

Case Number:	CM15-0040601		
Date Assigned:	03/10/2015	Date of Injury:	01/30/2007
Decision Date:	04/21/2015	UR Denial Date:	02/20/2015
Priority:	Standard	Application Received:	03/03/2015

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: Iowa

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 47-year-old male, who sustained an industrial injury on January 30, 2007. The injured worker had reported a low back injury. The diagnoses have included post lumbar laminectomy syndrome, lumbar radiculopathy and lumbar disc disorder. Treatment to date has included medications, radiological studies, intrathecal pump placement, intrathecal injections, a lumbar discectomy at level four-level five in 2007 and a lumbar revision in 2011. Current documentation dated January 30, 2015 notes that the injured worker complained of increasing low back pain rated at a nine out of ten on the Visual Analogue Scale with medications. Physical examination of the lumbar spine revealed loss of normal lordosis, a restricted range of motion and tenderness over the sacroiliac joint spine. A straight leg raise test was positive on the right side and a lumbar facet loading maneuver was positive bilaterally. The treating physician's recommended plan of care included Lunesta 3 mg # 15 and Hydromorphone PF 20 mg/ml and Bupivacaine 10 mg/ml compounded, for intrathecal use # 40. A utilization review dated 2/19/15 did not certify the request for Lunesta and intrathecal hydromorphone and bupivacaine.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Lunesta 3mg @ HS #15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Implantable Drug-delivery systems Page(s): 52. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment Index, 13th Edition (web), 2015, Pain insomnia Treatments.

MAXIMUS guideline: Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, insomnia treatment.

Decision rationale: Eszopiclone (Lunesta) is a short acting, non-benzodiazepine hypnotic, which is approved for short-term treatment of insomnia. MTUS does not provide recommendations on use of this medication. ODG recommends teaching and practicing proper sleep hygiene prior to initiation of medication and diagnosis of the specific component of insomnia to be addressed. Sleep hygiene recommendations include: (a) Wake at the same time everyday; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; (i) Avoid napping. Specific components of insomnia include: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; (d) Next-day functioning. The treating physician has not provided any documentation of discussion of sleep hygiene, diagnosis of the sleep component at issue, response to prior first-line therapies, or the specific need for sleep medication. The patient appears to have been taking this medication for an extended period of time. There has been no documented discussion of the patient's sleep hygiene or any indication for continuing the medication other than listing in the treatment plan. There is minimal documentation relating to the current need to continue this therapy. Therefore the request for Lunesta 3 mg #15, is not medically necessary.

Hydromorphone PF 20mg/ml and Bupivacaine 10mg/ml compounded #40: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Implantable Drug-delivery systems Page(s): 52. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment index, 13th edition, (web), 2015, Pain insomnia Treatments.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Intrathecal Drug Delivery System (IDDS) Page(s): 52-54. Decision based on Non-MTUS Citation ODG Pain Intrathecal drug delivery systems; medications.

Decision rationale: According to MTUS guidelines, intrathecal drugs through an intrathecal drug delivery system (IDDS) are recommended as end-stage treatment alternative for selected patients after failure of at least 6 months of less invasive methods. The typical indication is for cancer patients, and use of opioids is still limited for a treatment length of 2 weeks, which is typically not consistent with pump use. Morphine is generally the initial IDDS medication, with other non-FDA approved opioids generally used as an alternative such as hydromorphone. Clonidine is typically recommended as a 2nd stage drug if indicated, with bupivacaine as an alternative. ODG has similar recommendations. The guidelines state there is insufficient

evidence to recommend use of the medications for treatment of chronic pain, and there are no high quality studies that document the therapy is safe and effective and significant complications and risks have been documented. For most patients, it should be used as part of a program to facilitate restoration of function and return to activity, not just pain reduction, and should be used late in the treatment continuum. Indications for IDDS include diagnosis of several types of cancer or severe and refractory cerebral or spinal cord spasticity. The medical documentation does not indicate a cancer diagnosis, and there is no detailed discussion of previous interventions for patient's diagnosis of back pain. The medical documentation indicates the patient has been on this medication for an extended period of time, exceeding the two-week recommendation for treatment length. There is not sufficient documentation regarding the reported pain over time or specific improvement while on this medication and device. The documentation indicates that the patient continues to have severe pain and decreased functional status with little improvement. Given the lack of efficacy and safety data regarding this therapy, a detailed rationale should be present to support use of this method and medication. Therefore, the request for hydromorphone 20 mg/ml and bupivacaine 10 mg/ml, compounded, is not medically necessary at this time.