicates numerous adverse effects with long-term use. The latter includes the risk of ongoing psychological dependence with difficultly weaning. See <a href="#">Opioids for chronic pain</a>.</p> <p>7) When to Continue Opioids</p> <p>(a) If the patient has returned to work</p> <p>(b) If the patient has improved functioning and pain (<a href="#">Washington, 2002</a>) (<a href="#">Colorado, 2002</a>) (<a href="#">Ontario, 2000</a>) (<a href="#">VA/DoD, 2003</a>) (<a href="#">Maddox-AAPM/APS, 1997</a>) (<a href="#">Wisconsin, 2004</a>) (<a href="#">Warfield, 2004</a>)</p>
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**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)**