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Notice of Independent Review Decision

Date notice sent to all parties: 01/30/14

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Subsys, 100 mg SL spray to use at the immediate onset of a cluster NTE, twice a day, quantity 120, refill 0

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

Board Certified in Anesthesiology
Fellowship Trained in Pain Management

REVIEW OUTCOME:

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

X Upheld (Agree)

☐ Overturned (Disagree)

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

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

Subsys, 100 mg SL spray to use at the immediate onset of a cluster NTE, twice a day, quantity 120, refills 0 - Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW:
Reports dated 05/05/11, 03/19/12, 05/16/12, 12/19/12, 08/21/13, 09/16/13, 10/27/13, and 11/25/13
Toxicology reports collected on 03/19/12 and 12/19/12

Rejected claim response for Subsys 100 mcg AER dated 10/18/13
Letter addressed To Whom It May Concern dated 10/29/13
Utilization Review Notices dated 11/04/13 and 12/18/13
The Official Disability Guidelines (ODG) for Pain (Chronic) was provided by the carrier/URA
Undated Treatment History
Undated list of facilities and providers

PATIENT CLINICAL HISTORY [SUMMARY]:

This patient was allegedly injured on xx/xx/xx in a fall. He was diagnosed with back pain and chronic pain syndrome, neck pain, and generalized pain. The patient apparently had a previous history of multiple back surgeries, including lumbar fusion, right shoulder and wrist surgeries in 1996, and spinal cord implantation in approximately 2003. The patient was seen in follow-up on 04/11/11 for his complaints of low back pain, neck pain radiating to both shoulders, forearms, and hands, carpal tunnel syndrome, and generalized chronic pain syndrome. The patient stated that his pain was "severe" with a pain level of 7/10 at best, 8/10 most of the time, and 9/10 at worst. The patient stated that his functional status was "poor." documented that the patient had undergone an MRI scan in January 2008, demonstrating L3-S1 fusion. He noted the patient had a spinal cord stimulator implanted in August 2003 and revised in February 2006. The patient was taking Gabapentin, Ambien, Lortab, Soma, Zanaflex, Lidoderm patch, and Lexapro. followed-up with the patient on 03/19/12 for the same complaints as documented in the previous note. The patient noted "no changes" in his pain and continued to complain of pain level 6/10 generally, 8/10 at worst, and 9/10 at the current visit. noted that the patient was continuing to take all the same medications, including Lortab 10 mg six times daily, as well as Soma and Zanaflex, Gabapentin, and Ambien. performed trigger point injections in the thoracic region, the lumbar region, and the buttock region. He refilled all the patient's medications as well. Seven months later, on 12/19/12, again followed-up with the patient, documenting exactly the same pain complaints as before. stated that the patient's trigger point injections had helped the pain for four to six weeks with "improved mobility" and making the patient "able to take less medication." In addition, noted the patient had undergone left hip replacement six weeks before. The patient's pain level was 5/10 generally and 8/10 at the current visit. The patient was taking all of the same medications as before at all of the same doses and frequency. All of the patient's medications were refilled with the addition of Topamax 25 mg four times daily. followed-up with the patient on 08/21/13, documenting again exactly the same pain complaints as before with a new diagnosis of trigeminal neuralgia that nothing helped. The patient also described cluster headaches. noted that the patient had decreased taking Topamax and had regained weight lost while on Topamax. recommended adding Subsys for the patient's increased pain, to be taken at the onset of cluster headache. The patient stated his pain was 4/10 generally and 5/10 most of the time, including the current visit. The patient was still taking all of the same medications as before. refilled the patient's medications.

On 10/27/13, again followed-up with the patient, documenting essentially the same pain complaints as before, including the ongoing “cluster headaches.” stated that Subsys was controlling the patient’s “severe episodes” and he was taking Subsys twice daily. noted the patient’s request to increase sleeping pills, but stated that the patient was “now sleeping all day long (because of the meds).” The patient had undergone trigeminal neuralgia surgery on 10/10/13, which stated had “resolved” those symptoms, although the patient continued to get a headache “every day at around 7:00 p.m.” The patient’s pain level had increased to 7/10 at the current visit and most of the time, increasing to 10/10 at worst. noted that the patient’s daily 7:00 p.m. headaches were “as severe as the trigeminal neuralgia pain.” The patient was still taking all of the same medications as before at all the same doses and frequencies, despite the addition of Subsys and Endocet (Oxycodone/Acetaminophen). Despite the patient’s assertion of 7/10 pain, physical examination documented a heart rate of 64 and a blood pressure of 102/74, stated that the patient’s “daily dosage of opiates is less since his headaches are not as severe as the trigeminal neuralgia,” although the refills documented clearly contradicted that statement. On 10/29/13, wrote a letter of medical necessity in response to the denial of Subsys. He stated the patient had an improved quality of life and was able to function more productively on the medication, providing no objective support for those statements. Initial physician advisor review on 11/04/13 recommended non-authorization of the request for Subsys, citing the ODG and documentation of the patient “sleeping all day long” and there being no “objective evidence” to support assertion of functional improvement with Subsys. On 11/25/13, four weeks later, followed-up with the patient, noting that the patient had increased left leg pain recently, which had been evaluated with a Doppler study on 11/23/13, demonstrating blood clots in the left leg. The patient’s pain level was 6/10 at best, 7/10 most of the time, and 9/10 at worst. The current pain level was 7/10. noted the patient was still taking Topamax, Carisoprodol and Tizanidine, Gabapentin, Hydrocodone and Oxycodone, Lidocaine, Depakote, Ambien, Klonopin, Lexapro, and Subsys. noted that the patient had a positive Homan's sign on exam and diagnosed the patient with deep venous thrombosis (DVT). He recommended the patient be started on Coumadin for the blood clots and noted that the patient was to be seen by his internist later on. A second physician advisor reviewing the case on 12/18/13 supported the previous recommendation for non-authorization of the requested medication. He cited the ODG Guidelines and the ODG formulary.

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

Despite assertions that the use of Subsys decreased the use of opiates, provided significant pain relief, and improved his functional status, there is, in fact, no objective evidence or documentation in the medical records that were supplied for this review that supports any of those assertions. The patient continues taking two other oral opiates at the same dose and frequency as always, two different muscle relaxants at the same dose and frequency as always, and complains of

essentially the same pain level as he did before Subsys was started. Moreover, no objective evidence of functional improvement has ever been documented since the records of 04/11/11, in which the patient self reported his functional status as poor. In fact, records also document that the patient was unable to work around the house more than one hour daily and there has been no documentation of that status changing with the addition of Subsys.

Subsys is on the "N" list of the ODG formulary. It is indicated only for breakthrough pain in cancer patients. It is specifically not recommended in the ODG guidelines for musculoskeletal pain. Clearly, this patient has no diagnosis of cancer that would provide a valid medical indication for the use of Subsys at this time. There is no medical indication for its use to treat any type of headache. Additionally, the patient has not been officially diagnosed with cluster headache by a neurology/headache specialist and, in fact, stated that his trigeminal neuralgia headaches had improved following trigeminal neuralgia surgery, but he continued to have these non-specified generalized headaches once daily at 7:00 p.m. every day.

The use of Subsys is not medically reasonable, necessary, appropriate, or in accordance with the ODG for this patient's current clinical condition nor for the patient's clinical condition as related to the work injury of xxxx. Therefore, according to the ODG guidelines, FDA approved indications for the requested medication, and the lack of objective documentation in the medical records reviewed to support any clinically significant beneficial effect from the use of Subsys, the non-authorization of the requested Subsys, 100 mg SL spray to use at the immediate onset of a cluster NTE, twice a day, quantity 120, refill 0 is upheld at this time.

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**
- 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 REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**