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July 20, 2018
Amended July 26, 2018

IRO CASE #: XXXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Refill of the intrathecal pump (XX 10 mg/ml, XX 3.2 mg/ml, XX 75 mcg/ml, XX 0.9%)

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
American Board of Physical Medicine & Rehabilitation
American Board of Pain Medicine

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

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

Medical documentation **partially supports** the medical necessity of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is XX XX who was injured on XX. The patient was XX XX in a XX XX when XX fell on XX.

From XX through XX, XX, M.D./XX, LVN, performed pump refill (XX,XX,XX). The diagnosis was postlaminectomy syndrome.

On XX, XX, M.D., evaluated the patient for follow up prior to the pump refill. The patient complained of back pain radiating to the left hip and left leg. The pain was aggravated by bending and walking. The VAS was 5-6/10. The patient stated XX ended up with intrathecal pump (ITP) status post 360 lumbar surgery with persistent low back pain. The patient was status post bilateral lower extremity amputation secondary to leg infections after stepping on a nail on the right lower extremity and blister on the bottom of the left heel. The patient was now bilateral BKA due to complications with XX diabetes and lower extremity infections. The medical history was positive for myocardial infarction, insulin-dependent diabetes mellitus (IDDM) and peripheral neuropathy. The surgical history was positive for carpal tunnel repair, coronary artery stent placement, laminectomy, bilateral toe amputation, below knee amputation right leg XX, left below knee amputation XX and IT pump XX and spinal cord stimulation (SCS). Dr. XX diagnosed postlaminectomy syndrome lumbar region, chronic pain syndrome, diabetes mellitus (DM) type 1, CAD and major depression. Dr. XX stated the pain was well controlled with the ITP, and there was no aberrant or addictive traits noted. No adverse side effects were noted.

On XX, Dr. XX noted the pain was well controlled with current pain regimen at 4/10. The patient reported pain level had stayed pretty steady and XX had to get up and move around if sitting or standing for too long. Dr. XX recommended continuation of current ITP rate.

On XX, a urine drug screen (UDS) was positive for XX.

On XX, and XX, Dr. XX evaluated the patient and noted no changes in health status since last seen. The pain was kept at a tolerable level with current ITP regimen and p.o. pain medications. The patient was recommended continuing the current ITP rate. The patient was recommended continuing XX and XX. The patient reported XX was started on constipation medication which XX could not recall the name.

On XX, Dr. XX noted no changes and recommended continuing XX and XX and current ITP rate. The patient was prescribed XX and XX.

On XX, UDS was positive for XX.

On XX, XX performed pump refill.

On XX, Dr. XX stated the ITP had been implanted in XX, and would need to be replaced within next year as XX guidelines stated battery life was between XX. The patient was taking XX depending on XX activity levels. Dr. XX continued XX and XX. Dr. XX recommended decreasing XX.

On XX, XX performed pump refill. The pump was filled with XX 10 mg/ml, XX 3.3 mg/ml and XX 75 mcg/ml. The pump was reprogrammed XX XX.

On XX, Dr. XX once again discussed the need to get the pump replaced XX XX. Dr. XX advised refilling pump in XX and then referring the patient to Dr. XX for replacement prior to next refill. The patient complained of back pain radiating to the left hip and left leg. The aggravating factors included bending and walking. The pain level was 8/10 with medications. The patient reported the pain had recently been bothersome but was unsure if it was due to changes in weather. Dr. XX continued XX and XX. The patient was ready to come down on XX rate and seeing where XX actually needed to be with XX ITP. Dr. XX recommended ITP rate decreased XX

On XX,. XX refilled the pump with XX, XX, and XX. The pump was reprogrammed to run at a rate of XX per day.

On XX, Dr. XX noted increased back pain approximately XX ago. The pain radiated to the left hip and left leg. The pain level was 6. The patient stated XX had an increase in the pain intermittently. The patient had mild chest pain and presented to the ER last week and was told XX might have had a mild stroke and was recommended follow up with a cardiologist every XX. Dr. XX continued XX and XX and prescribed XX. Dr. XX recommended continuing pump and recommended to hold off on decreases until the weather improved.

On CC, UDS was positive for XX.

On XX, Dr. XX prescribed XX, XX, XX for the intrathecal pump.

Per utilization review dated XX, by XX, M.D., the request for intrathecal pump refill (XX, XX, XX, XX,) was denied. Rationale: *"ODG states there is insufficient evidence to recommend the use of implantable drug-delivery systems (IDDS) for the treatment of a chronic pain. There are no high-quality studies on this topic that document that this therapy is safe and effective. Further, significant complications and adverse events have been documented and the data identifies a substantial risk to patients. (XX XX) Results of studies of opioids for musculoskeletal conditions (as opposed to cancer pain) generally recommend short use of XX for severe cases, not to exceed two weeks, and do not support chronic use (for which a pump would be used). This treatment may be considered relatively late in the*

treatment continuum, when there is little hope for effective management of chronic intractable pain from other therapies. (Angel, 1998) (Kumar, 2002) (Hassenbusch, 2004) (Boswell, 2005) (Deer, 2009) (Patel, 2009). In this case, the provider is requesting an intrathecal medication refill. As per the latest office visit note, there is no clear documentation of efficacy from the intrathecal meds. It is stated claimant takes XX 10 mg 6 tabs a day. Without clear efficacy from the intrathecal medications, there is no rationale to continue. As such, medical necessity of this request is not established."

On XX, XX refilled pump with XX, XX, XX ,XX. The pump was reprogrammed to run at a rate of XX.

On XX, a phone note was documented. XX reported the pump refill medication was denied. XX opined this could be detrimental to the patient. The patient was with synchromed pump since XX. The patient would have withdrawal and possible hospitalization if unable to continue with pump medication. If time was given, then the patient could decrease the daily rate. The patient was still on a dose that would not be advisable to just stop, and this would be the case with denial for pump refill medication.

On XX, Dr. XX reported they were decreasing the patient's pump over the past year. The patient reported XX felt XX pump covered approximately 70% of XX pain. The patient was taking XX 10 mg two t.i.d. The patient had tried not taking XX, but XX felt the XX took the "edge off of XX pain." Dr. XX requested IRO and pain pump programming.

Per reconsideration review dated XX, a request for intrathecal pump refill (XX, XX, XX, XX) was denied by Dr. XX. Dr. XX noted the following treatment history: "*The patient's diagnosis includes post-laminectomy syndrome of the lumbar region. Treatment history Includes past surgical carpal tunnel release (CTR)(XX), laminectomy 360 (XX), amputation toes bilateral (XX), below knee amputation left side (XX), stimulation implant (XX), XX pump implant (XX), stimulator removed (XX), XX pump replaced (XX), pump replaced (XX), coronary artery stent placement (XX,XX) and current medications (XX 10 mg given by Dr. XX, XX). On XX it was noted that the claimant was seen for medication evaluation and routine follow up prior to XX pump refill. The attending provider stated that the daily rate was decreased by 5 percent (%) approximately XX XX ago. The pain was described as radiation into the left hip and left leg. It is aggravated by bending and walking. It is relieved by rest. The claimant states XX has had an increase in pain intermittently. The claimant states XX had mild chest pain and presented to an emergency room (ER) a week prior to this appointment. XX was told XX may have had a mild stroke. The claimant has a follow up with a cardiologist every 3 months and states XX informed them of XX recent episode. The attending provider's objective findings included the lumbosacral region being noted with well healed lumbar surgical scars. Palpation resulted in no spinal tenderness. Strength in the lower extremities is normal with exception of inability to test dorsi plantar flexion of feet secondary to BKA prosthesis bilaterally. The current request is for a reconsideration of Intrathecal Pump Refill (XX, XX)*. The request was denied based on the following rationale: *"No, the proposed treatment consisting of Intrathecal Pump Refill (XX ,XX, XX ,XX) is not appropriate or medically necessary for this diagnosis and clinical findings. ODG (XX) states, "There is insufficient evidence to recommend the use of implantable drug delivery systems (IDDS) for the treatment of chronic pain. There are no high-quality studies on this topic that document that this therapy is safe and effective. Further, significant complications and adverse events have been documented and the data identifies a substantial risk to patients. (XX, XX) Results of studies of XX for musculoskeletal conditions (as opposed to cancer pain) generally recommend short use of XX for severe cases, not to exceed 2 weeks, and do not support chronic use (for which a pump would be used). This treatment may be considered relatively late in the treatment continuum, when there is little hope for effective management of chronic intractable pain from other therapies. (Angel, 1998) (Kumar, 2002) (Hassenbusch, 2004) (Boswell, 2005) (Deer, 2009) (Patel, 2009)." ODG also goes on to state, "If treatment is determined to be medically necessary, as with all other treatment modalities, the efficacy and continued need for this intervention and refills should be periodically reassessed and documented." In this case, the provider is requesting an intrathecal medication refill. As per the latest office visit note, there is no clear documentation of efficacy from the intrathecal medications. It is stated that the claimant takes XX 10 mg XX a day without clear efficacy from the intrathecal medications, there is no rationale to continue. Therefore, the request has been found to not be medically necessary. However, due to the nature of this drug, weaning is recommended."*

On XX and XX, requests for IRO was submitted.

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

Several situations may warrant the weaning of a patient from intrathecal XX. In this case, there is no clear documentation of efficacy from the intrathecal medications. A schedule can be tailored to meet the needs of the patient while minimizing the symptoms of withdrawal. The aggressiveness of the weaning schedule will vary between patients and will depend on the medical and psychological condition of the patient before weaning, as well as the patient's reaction to dose decreases.

A common misconception regarding intrathecal XX XX. This task would be quite daunting, since equianalgesic oral to intrathecal dosing ratios suggested in the literature vary widely.[2,3] The overall goal is not equianalgesic conversion, but rather the prevention or minimization of XX withdrawal symptoms. A short-acting XX can be made available to the patient via a small, limited prescription in order to minimize the symptoms of XX withdrawal (The patient is taking XX).

In addition to the dosing concerns that clinicians may have about weaning patients from intrathecal XX, other issues exist regarding the weaning process. Patients may have a component of psychological dependence and may be anxious at the prospect of weaning. Also, some patients may experience XX withdrawal effects during the weaning process. Signs and symptoms of XX withdrawal include lacrimation, rhinorrhea, yawning, insomnia, restlessness, mydriasis, nausea, vomiting, diarrhea, piloerection, abdominal cramps, anxiety, agitation, muscle twitching, diaphoresis, a feeling of "heart pounding," flu-like feelings, hypertonia, and increased pain.[4,5] Hypertension and hyperthermia may also occur in rare cases.[4] Withdrawal symptoms vary widely in type and severity among patients and may be affected by the type of XX, dose, duration of use, frequency of dosing, degree of dependence, rate of weaning, and psychological factors (e.g., depression, distress, mental state at the time of withdrawal).[5-9XX] withdrawal is generally not life threatening, but it can be very unpleasant for patients.[4] This article will focus on the weaning off intrathecal XX, but clinicians should also be aware of issues that they may encounter when discontinuing other intrathecal medications. XX, XX may be associated with dangerous, sometimes life-threatening withdrawal syndromes upon abrupt discontinuation,[10-16] whereas other intrathecal drugs (e.g., XX local anesthetics) can be discontinued abruptly without issue.[17]

Guidelines for Weaning

Risk Assessment. Before the intrathecal XX weaning process begins, patients should undergo a risk assessment to help determine if weaning is appropriate and how aggressive the weaning schedule should be. In cases of serious infection, immediate removal of the intrathecal pump without weaning off intrathecal XX may be warranted. In less serious cases—or when pump explantation is elective—ultra-rapid weaning may be appropriate. This ultra-rapid weaning can be accomplished in a few days but should occur only in an inpatient setting.

In an outpatient setting, rapid, aggressive weaning can be completed in approximately 16 days, whereas slower, less aggressive weaning can take up to two months (but may be accelerated as tolerated). Patients with significant cardiac disease or poorly controlled hypertension may require a longer and more conservative weaning schedule. Results from animal studies have indicated that cardiovascular changes—such as increased heart rate and/or blood pressure—may be associated with morphine withdrawal.[18-20]Case reports[21,22] exist that describe cardiovascular events such as "broken heart" syndrome and myocardial ischemia associated with XX withdrawal. A history of sensitivity to XX withdrawal may also warrant a less aggressive weaning schedule. Additionally, less aggressive weaning may be advisable for patients with a minimal social support structure; patients who live alone may have more difficulty contacting their clinic or physician if problems arise during the weaning process. Finally, less aggressive weaning may be appropriate for patients who have a history of requiring high doses of XX and/or who have had frequent dose increases. There is evidence to suggest that patients receiving higher XX doses may be more prone to experience withdrawal syndrome than are patients receiving lower doses.[23] High doses and frequent dose increases may also reflect a patient's psychological dependence on XX, and the patient's anxiety and fears should be addressed before beginning the weaning process. In such patients, inadequate pain relief may serve as a motivator for change, and the patient should be a partner in the decision to begin weaning from intrathecal XX. If none of the conditions discussed above are present, an aggressive weaning schedule may be considered.

An example of an Intrathecal XX Weaning Protocol. The patient's intrathecal XX dose should be decreased by an amount that is in the range of 10 percent to 25 percent of the current dose. Decrements of 10 percent are appropriate for slow weaning, whereas 25-percent decrements can be used for aggressive weaning.
The initial dose reduction should be followed by a four- to seven-day stabilization period. During this period, patients should be assessed for symptoms of XX withdrawal. Scales, such as the Clinical XX Withdrawal Scale, can be used to document and assess the severity of signs and symptoms of withdrawal.[24] The frequency and severity of withdrawal symptoms can be related to the rate of XX weaning[6]; therefore, assessments of withdrawal symptoms are useful in determining the magnitude of further intrathecal XX dose decreases.
After the stabilization period, the intrathecal XX dose should again be decreased in the range of 10 percent to 25 percent of the patient's initial intrathecal XX dose (based on the frequency and severity of withdrawal symptoms), followed by another four- to seven-day stabilization period. Dose decreases (10 percent to 25 percent of the patient's initial intrathecal XX dose), followed by four- to seven-day stabilization periods, should continue as tolerated. The magnitude of the dose decrement (as a percentage of the patient's initial intrathecal XX dose) should decrease as the patient nears the end of the weaning process. For example, if a patient has undergone three dose reductions (each being 25 percent of the original dose) and is receiving a dose that is 25 percent of XX or XX original dose, the remaining decreases should be performed in smaller decrements (e.g., three decreases, each being one-third of the patient's current intrathecal XX dose, or approximately 8 percent to 10 percent of the original dose).
Dose decreases should be individualized for each patient. Patients should be assessed for symptoms of withdrawal at the end of each stabilization period to guide the next dose decrease. Patients may be less anxious if they know they will be evaluated by their physician before a further decrease in dose.

XX (ITB)
XX is a gamma-aminobutyric acid (GABA) analog that has inhibitory effects on spinal cord reflexes and brain. Intrathecal XX (ITB) therapy consists of long-term delivery of XX to the intrathecal space. Intrathecal XX has been used to treat spasticity due to cerebral palsy, brain or spinal cord injury, multiple sclerosis, dystonia, stroke and stiff-man syndrome, particularly for those patients who are unresponsive to conservative pharmacotherapy or develop intolerable side effects at therapeutic doses of oral XX [1]. Side effects such as drowsiness, nausea, headache, muscle weakness and light-headedness can occur as a result of the pump delivering an incorrect dose of XX. Sudden cessation of ITB administration can cause mild symptoms like reappearance of baseline level of spasticity associated with pruritis, anxiety and disorientation [2]. These mild symptoms represent "loss of drug effect". All patients experience "loss of drug effect" when ITB is discontinued, only a small (but unknown) proportion of patients develop a full-blown potentially life-threatening withdrawal syndrome.

XX withdrawal syndrome is a potentially life-threatening complication of intrathecal XX pump. Empty pump reservoir, catheter leaks or displacement, pump malfunction, programming error and refill of pump with improper drug concentration are the possible mechanisms which could lead to an ITB withdrawal syndrome. Regular check-up of the ITB pump by a specialist, educating patients and their caregivers may decrease the incidence of ITB withdrawal syndrome. Oral XX replacement may not be an effective method to treat or prevent ITB withdrawal syndrome. Early recognition of syndrome, high-dose XX, prompt analysis of the ITB pump with reinstitution of XX, and proper intensive care management are mainstays for the management of ITB withdrawal syndrome.
Due to the potentially life-threatening complication of ITB abrupt withdrawal, it is the opinion of this reviewer that the patient continue to have access to ITB. An ITB wean should be done by an experienced physician with proper intensive care management available for ITB withdrawal syndrome.

Thus, X X may be weaned as indicated above under the direct supervision of the attending physician and cardiologist (for potential cardiac complications). XX can be discontinued abruptly without issue. See ITB wean above. The time frame would be dictated by the attending physician. The refill of the intrathecal pump for XX, XX, and XX is certified until the patient is successfully weaned off the medication. The ITB would continue to be certified if weaning is not considered to be safe for the patient.

The refill of the intrathecal pump for XX, XX, and XX would be medically necessary while attempting to wean the patient

off the medication, if the weaning off the medication as suggested above is not possible then it would need to continue. The XX is not medically necessary.

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

☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**