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Notice of Independent Review Decision

Date notice sent to all parties: 02/18/14

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Intrathecal pump refill

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:

- 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.

Intrathecal pump refill - Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Operative report dated 07/25/13
Drug screen collected dated 09/30/13
Office visits with various providers dated 10/09/13, 11/25/13, 11/26/13, 12/30/13, 12/31/13, and 01/27/14

Referral form dated 10/14/13
Pain pump refills dated 11/07/13 and 12/05/13
Letters of Medical Necessity dated 11/07/13 and 02/03/14
Plan of Treatment dated 11/25/13
Report dated 11/27/13
Notices of Utilization Review dated 12/04/13, 01/09/14, and 01/10/14
Preauthorization note dated 12/05/13
Undated request for preauthorization
The Official Disability Guidelines (ODG) were not provided by the carrier or the URA

PATIENT CLINICAL HISTORY [SUMMARY]:

This patient allegedly was injured at work on xx/xx/xx. On 07/25/13, the patient was seen for an intrathecal pump dye study to evaluate the functionality of an implanted intrathecal pump. The dye study demonstrated that there were no functional abnormalities of the pump. On 09/30/13, a urine drug screen was performed. It demonstrated evidence of metabolites of Morphine, Hydromorphone, Methadone, and various benzodiazepines. On 11/07/13, a physician assistant wrote a letter of medical necessity for refill of the patient's intrathecal pump with Prialt and Sufentanil. In that letter she stated the patient's functional status had improved, as evidenced by the patient being "able to hold his young son for a moment in the office last week." She also stated the patient had been "able to decrease short acting opiates" with no objective evidence provided to support that assertion. On 11/07/13, refilled the patient's intrathecal pump with Prialt and Sufentanil. In the procedure note, he noted the patient's pain level was 8/10. continued the Prialt and Sufentanil at the same doses following the refill that they were being administered prior to the refill, even though the patient's pain level was listed as 8/10. On 11/25/13, the patient followed-up with Ms., who noted that the patient was still using immediate relief Morphine 15 mg half tablets twice a day. She again cited, as evidence of the patient's functional improvement, that he "could manage his son for a few hours at a time." The patient complained of continued difficulty with the placement of the intrathecal pump and pain at the implant site. She also noted the patient continued to have anxiety and depression and was not sleeping well. She stated the patient expressed "about 60% pain relief," but provided no Visual Analogue Scale or pain level. Despite her assertion that the patient was only using 7.5 mg immediate release Morphine twice daily, the current medications were listed as morphine sulfate 15 mg four times daily and extended release Morphine 60 mg one daily. Physical examination documented "significant allodynia diffusely through the left arm with mottled skin and left hand and wrist held flexed, close to the body." She also documented "heightened" sensation to light touch in the left arm, worse distally than proximally. indicated that a neurosurgeon would be seeing the patient in two days to evaluate revision of the location of the intrathecal pump. She also stated that the patient would decrease immediate release Morphine to 3.75 mg once weekly and then discontinue, noting that the short acting opiates were being weaned "as it seems to be causing more side effect than benefit." In the patient's plan of treatment,

however, Ms. stated that the patient would continue Morphine sulfate extended release 60 mg daily and Morphine sulfate 15 mg four times daily, as well as Baclofen, Promethazine, and Amitriptyline, contradicting what she documented in the progress note.

saw the patient on 11/27/13 to evaluate for repositioning of the pump. noted the patient's pain level as "9.0." Physical examination documented normal skin temperature, no sensory abnormalities, normal reflexes, normal muscle bulk and tone, and normal motor strength in all four extremities. On 12/04/13, a physician advisor recommended non-certification for the request of refilling the intrathecal pump with Prialt and Sufentanil. The physician advisor made two attempts to do a peer-to-peer discussion, but neither attempt led to a return phone call to discuss the proposed treatment. The advisor cited, "No mention anywhere as to what specific overall functionality has been achieved" and stated that it was unclear why all medications had not been weaned and discontinued (as had been indicated in the plans for the progress note). Furthermore, the physician advisor cited the ODG criteria for treatment of non-malignant pain with a duration of greater than six months through use of an intrathecal pump. On 12/06/13, again refilled the intrathecal pump with Prialt and Sufentanil, running them at exactly the same dosage as before, with the patient's current pain level reported as 8/10. On 12/30/13, followed-up with the patient. She indicated that she "discussed" eliminating immediate release Morphine and decreasing the strength of extended release Morphine from 30 mg to 15 mg every 12 hours. She cited the patient's functional improvement as him being able to "manage his son for a few hours at a time". also indicated that the patient "does finally have an appointment with neurosurgeon on 11/27" when, in fact, the patient had seen four weeks before. stated the patient's report of "60% pain relief," but again provided no VAS or pain score anywhere in her progress note. She also documented that the patient's medications were exactly the same as before with no reduction in Morphine 15 mg four times a daily, but reduction in extended release Morphine to 15 mg every 12 hours. Physical examination was no different than the last visit. Ms. stated the patient "defers all oral opiates at this time," "as he is experiencing over 60-75 % relief" and "his function has been improved by over 50 %".

On 01/07/14, the patient was again seen. She again cited evidence of the patient's functional improvement as being that he "can care for his son for a few hours at a time," again bringing into serious question the validity of the accuracy of these notes. stated the patient "has been able to discontinue all oral opiates" and that he "expresses about 70% pain relief." However, in the exact same note documented the patient's current medications as being extended release Morphine 30 mg every 12 hours (double the previous dose) and Morphine sulfate immediate release 15 mg tablets four times daily, neither of which would demonstrate any reduction whatsoever in multiple oral opiate use. She again documented exactly the same physical examination, but no VAS or pain level. documented that her plan was to "discontinue immediate release Morphine" and "slowly wean off extended release Morphine." However, she also documented at the beginning of this note that the patient was now off all oral opioids, again

bringing into serious question the validity and accuracy of her progress notes. She also indicated that instead of oral Morphine she would start the patient on Hydrocodone 10 mg once daily as needed. A second physician reviewer, on 01/10/14, also recommended non-certification of the request for refill of the intrathecal pump with Prialt and Sufentanil. This reviewer noted the patient's most recent pain scores as being 9/10 and 8/10 and stated, "There is no indication that the pump is providing any significant benefit from the notes reviewed." The reviewer also noted that the patient was continuing "multiple opioids with no indication of reduction." This reviewer also made two separate attempts to complete a peer-to-peer discussion. Again, no return calls followed either of these attempts. Finally, on 02/03/14, Ms. submitted a letter of medical necessity for refill of the pump again with Prialt and Sufentanil. She again stated that the patient had "weaned off all oral opiates" and that he was now "working two hours daily," although no objective evidence of either of those statements was provided. She also indicated, as evidence of the patient's functional improvement, that he could "care for his young son for an hour or two at a time."

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

Despite assertions of the patient being off all oral opiates and having 60-75% pain relief and having significantly improved functional status, there is, in fact, no objective evidence to support any of those assertions. Given the extremely contradictory information she presents in each of her progress notes, the validity and accuracy of the progress notes is highly questionable and suspect, in my opinion. She indicates simultaneously in progress notes that the patient has stopped taking oral medication and that the patient has continued all oral opiates and that the patient continues to take two oral opiates at the same doses as always. Therefore, there does not appear to be any valid evidence whatsoever of significant clinical benefit or functional improvement nor of decreased oral opiate use through use of Prialt and Sufentanil intrathecally. In each of his procedure notes for refill of the pump, never changes the dose of either Prialt or Sufentanil, despite documenting the patient's pain level of 8/10 on both instances. In his evaluation of the patient for pump revision, documented the patient's pain level as 9/10. Therefore, there is, quite clearly, no evidence of pain relief whatsoever through the use of Prialt and Sufentanil intrathecally in this patient, whose pain level remains the same despite both of those drugs intrathecally and multiple oral opiates, apparently at unchanged doses.

Additionally, according to the ODG treatment guidelines, Prialt is a medication on the ODG formulary "N" list, meaning its use is not recommended. The ODG guidelines also cite criteria for the use of intrathecal medications for non-malignant pain, criteria which are not entirely met in this patient's case. No documentation has been provided of prior treatment attempts for this patient nor any valid reason why he cannot be treated with oral medications. In fact, given the clear lack of any significant benefit, functional improvement, or pain relief with the use of intrathecal Sufentanil and Prialt, as well as multiple oral opiates at

unchanged doses, the only logical conclusion that can be reached is that the use of intrathecal Prialt and Sufentanil is not providing any greater benefit than the use of oral medication alone. Furthermore, there is no medical documentation as to why this patient cannot be managed on oral medication alone nor what other treatment modalities may have been attempted, or not attempted, leading up to the decision to place an intrathecal pump. The overwhelming evidence in this case indicates that neither intrathecal Prialt nor intrathecal Sufentanil is providing significant clinical benefit, functional status, pain relief, or reduction in the use of oral medications. The medication is also on the "N" list of the ODG formulary. Therefore, according to the entirety of the records I reviewed and the significant discrepancies and contradictions within those records, the previous recommendations for non-authorization of intrathecal pump refill with Sufentanil and Prialt are upheld. Despite the discrepancies and contraindications within the progress notes, there is no discrepancy or lack of clarity regarding the lack of pain relief documented in their evaluations of the patient. Therefore, it is my opinion that the requested intrathecal pump refill is not medically necessary, appropriate, or in accordance with the ODG treatment guidelines and the previous adverse determinations should be 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
- 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)