

SENT VIA EMAIL OR FAX ON
Sep/09/2010

IRO Express Inc.

An Independent Review Organization
835 E. Lamar Blvd. #394
Arlington, TX 76011
Phone: (817) 349-6420
Fax: (817) 549-0310

Email: resolutions.manager@iroexpress.com

NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Sep/09/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Oxycontic, Oxycodone, Xanax, Temazepam, Garbirril, and Imitrex

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

Oxycontic—Is Medically Necessary
Oxycodone—Is Medically Necessary
Xanax—Is Medically Necessary
Temazepam—Is Medically Necessary
Garbirril—Is Medically Necessary
Imitrex—NOT Medically Necessary

INFORMATION PROVIDED TO THE IRO FOR REVIEW

OD Guidelines
Denial Letters 6/18/10 and 7/8/10
Letter from Patient 8/27/10 and 8/24/10
768 pages from the patient 1995-2010
Dr. 5/31/10 and 6/18/10
Peer Review 6/17/10
Elite Physicians 7/7/10

PATIENT CLINICAL HISTORY SUMMARY

This is an internist who had tendinitis in xxxx determined to be CRPS in 1996 and described as total body RSD by 2000. He objected to decisions by. There are a large number of records over a xx years discussing his RSD and treatment including medication use and nerve blocks. Current medications are denied and are under appeal.

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

This is very complex situation. The initial question posed is whether the man has RSD or not. The plethora of material reviewed shows that his treating doctors agree are in agreement with the diagnosis of RSD. The URA reviewers, however, do not feel RSD is present based upon

the ODG criteria. The ODG describes different criteria by different organizations for the diagnosis of RSD/CRPS. Most of the diagnostic criteria emphasize the acute to subacute stages in making the diagnosis. The IRO reviewer would presume the variable findings can be seen at some time or other over the past 15 years. One reviewer stated the diagnosis of RSD is made by exclusion of other potential conditions. He cited other diagnoses could explain some of the symptoms. The ODG notes the high percentage of false positive diagnoses of CRPS that is made. There were several over the years. Therefore, the IRO reviewer needs to presume that RSD/CRPS is present. While this contradicts the prior URA reviewers who question the diagnosis, the IRO reviewer found no independent examination to confirm or refute the diagnosis.

The ODG treatment section for CRPS recognizes the accepted, if unproven, use of opiates and antidepressants and anticonvulsants based upon the neuropathic pain model. This includes the Oxycodone, Oxycontin, and Gabapril in question. There are pro and con arguments for the chronic use of opioids for chronic pain in the ODG. The issue of hyperalgesia was mentioned in a review, but that has also been a point of controversy. However, the request is medically necessary.

The IRO reviewer saw the request for Imitrex. It is used for the treatment of migraines. The IRO did not see its use approved for RSD and cannot justify its medical necessity. Dr. cited Dr. saying migraines are part of the disorder. Dr. also noted that he needed this medication for his migraines. The IRO reviewer could not find where migraines were listed in the ODG description of CRPS/RSD. Without more information, the IRO reviewer cannot justify its use as medically necessary.

Temazepam is a benzodiazepine. Both the ODG and FDA approve its short-term use for insomnia. He has been on it for years. Chronic use is essentially an off label use of the drug. There are risks, but the multiple doctors describe its effectiveness for his insomnia. He is also on Xanax, another benzodiazepine. The ODG also does not approve it for long-term use for anxiety. Gabapril can also be used off label for anxiety. The IRO reviewer did not see any psychiatric report to justify the long-term use of either medication as the ODG advises. Dr. noted that Dr., a psychiatrist or psychologist (it was not clear which) supervised the medication use. Again, there may be some justification for the use of these medications. The IRO reviewer is giving the treating doctors the benefit of their direct observation of the effectiveness. Therefore, the request is medically necessary.

CRPS, diagnostic criteria

Recommend using a combination of criteria as indicated below. There are no objective gold-standard diagnostic criteria for CRPS I or II. A comparison between three sets of diagnostic criteria for CRPS I concluded that there was a substantial lack of agreement between different diagnostic sets. ([Perez, 2007](#))

A. CRPS-I (RSD):

The IASP (International Association for the Study of Pain) has defined this diagnosis as a variety of painful conditions following injury which appear regionally having a distal predominance of abnormal findings, exceeding in both magnitude and duration the expected clinical course of the inciting event and often resulting in significant impairment of motor function, and showing variable progression over time. ([Stanton-Hicks, 1995](#)) Diagnostic criteria defined by IASP in 1995 were the following: (1) The presence of an initiating noxious event or cause of immobilization that leads to development of the syndrome; (2) Continuing pain, allodynia, or hyperalgesia which is disproportionate to the inciting event and/or spontaneous pain in the absence of external stimuli; (3) Evidence *at some time* of edema, changes in skin blood flow, or abnormal sudomotor activity in the pain region; & (4) The diagnosis is excluded by the existence of conditions that would otherwise account for the degree of pain or dysfunction. Criteria 2-4 must be satisfied to make the diagnosis. These criteria were found to be able to pick up a true positive with few false negatives (sensitivity 99% to 100%), but their use resulted in a large number of false positives (specificity range of

36% to 55%). ([Bruehl, 1999](#)) ([Galer, 1998](#)) Up to 37% of patients with painful diabetic neuropathy may meet the clinical criteria for CRPS using the original diagnostic criteria. ([Quisel, 2005](#)) To improve specificity the IASP suggested the following criteria: (1) Continuing pain disproportionate to the inciting event; (2) A report of one *symptom* from each of the following four categories and one *physical finding* from two of the following four categories: (a) Sensory: hyperesthesia, (b) Vasomotor: temperature asymmetry or skin color changes or asymmetry, (c) Sudomotor/edema: edema or sweating changes or sweating asymmetry, or (d) Motor/trophic: reports of decreased range of motion or motor dysfunction (weakness/tremor or dystonia) or trophic changes: hair, nail, skin. This decreased the number of false positives (specificity 94%) but also decreased the number of true positives (sensitivity of 70%). ([Bruehl, 1999](#))

The Harden Criteria have updated these with the following four criteria: (1) Continuing pain, which is disproportionate to any inciting event; & (2) Must report at least one symptom in three of the four following categories: (a) Sensory: Reports of hyperesthesia and/or allodynia; (b) Vasomotor: Reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry; (c) Sudomotor/Edema: Reports of edema and/or sweating changes and/or sweating asymmetry; (d) Motor/Trophic: Reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin); & (3) Must display at least one sign at time of evaluation in two or more of the following categories: (a) Sensory: Evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch and/or temperature sensation and/or deep somatic pressure and/or joint movement); (b) Vasomotor: Evidence of temperature asymmetry (>1°C) and/or skin color changes and/or asymmetry; (c) Sudomotor/Edema: Evidence of edema and/or sweating changes and/or sweating asymmetry; (d) Motor/Trophic: Evidence of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin); & 4. There is no other diagnosis that better explains the signs and symptoms ([Harden, 2007](#))

The Washington State Department of Labor and Industries guidelines include the presence of four of the following physical findings: (1) Vasomotor changes: temperature/color change; (2) Edema; (3) Trophic changes: skin, hair, and/or nail growth abnormalities; (4) Impaired motor function (tremor, abnormal limb positioning and/or diffuse weakness that can't be explained by neuralgic loss or musculoskeletal dysfunction); (5) Hyperpathia/allodynia; or (6) Sudomotor changes: sweating. Diagnostic tests (only needed if four physical findings were not present): 3-phase bone scan that is abnormal in pattern characteristics for CRPS. ([Washington, 2002](#))

The State of Colorado Division of Workers' Compensation Medical Treatment Guidelines adopted the following diagnostic criteria in 2006: (1) The patient complains of pain (usually diffuse burning or aching); (2) Physical findings of at least vasomotor and/or sudomotor signs, allodynia and/or trophic findings add strength to the diagnosis; (3) At least two diagnostic testing procedures are positive and these procedures include the following: (a) Diagnostic imaging: Plain film radiography/triple phase bone scan, (b) Injections: Diagnostic sympathetic blocks, (c) Thermography: Cold water stress test/warm water stress test, or (d) Autonomic Test Battery. The authors provide the following caveat: Even the most sensitive tests can have false negatives, and the patient can still have CRPS-I, if clinical signs are strongly present. In patients with continued signs and symptoms of CRPS-I, further diagnostic testing may be appropriate. ([Colorado, 2006](#))

Other authors have questioned the usefulness of diagnostic testing over and above history and physical findings. ([Quisel, 2005](#)) ([Yung, 2003](#)) ([Perez2, 2005](#)) A negative diagnostic test should not question a clinically typical presentation of CRPS and should not delay treatment. ([Birklein, 2005](#))

B. CRPS-II (causalgia):

Nerve damage can be detected by EMG but pain is not contained to that distribution. ([Stanton-Hicks, 1995](#)) CRPS I and II appear to be clinically similar. ([Bruehl, 1999](#)) CRPS-II is defined by the IASP as: (1) The presence of continuing pain, allodynia, or hyperalgesia after a nerve injury, not necessarily limited to the distribution of the injured nerve; (2) Evidence at some time of edema, changes in skin blood flow, and/or abnormal sudomotor activity in the region of pain; & (3) The diagnosis is excluded by the existence of conditions that would otherwise account for the degree of pain and dysfunction. The state of Colorado also uses the above criteria but adds that there must be documentation of peripheral nerve injury with pain initially in the distribution of the injured nerve. ([Colorado, 2006](#))

C. Differential Diagnoses of CRPS

These need to include local pathology, peripheral neuropathies, infectious processes, inflammatory and vascular disorders. ([Quisel2, 2005](#)) ([Stanton-Hicks, 2006](#)) Also include the following conditions: pain dysfunction syndrome; cumulative trauma syndrome; repetitive strain syndrome; overuse syndrome; tennis elbow; shoulder-hand syndrome; nonspecific thoracic outlet syndrome; fibromyalgia; posttraumatic vasoconstriction; undetected fracture; post-herpetic neuralgia; diabetic neuropathy. ([Stanton-Hicks, 2004](#)) Others have suggested that likely differential diagnoses should include: (1) Disuse; (2) Somatoform disorder (symptoms related to psychological factors); & (3) Factitious disorder (deliberately feigning symptoms). ([Barth, 2009](#)) See also [Treatment for CRPS](#); [Sympathetically maintained pain \(SMP\)](#); [CRPS, medications](#); [CRPS, prevention](#); [CRPS, sympathetic and epidural blocks](#).

CRPS, medications

Recommended only as indicated below. Most medications have limited effectiveness. ([Ribbers, 2003](#)) ([Quisel2, 2005](#))

1. Regional inflammatory reaction: Commonly used drugs are NSAIDS, corticosteroids and free-radical scavengers. There is some evidence of efficacy for topical DMSO cream, IV bisphosphonates and limited courses of oral corticosteroids. Corticosteroids are most effective when positive response is obtained with sympathetic blocks. NSAIDs are recommended but no trials have shown effectiveness in CRPS-I, and they are recommended primarily in early or very late stages. ([Stanton-Hicks, 2004](#)) ([Sharma, 2006](#))

2. **Stimulus-independent pain: The use of antidepressants, anticonvulsants, and opioids has been primarily extrapolated based on use for other neuropathic pain disorders.** (See [Antidepressants for neuropathic pain](#); [Anticonvulsants for chronic pain](#); & [Opioids for neuropathic pain](#).) Mexiletine (oral lidocaine), lidocaine patches and capsaicin are used but efficacy is not convincing. For central inhibition opiates, gabapentin, TCAs, **GABA-enhancing drugs**, and clonidine may be useful.

3. Stimulus-evoked pain: treatment is aimed at central sensitization. With NMDA receptor antagonists (ketamine and amantadine) convincing controlled trials are lacking, and these drugs are recognized for their side effects.

4. Sympathetically maintained pain (SMP): α_1 adrenoceptor blocking agents (terazosin, prazosin, and phenoxybenzamine) have been shown to be effective in a case report. ([Ghoshine, 1984](#)) Sympathetic suppressors such as guanethadine, reserpine, droperidol, or atropine (in general or IV block) have shown low effectiveness. ([Perez, 2001](#)) ([Quisel2, 2005](#)) Phentolamine (IV) has been used as an alternative to determine responsiveness to α_1 adrenoceptor blocking agents. See also [Sympathetically maintained pain \(SMP\)](#).

5. Treatment of bone resorption with bisphosphonate-type compounds and calcitonin. Significant improvement has been found in limited studies of intravenous clodronate and intravenous alendronate. Alendronate (Fosamax®) given in oral doses of 40 mg a day (over an 8 week period) produced improvements in pain, pressure tolerance

and joint mobility. ([Manicourt, 2004](#)) Mixed results have been found with intranasal calcitonin (Miacalcin®). ([Sahin, 2005](#)) ([Appelboom, 2002](#)) ([Rowbathan, 2006](#)) ([Sharma, 2006](#))

CRPS, prevention

CRPS, treatment...

3. Pain management: (a) ***Pharmacological:*** antidepressants (particularly amitriptyline); anticonvulsants (particularly gabapentin); steroids; NSAIDs; opioids; calcitonin; bisphosphonates; α 1 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](#)) (b) ***Minimally invasive:*** depends on degree of SMP, stage of rehabilitation (passive or active movement), and response to blocks. (See [CRPS, sympathetic blocks](#).) Responders to sympathetic blocks (3 to 6 blocks with concomitant PT) may be all that is required. For non-responders somatic block or epidural infusion may be required to optimize analgesia for PT. (c) ***More invasive:*** After failure of progression or partial relief, consider tunneled epidural catheters for prolonged sympathetic or somatic blocks or neurostimulation with SCS in CRPS-I and II. See [CRPS, spinal cord stimulators](#). Also consider peripheral nerve stimulation in CRPS-II and intrathecal drug delivery in patients with dystonia, failed neurostimulation, long-standing disease, multi-limb involvement and requirement of palliative care. (d) ***Surgical:*** Sympathectomy is not generally recommended, but has been considered in patients that respond to sympathetic blocks. Pre-procedure the patient should have outcomes assessed with radiofrequency and neurolytic procedures. (See [CRPS, sympathectomy](#).) Motor Cortex Stimulation has been considered.

Outcome measures for all treatments of CRPS: Objective measures such as the Beck Depression Inventory, the State Trait Anxiety Inventory, McGill Pain Questionnaire-Short Form, the Pain Disability Index, & the Treatment Outcomes in Pain Survey (the last three may not meet the APA standards for standardized test in clinical use). See [Psychological evaluations](#). See also [CRPS, diagnostic criteria](#); [CRPS, medications](#); [CRPS, prevention](#); [CRPS, sympathetic blocks](#); & [Sympathetically maintained pain](#) (SMP). See also [Spinal cord stimulators](#) (SCS).

Imitrex is used for migraines. The IRO reviewer did not see its use in the ODG for the treatment of RSD. The request is not medically necessary.

Insomnia treatment...

Benzodiazepines: FDA-approved benzodiazepines for sleep maintenance insomnia include estazolam (ProSom®), flurazepam (Dalmane®), quazepam (Doral®), and **temazepam (Restoril®)**. Triazolam (Halcion®) is FDA-approved for sleep-onset insomnia. These medications are only recommended for short-term use due to risk of tolerance, dependence, and adverse events (daytime drowsiness, anterograde amnesia, next-day sedation, impaired cognition, impaired psychomotor function, and rebound insomnia). These drugs have been associated with sleep-related activities such as sleep driving, cooking and eating food, and making phone calls (all while asleep). Particular concern is noted for patients at risk for abuse or addiction. Withdrawal occurs with abrupt discontinuation or large decreases in dose. Decrease slowly and monitor for withdrawal symptoms. Benzodiazepines are similar in efficacy to benzodiazepine-receptor agonists; however, the less desirable side-effect profile limits their use as a first-line agent, particularly for long-term use.

Xanax® (Alprazolam)

Not recommended for long-term use. See [Alprazolam](#); & [Benzodiazepines](#).

Alprazolam, also known under the trade name Xanax and available generically, is a short-acting drug of the benzodiazepine class used to treat moderate to severe anxiety disorders, panic attacks, and as an adjunctive treatment for anxiety associated with major depression.

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

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)