

<b>Case Number:</b>	CM15-0139203		
<b>Date Assigned:</b>	07/29/2015	<b>Date of Injury:</b>	11/09/1995
<b>Decision Date:</b>	09/21/2015	<b>UR Denial Date:</b>	07/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/17/2015

### 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: Arizona, Michigan

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 55 year old male, who sustained an industrial injury on 11/09/1995. The injured worker is currently permanent and stationary. The injured worker is currently diagnosed as having post lumbar laminectomy syndrome, lumbar disc displacement without myelopathy, and major depression. Treatment and diagnostics to date has included history of lumbar laminectomy and fusion in 2002 and use of medications. In a progress note dated 06/30/2015, the injured worker presented with complaints of low back pain with radiation into the lower extremities. Objective findings include an antalgic gait and spasm and guarding to the lumbar spine. The physician noted a lumbar spine MRI dated 06/15/2015 showed trace degenerative retrolisthesis at L3-4 with annular bulge and facet degenerative change, annular bulge and endplate ridging at L5-S1 with bilateral foraminal narrowing, and posterior hardware at L4-5. The treating physician reported requesting authorization for Ketamine cream, Baclofen, Viagra, Ambien CR, and Fioricet.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketamine cream 60gr #2:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

**Decision rationale:** As per California MTUS Chronic Pain Guidelines, topical analgesics are "largely experimental in use with few randomized control trials to determine efficacy or safety. Primarily, recommended for neuropathic pain when trials of anti-depressants and anti-convulsants have failed". MTUS also states that Ketamine is "under study and only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical Ketamine has only been studied for use in non-controlled studies for CRPS (chronic regional pain syndrome) I and post-herpetic neuralgia." Since Ketamine is not recommended for topical analgesia, the request for Ketamine cream is not medically necessary.

**Baclofen 10mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain), Baclofen.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-66.

**Decision rationale:** According to California MTUS Chronic Pain Medical Treatment Guidelines, anti-spasticity drugs are "used to decrease spasticity in conditions such as cerebral palsy, MS (multiple sclerosis), and spinal cord injuries (upper motor neuron syndromes). Associated symptoms include exaggerated reflexes, autonomic hyper-reflexia, dystonia, contractures, paresis, lack of dexterity and fatigability". Regarding Baclofen, it states that "the mechanism of action is blockade of the pre- and post-synaptic GABA<sub>B</sub> receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lacerating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved)." After review of medical records, the injured worker's documented diagnoses include post-lumbar laminectomy syndrome, lumbar disc displacement without myelopathy, and major depression. There is documentation of lumbar muscle spasms, but there is no indication that the muscle spasms are related to multiple sclerosis and/or spinal cord injuries. Therefore, based on the Guidelines and the submitted records, the request for Baclofen is not medically necessary.

**Viagra 100mg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.pdr.net/full-prescribing-information/viagra druglabelid=471](http://www.pdr.net/full-prescribing-information/viagra%20druglabelid=471).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Physicians' Desk Reference (PDR.net) /Viagra.

**Decision rationale:** The MTUS/ ACOEM and ODG did not address the use of Viagra therefore other guidelines were consulted. Per the ODG, Viagra (sildenafil citrate) is a phosphodiesterase 5 (PDE5) inhibitor used in the treatment of erectile dysfunction (ED). However, a review of the injured workers medical records that are available to me did not reveal a clear rationale or benefit from the use of this medication. Without this information it is not possible to establish medical necessity, therefore the request for Viagra 100mg #30 is not medically necessary.

**Ambien CR 12.5mg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, Zolpidem (Ambien).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Insomnia treatment.

**Decision rationale:** Regarding the request for Zolpidem (Ambien), California MTUS Guidelines are silent. Official Disability Guidelines (ODG) recommends that "pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or mental illness...the specific component of insomnia should be addressed: sleep onset, sleep maintenance, sleep quality, and next day functioning". The treating physician noted use of Ambien for sleep, but no discussion regarding how frequently the insomnia complaints occur, how long the insomnia has been occurring, what other treatments have been attempted or any quantifiable improvements in sleep latency, duration or quality with the use of Ambien, Therefore, the request for Zolpidem (Ambien) is not medically necessary.

**Fiorcet-Butalbital/APAP/Caffeine #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Barbiturate-containing analgesic agents.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Barbiturate-containing analgesic agents (BCAs) Page(s): 23.

**Decision rationale:** Fioricet contains Butalbital, Acetaminophen, and Caffeine. According to California MTUS Chronic Pain Medical Treatment Guidelines, Barbiturate containing analgesic agents (BCAs) are "not recommended for chronic pain. The potential for drug dependence is high and no evidence exists to show a clinically important enhancement of analgesic efficacy of BCAs due to the barbiturate constituents. (McLean, 2000) There is a risk of medication overuse as well as rebound headache. (Friedman, 1987)". After review of the medical records, the injured worker has been prescribed Fioricet for daily headaches and the Fioricet helps to minimize the intensity of the headaches. Since the Guidelines do not recommend Fioricet for chronic pain and can contribute to a sustained rebound headache cycle, the request for Fioricet is not medically necessary.