SENT VIA EMAIL OR FAX ON
Apr/13/2009

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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:
Apr/10/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
1. Baclofen 10mg SIG 1 tabpo tid for muscle spasms #90 X 2 refills; 2. Cymbalta 60mg SIG 1 po qd #30 X 2 refills; 3. Fentanyl Patch 50meg/hr SIG q2d for chronic pain #15 X 2 refills; 4. Lortab 10/500 SIG 1 tab po q6h prn for breakthrough pain #60 X 2 refills; 5. Neurontin 600 mg SIG 1 tab po qid for neuropathic pain #120 X 2 refills

DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
Board Certified in Physical Medicine and Rehabilitation
Subspecialty Board Certified in Pain Management
Subspecialty Board Certified in Electrodiagnostic Medicine
Residency Training PMR and ORTHOPAEDIC SURGERY

REVIEW OUTCOME:

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

[ ] Upheld (Agree)

[X] Overturned (Disagree)

[ ] Partially Overturned (Agree in part/Disagree in part)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

PATIENT CLINICAL HISTORY SUMMARY
This is a woman who developed RSD/CRPDI after a left fibular fracture in xxxx. She has had spread of the disorder. She had a spinal cord stimulator inserted in the cervical and lumbar region. There was a revision i2 2008. She had exacerbation of the disorder with a fall this past winter that required additional sympathetic blocks. She is confined to a motorized wheelchair. Dr. and Dr. wrote that she was being managed for her pain with polypharmacology consisting of gapapentin, Hydrocodone. Fentanyl patches, baclofen and Cymbalta.

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

The diagnosis of RSD or CRPD has been accepted. The question posed was the ongoing need for the medications listed above. The records stated ongoing use without an increase in their use. The treating doctors stated that she had a pain agreement. They did not provide urine screening as a precaution against diversion or abuse.

Because of the amount of material cited in the ODG, the Reviewer is extracting relevant parts. Section 3 of CRPS treatment cites the use of antidepressants and anticonvulsants. In fact, it advises gabapentin sepcifically. It discusses clonidine which chemically is related to baclofen. The ODG notes that CRPD has a neuropathic component and that Cymbalta is used in the treatment of neuropathic pain and depression. Its use in CRPD is accepted as an off label use of the medication. While the ODG advises the uses of tricyclics first, I do not know if that was previously been tried. There are multiple problems tolerating the tricyclic antidepressants. The ODG also warns about abrupt discontinuation of gabapentin (generic name for Neurotonin).

The ODG discussed the neuropathic pain relief for baclofen independent of its antispasticity component. It can also lead to hallucinations with aburpt discontinuation.

The last 2 mediations are hydrocodone and fentanyl. These are opiates and controlled substances. Opiates were once thought not to help the management of neuropathic pain. It is now known to be beneficial, but with risks. The ODG addresses the use of opiates in the management of neuropathic pain, but not specifically CRPD.

Dr. reported on 3/5/09 the specific improvement and pain control with each of the medications. He apparently did this in response to the prior lack of documentation of the benefits. He did not mention the drug screens that are recommended, not required, under law.

Therefore, the medications used and requested are appropriate. The Reviewer recognize others have different opinions on the use of opiates for controlled pain.

CRPS, treatmen

Recommended hierarchy of options as indicated below. The goal is to improve function.

Multiple pathophysiological mechanisms are responsible including neuropathic (sympathetic and independently-maintained pain), and immunologic (regional inflammation and altered human leukocyte antigens). Both peripheral sensitization and central sensitization have been proposed. (Ribbers, 2003) (Stanton-Hicks, 2006) There are no evidence-based treatment guidelines but several groups have begun to organize treatment algorithms. Recommendations:…

3. Pain management: (a) Pharmacological: antidepressants (particularly amitriptyline); anticonvulsants (particularly gabapentin); steroids; NSAIDS; opioids; calcitonin; bisphosphonates; α1 adrenoceptor antagonists (terazosin or phenoxybenzamine). The latter class of drugs has been helpful in SMP. Clonidine has been given transdermally and epidurally. (See CRPS, medications.) Bisphosphonates have some literature support in the presence of osteopenia. (Rho, 2002)

Cymbalta® (duloxetine)

Cymbalta® is the brand name for duloxetine, and it is supplied by Eli Lilly and Company. Duloxetine is an antidepressant in the class called Selective serotonin and norepinephrine reuptake inhibitors (SNRIs). See Duloxetine (Cymbalta®).

Duloxetine (Cymbalta®

Recommended as an option in first-line treatment of neuropathic pain. Duloxetine (Cymbalta®) is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRIs). It has FDA approval for treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy…

Antidepressants for chronic pai

Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur. (Saarto-Cochrane, 2005) Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment.

Neuropathic pain: Recommended (tricyclic antidepressants) as a first-line option, especially if pain is accompanied by insomnia, anxiety, or depression. (Saarto-Cochrane, 2007) (ICSI, 2007) Other recent reviews recommended both tricyclic antidepressants and SNRIs (i.e. duloxetine and venlafaxine) as first line options. (Dworkin, 2007) (Finnerup, 2007)…

Duloxetine (Cymbalta®): FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Used off-label for neuropathic pain and radiculopathy. Duloxetine is recommended as a first-line option for diabetic neuropathy. (Dworkin, 2007) No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. (Dworkin, 2007) More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain

Side effects: CNS: dizziness, fatigue, somnolence, drowsiness, anxiety (3% vs.2% for placebo), insomnia (8-13% vs. 6-7% for placebo). GI: nausea and vomiting (5-30%), weight loss (2%). Duloxetine can worsen diabetic control in some patients. It also causes sexual dysfunction. (Maizels, 2005)

Dosing: 60 mg once a day as an off-label option for chronic pain syndromes. Dosage adjustment may be required in patients with renal insufficiency.

Anti-epilepsy drugs (AEDs) for pai

Anti-epilepsy drugs (AEDs) are also referred to as anti-convulsants.

Recommended for neuropathic pain (pain due to nerve damage), but not for acute nociceptive pain (including somatic pain). …) The choice of specific agents reviewed below will depend on the balance between effectiveness and adverse reactions. See also specific drug listings below: Gabapentin (Neurontin®)…

Specifically studied disease states: (also see below for specific drugs)

Gabapentin (Neurontin®, Gabarone™, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006) This RCT concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. (Backonja, 1998) It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat (NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen2-Cochrane, 2005) (Zaremba, 2006) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005) Recommendations involving combination therapy require further study

Mechanism of action: This medication appears to be effective in reducing abnormal hypersensitivity (allodynia and hyperalgesia), to have anti-anxiety effects, and may be beneficial as a sleep aid. (Arnold, 2007)…

Weaning and/or changing to another drug in this class: Gabapentin should not be abruptly discontinued, although this recommendation is made based on seizure therapy. Weaning and/or switching to another drug in this class should be done over the minimum of a week. (Neurontin package insert)

Muscle relaxants (for pain)…

ANTISPASTICITY DRUGS: Used to decrease spasticity in conditions such as cerebral palsy, MS, and spinal cord injuries (upper motor neuron syndromes). Associated symptoms include exaggerated reflexes, autonomic hyperreflexia, dystonia, contractures, paresis, lack of dexterity and fatigability. (Chou, 2004

Baclofen (Lioresal®, generic available): The mechanism of action is blockade of the pre- and post-synaptic GABAB receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved). (ICSI, 2007)

Fentany

Fentanyl is an opioid analgesic with a potency eighty times that of morphine. Weaker opioids are less likely to produce adverse effects than stronger opioids such as fentanyl. Due to significant side effects, not for use in routine musculoskeletal pain. For more information and references, see Opioids for general guidelines, as well as specific Fentanyl listing for more information and references. See also Actiq® (fentanyl lollipop); Duragesic® (fentanyl transdermal system); & Fentora® (fentanyl buccal tablet).

Duragesic® (fentanyl transdermal system

Not recommended as a first-line therapy. Duragesic is the trade name of a fentanyl transdermal therapeutic system, which releases fentanyl, a potent opioid, slowly through the skin. It is manufactured by ALZA Corporation and marketed by Janssen Pharmaceutica (both subsidiaries of Johnson & Johnson). The FDA-approved product labeling states that Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means. Due to the significant side effects, not for use in routine musculoskeletal pain. See Fentanyl.

Hydrocodone (Vicodin®, Lortab®

Hydrocodone or is a semi-synthetic opioid which is considered the most potent oral opioid that does not require special documentation for prescribing in some states (not including California). See Opioids

Hydrocodone/ Acetaminophen (e.g., Vicodin®

See Opioids for general guidelines, as well as specific Hydrocodone/Acetaminophen (Anexsia®, Co-Gesic®, Hycet™; Lorcet®, Lortab®; Margesic-H®, Maxidone™; Norco®, Stagesic®, Vicodin®, Xodol®, Zydone®) listing for more information and references.

Opioids, criteria for us

CRITERIA FOR USE OF OPIOID

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 Therap

(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 dairy 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 month

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

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 circumstance

(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 functionin

(d) Resolution of pai

(e) If serious non-adherence is occurrin

(f) The patient requests discontinuin

(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 Opioid

(a) If the patient has returned to wor

(b) If the patient has improved functioning and pai

(Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004

Opioids for back pai

See Opioids for chronic pain

Opioids for chronic pai

Recommendations for general conditions:

- Neuropathic pain: Opioids have been suggested for neuropathic pain that has not responded to first-line recommendations (antidepressants, anticonvulsants). There are no trials of long-term use. There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant neuropathy. See Opioids for neuropathic pain…

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Opioids for neuropathic pai

Not recommended as a first-line therapy. Opioid analgesics and Tramadol have been suggested as a second-line treatment (alone or in combination with first-line drugs). A recent consensus guideline stated that opioids could be considered first-line therapy for the following

circumstances: (1) prompt pain relief while titrating a first-line drug; (2) treatment of episodic exacerbations of severe pain; (3) treatment of acute neuropathic pain; & (4) treatment of neuropathic cancer pain. (Dworkin, 2007) Response of neuropathic pain to drugs may differ according to the etiology of therapeutic pain. There is limited assessment of effectiveness of opioids for neuropathic pain, with short-term studies showing contradictory results and intermediate studies (8-70 days) demonstrating efficacy. (Eisenberg-Cochrane, 2006) (Eisenberg-JAMA, 2005) The results of short-term trials were mixed with respect to analgesia (less than 24 hours of treatment). Intermediate trials (average treatment duration of 28 days) showed statistical significance for reducing neuropathic pain by 20% to 30% (and 30% may be the threshold for describing a meaningful reduction of pain)….

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

[ ] ACOEM-AMERICA 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

[X] MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

[ ] MERCY CENTER CONSENSUS CONFERENCE GUIDELINES

[ ] MILLIMAN CARE GUIDELINES

[X] 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 ERVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

[ ] OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)