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Notice of Independent Review Decision

[Date notice sent to all parties]:

06/12/2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: APPEAL Methadone
HCL 1 tab every 8 hours for pain #90/month

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

Board Certified Anesthesiologist; Board Certified Pain Medicine

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Clinical reports dated 08/06/08 – 04/23/13
Independent medical evaluations dated 10/22/08 & 03/23/11
Radiographs of the lumbar spine dated 09/29/11
MRI of the lumbar spine dated 07/02/12
Urinary drug screens dated 11/16/09 – 04/08/13
Prior review dated 03/07/13

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who previous sustained an injury on xx/xx/xx and has undergone
multiple prior surgical procedures to include lumbar laminectomies in xxxx as well as in xxxx
and a revision decompression at L4-5 with additional hemilaminotomies at L3-4 and L5-S1
in May of 2002. The patient has completed an extensive amount of treatment to include the
use of multiple medications including opiates and muscle relaxers as well as prior physical
therapy and psychological treatments. The patient was initially started on Methadone in
August of 2011. The patient has continued to report pain despite multiple medications;
however, the clinical notes indicate the patient did have good pain control with the use of

Methadone. Recent urinary drug screens completed on 04/08/13 identified positive results for Methadone. The patient also had recent EKG studies which were negative for any significant pathology. The most recent clinical report on 04/23/13 stated that the patient continued to have good control of pain with the use of Methadone. However, the clinical report noted that the patient's pain level was at 10/10 on the VAS scale and was unchanged. The clinical report indicated that Methadone was a cost effective therapy for the patient's pain and Dr. recommended that this medication be continued. Physical examination was limited.

The request for Methadone was denied by utilization review on 03/07/13 as there was no documentation regarding recent compliance assessments or EKG monitoring.

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

The patient has been followed for ongoing long term chronic postlaminectomy syndrome that has been refractory to almost all treatments completed to date. Per the most recent clinical reports, the patient did have positive results on urinalysis for Methadone and there were EKG studies which ruled out any significant problems with long term use of Methadone. However, upon review of Dr. 04/23/13 report, the patient reported 10/10 and unchanged levels of pain. This report indicates that the use of Methadone is not beneficial for the patient. If the patient was having good control of pain with the use of Methadone, it would be expected that his VAS pain scores would be lower. Given that the patient is reporting 10/10 pain that is unchanged on the most recent clinical report by Dr., this would call into question the efficacy of Methadone in the patient's treatments. Given the physical examination findings which were limited for any evidence of functional improvement as well as the ongoing severe pain reported by the patient, it is this reviewer's opinion that Methadone is not beneficial for the patient and is therefore not medically necessary per guideline recommendations.

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Official Disability Guidelines, Online Version, Pain Chapter
Methadone

Recommended as a second-line drug for moderate to severe pain, only if the potential benefit outweighs the risk, unless methadone is prescribed by pain specialists with experience in its use and by addiction specialists, where first-line use may be appropriate. Due to the complexity of dosing and potential for adverse effects including respiratory depression and adverse cardiac events, this drug should be reserved for use by experienced practitioners (i.e. pain medicine or addiction specialists).

([ICSI, 2009](#)) Methadone is considered useful for treatment when there is evidence of tolerance to other opiate agonists or when there is evidence of intractable side effects due to opiates. Limited evidence suggests there may be a role for this drug for neuropathic pain, in part secondary to the N-methyl-D-aspartate (NMDA) receptor effect. While methadone is considered safe and effective when used as prescribed it has been suggested by government agencies such as the National Drug Intelligence Center that patients prescribed methadone should be monitored by a physician well trained in the pharmacodynamic and pharmacokinetic properties of the drug, particularly if the patient is opioid naïve. In addition, the patient should be made aware of potential adverse effects including drug-drug interactions. If methadone is used, see [Opioids, criteria for use](#) for general recommendations.

FDA Activity: Increased reports by the FDA of severe morbidity and mortality have prompted the following. In November 2006 the FDA issued a black-box warning for methadone that stated, in part, that methadone treatment should only be initiated if potential benefits outweigh risks of treatment. Their particular concerns included respiratory and cardiac related complications, including death. In the same month they issued a monograph, “Information for Healthcare Professionals, Methadone Hydrochloride, FDA ALERT [11/2006]: Death, Narcotic Overdose, and Serious Cardiac Arrhythmias.” In July 2007 the FDA issued “Public Health Advisory, Methadone Use for Pain Control May Result in Death and Life-Threatening Changes in Breathing and Heart Beat.” ([National Drug Intelligence Center, 2007](#))

Pharmacokinetics and pharmacodynamics: Increased morbidity and mortality appears, in part, secondary to the long and variable half-life of the drug (8-59 hours; up to 110 hours in patients with cancer). Pain relief on the other hand only lasts from 4-8 hours. It may take several days to weeks to obtain adequate pain control. Genetic differences appear to influence how an individual will respond to this medication. Following oral administration, significantly different blood concentrations may be obtained. Vigilance is suggested in treatment initiation, conversion from another opioid to methadone, and when titrating the methadone dose. Frequent or large dose changes are generally not necessary after initial titration. If analgesia is lost this may reflect the addition of a medication that affects metabolism. ([Weschules 2008](#)) ([Fredheim 2008](#))

Adverse effects and mortality: Methadone-related deaths are noted to be increasing at a faster rate than other poisoning deaths using data from the National Center for Health Statistics, increasing by 468% from 1999 to 2005 (total poisoning deaths increased by 66%). Methadone-related poisoning deaths had the greatest percentage increase of deaths compared with other opioids although the actual number of deaths is less than from other opioids or cocaine. The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System found that from 2003 until 2006 patients that filled prescriptions for methadone had the highest fatal poisoning rate for all people filling prescriptions. Approximately 35% of methadone deaths were characterized as resulting from an abuse situation. Two-thirds involved use of multiple drugs including antidepressants, alcohol and cocaine. Deaths can also occur with too rapid titration. Delayed adverse effects may occur due to methadone accumulation during chronic administration. ([Fingerhut, 2008](#)) ([Dart, 2007](#)) ([Center for Substance Abuse Treatment, 2009](#)) Systemic toxicity is more likely to occur in patients previously exposed to high doses of opioids. This may be related to tolerance that develops related to the NMDA receptor antagonism properties. Patients may respond to lower doses of methadone than would be expected based on this antagonism. One severe side effect is respiratory depression (which persists longer than the analgesic effect). Methadone should be given with caution to patients with decreased respiratory reserve (asthma, COPD, sleep apnea, severe obesity). QT prolongation with resultant serious arrhythmia has also been noted. Use methadone carefully in patients with cardiac hypertrophy and in patients at risk for hypokalemia (including those patients on diuretics).

Abuse potential: Methadone does have the potential for abuse. “Street methadone” is primarily used for self-medication of detoxification and withdrawal symptoms. According to CDC, methadone has played a central role in the increase in overdose deaths from prescription painkillers. More than 30% of prescription painkiller deaths involve methadone, even though only 2% of painkiller prescriptions

are for this drug. Six times as many people died of methadone overdoses in 2009 than a decade before. ([CDC, 2012](#))

Cardiac safety and EKG monitoring: Methadone use is associated with an increased risk for QT prolongation and torsade de pointes (TdP). Patients who are at most risk for TdP include those on high daily methadone doses, those who take medications that cause QTc prolongation or inhibit CYP3A4 enzymes, and patients with electrolyte imbalances (low magnesium or potassium). There is no current evidence to firmly advise EKG monitoring when prescribing methadone. Expert opinion includes the use of an EKG for doses of methadone > 100 mg/day or if there are factors that may lead to prolonged QTc intervals (such as underlying cardiac disease). If the QTc interval is > 500 ms methadone should be weaned. ([Peng, 2008](#)) Others have suggested EKGs in patients over the age of 40 years and during dose stabilization in “high risk” patients, and a recent consensus guideline recommended a pretreatment EKG to measure QTc interval in all patients prescribed methadone, with a repeat in 30 days and then annually. ([Krantz, 2009](#)) Overall, there appears to be a high “tolerance” for EKG monitoring and particularly if there is a history of arrhythmia, syncope, or structural heart disease, or if seizures of syncope develop after initiation of treatment. See also [Opioids](#) for general guidelines, as well as specific [Methadone](#) (Dolophine®, Methadose®) listing for more information and references.

Steps for prescribing methadone:

(1) Basic rules

- Weigh the risks and benefits before prescribing methadone.
- The drug should be used with caution in opioid-naïve patients due to the risk of life-threatening hypoventilation.
- Avoid prescribing 40 mg Methadone diskettes for chronic non-malignant pain. This product is only FDA-approved for detoxification and maintenance of narcotic addiction. DEA has secured an agreement from the manufacturers of this formulation to sell only to licensed Opioid Treatment Programs.
- Closely monitor patients who receive methadone, especially during treatment initiation and dose adjustments.

(2) Know the information that is vital to give the patient:

- Inform the patient that methadone is not a breakthrough medication.
- Inform the patient that they should not be tempted to take more methadone than prescribed if they are not getting pain relief as this can lead to a dangerous build-up that can lead to death.
- All changes in methadone dose should be made by the treating practitioner.
- The patient should be warned to not use alcohol, benzodiazepines or other CNS depressants (particularly at night) unless specifically prescribed by the treating physician.
- Inform the patient of the potential adverse effects of methadone. These include respiratory depression, irregular heartbeat, dizziness, light-headedness, and/or syncope. An emergency number and/or plan should be given to the patient in case symptoms occur. ([FDA, 2006](#))
- Consider starting methadone early in the week to allow for titration and monitoring.

(3) Be familiar with the current SAMHSA health advisory on methadone:

- The medication has become more accessible to unauthorized users.
- It can accumulate in potentially harmful doses (especially during the first few days of treatment).
- There has been a rise in Methadone-associated mortality. ([SAMHSA, 2004](#))

(4) Be familiar with the FDA final policy statement on Methadone that explicitly discusses the topic, “Can Methadone be used for pain control?”

No separate registration is required to prescribe methadone for treatment of pain. ([DEA, 2006](#))

(5) Read the new prescribing information for Methadone and the new patient information section. ([Roxane, 2006](#))

(6) Multiple potential drug-drug interactions can occur with the use of Methadone. A complete list of medications should be obtained prior to prescribing methadone to avoid adverse events, and the patient should be warned to inform any other treating physician that they are taking this medication prior to starting and/or discontinuing medications.

(7) *Pre-use cardiac evaluation:* Patients should be informed of arrhythmia risk when prescribed methadone. An assessment should be made of history of structural heart disease, arrhythmia, and syncope. No firm guides are agreed upon in terms of pre-treatment or interval EKGs, but recommendation for use is particularly made for patients on high dose drug with cardiac history or evidence of syncope or seizures. ([Peng, 2008](#))