

INDEPENDENT REVIEWERS OF TEXAS, INC.

2150 S. Central Expressway · Suite 200-264 · McKinney, Texas 75070

Office 214-533-2864 Fax 214-380-5015

e-mail: independentreviewers@hotmail.com

[Date notice sent to all parties]:

05/19/2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: APPEAL:

SUFENTANYL 31.98 MCG/ML AT 11.013 MCG/ML

APPEAL: PRIALT 42 MCG/ML AT 14.5 MCG/DAY

**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.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male with ongoing complaints of left upper extremity pain. According to the clinical notes, the initial injury occurred in xxxx. The procedural note dated 04/02/14 indicates the patient undergoing the placement of an intrathecal pain pump. The pump refill note dated 09/25/14 indicates the patient utilizing Prialt at 40mcg per mL at 14.5mcg per day. The patient is also utilizing Sufentanil at 31.9mcg per mL at 11.013mcg per day. The note indicates the patient rating his ongoing pain as 7/10. The behavioral assessment dated 03/29/14 indicates the patient undergoing an assessment. The patient was provided with a sleep plan as well as information regarding his stress levels. There was also an indication the patient has been complaining of depressive symptomology. The pump refill note dated 11/06/14 indicates the patient continuing with the use of Prialt and Sufentanil. The pump refill note dated 12/23/14 indicates the patient continuing with the use of Prialt and Sufentanil. The pump refill note dated 02/12/15 indicates the patient

undergoing another refill of Prialt and Sufentanil. The note indicates the patient continuing with 7/10 pain. The clinical note dated 02/04/15 indicates the patient continuing with 3-9/10 pain. The patient had a present level of pain at 7/10. The patient reported functioning well around the house as he was caring for himself and his wife. The pump refill note dated 03/30/15 indicates the patient continuing with the use of Prialt and Sufentanil. The clinical note dated 04/02/15 indicates the patient continuing with complaints of 6-10/10 pain primarily at the left upper extremity. The pump refill note dated 04/08/15 indicates the patient continuing with 9/10 pain despite the use of the intrathecal pump with the use of Sufentanil and Prialt. Radiating pain was identified from the shoulder into the left anterior chest wall. The most severe pain was located at the left hand. There is an indication the patient had a reduction in the use of Amitriptyline. The patient had been utilizing this medication in lower doses which reduced the patient's daytime somnolence. There is an indication the patient had been diagnosed with reflex sympathetic dystrophy in the left upper extremity.

The utilization reviews dated 04/10/15 and 04/24/15 resulted in a denial for the continued use of Prialt and Sufentanil as the patient's response to the use of these medications had been minimal at best.

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

The documentation indicates the patient having been diagnosed with RSD in the left upper extremity. There is an indication that the patient also has complaints of radiating pain into the left upper chest. The continued use of Prialt and Sufentanil is indicated for patients with a positive response along with an objective functional improvement with the use of this medication via the pain pump. There is an indication the patient has undergone numerous pump refills with the use of this medication. However, the patient continues with pain that has been rated in the upper to severe levels to include 7-9/10 despite the use of this medication. Additionally, there is no indication the patient is showing an objective functional improvement as no range of motion, strength, or endurance improvements were identified in the clinical notes. Without the necessary information regarding the significant reduction in pain along with an objective functional improvement, the request is not indicated as medically necessary. As such, it is the opinion of this reviewer that the request for Sufentanil and Prialt via the pain pump is not recommended as medically necessary at this time.

IRO REVIEWER REPORT TEMPLATE -WC

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

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Implantable drug-delivery systems (IDDSs)

Refills: IDDSs dispense drugs according to instructions programmed by the clinician to deliver a specific amount of drug per day or to deliver varying regimens based on flexible programming options, and the pump may need to be refilled at regular intervals. The time between refills will vary based on pump reservoir size, drug concentration, dose, and flow rate. A programming session, which may occur along with or independent of a refill session, allows the clinician to adjust the patient's prescription as well as record or recall important information about the prescription. (Hassenbusch, 2004) According to the FDA, the manufacturer's manuals should be consulted for specific instructions and precautions for initial filling, refilling and programming. (FDA, 2010) For most pumps, the maximum dose that can be delivered between refills is 1000mg. If refills are usually administered after 16 to 17 mL have been infused, and most pumps are 18-20mL, the minimum time between each visit is 42 days if the daily dose rate is 20 mg/day. Given that a refill visit presents a good opportunity for monitoring, this panel suggested that the concentration be adjusted to allow refill visits a minimum of every 4 to 6 weeks, and maximum of every 2–3 months. (Bennett, 2000)

Ziconotide (Prialt®)

Recommended for use after there is evidence of failure of a trial of intrathecal morphine or hydromorphone (Dilaudid). Indicated for the management of severe chronic pain in patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or IT morphine, and only in individuals for whom the potential benefits outweigh the risks of serious neuropsychiatric adverse effects. The 2007 Polyanalgesic Consensus Conference Recommendations for the Management of Pain by Intrathecal Drug Delivery concluded that ziconotide should be updated to a first-line intrathecal drug. Ziconotide (Prialt®) is a synthetic calcium channel blocker that is delivered intrathecally, offering a non-opioid option for treatment of chronic pain, and possibly, spasticity associated with spinal cord trauma. It is FDA-approved for the management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of other treatments, such as systemic analgesics or adjunctive therapies. This medication is meant to be an option for patients who are intolerant and/or refractory to intrathecal morphine. The advantage of the medication is that it is considered non-addictive. Current case reports have described many challenges in converting from morphine to ziconotide, including inadequate analgesia, adverse medication effects, and opioid withdrawal symptoms. An option for treatment is combining ziconotide with other currently available intrathecal medications, although this has not been studied in placebo-controlled trials.

Adverse effects: Prialt has been associated with severe CNS-related adverse effects, and a "black-box" warning has been issued in this regard. Neurological warnings include hallucinations, paranoid ideation, hostility, delirium, psychosis, manic reactions and decreased alertness. Certain patients may be at increased risk for psychiatric side effects including those with pre-existing history of depression

with risk of suicide and patients with pre-existing psychosis. Cognitive impairment was noted in approximately 30% of patients in clinical trials, and this symptom was found to be reversible within about two weeks of discontinuation. Prialt is contraindicated in patients with a pre-existing history of psychosis. Prialt can be discontinued abruptly without evidence of withdrawal effects in the presence of serious adverse events.

Dosage requirements: The current recommendations suggested by the manufacturer for this medication include a low initial infusion rate (0.1 mcg/hour for a total of 2.4 mcg/day) and limiting infusion increases to 2-3 times a week. Current drug trials have evaluated the efficacy of the medication for a 3-week duration only, but preliminary trials suggested that analgesic efficacy would be maintained long-term in open label trials.

Post-marketing dose recommendations: Post-marketing, an expert consensus panel recommended a starting dose of 0.5 mcg/24 hours with upward titration of no more than 0.5 mcg/week due to increased risk of adverse effects with higher doses. (Fisher, 2005)

Filling intervals: The reservoir should be refilled initially at 14 days. For subsequent pump refills, fill the pump at least every 40 days if used diluted. For undiluted Prialt, fill the pump at least every 84 days.

Other precautions: This medication is associated with elevation of serum creatinine kinase, with risk factors including male gender and concomitant use of anti-depressants, anti-convulsants and intrathecal morphine. This lab value should be monitored at least bi-weekly for the first month and at monthly intervals thereafter.

Symptoms of myalgia include myasthenia, muscle cramps and unusual fatigue. (Thompson, 2006) (Wermeling 2005) (Lyseng-Williamson, 2006) (Lynch, 2006) (Rauck, 2006) (Deer, 2007) Intrathecal ziconotide may increase risk for suicide. Researchers are calling for a comprehensive psychiatric evaluation in all patients before and during treatment, but ziconotide may pose a threat even in symptom-free patients with pain. Better monitoring of all patients on this medication is necessary, and strict compliance to the contradictions such as a history of depression is key. Ziconotide not only suppresses the transmission of pain stimuli but may also reduce impulse control, promoting suicidal tendencies in vulnerable patients. (Maier, 2010) See Intrathecal drug delivery systems, medications.