MAXIMUS Federal Services

| Case Number: | CM15-0125920 | | |
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| Date Assigned: | 07/16/2015 | Date of Injury: | 01/06/1998 |
| Decision Date: | 09/10/2015 | UR Denial Date: | 06/18/2015 |
| Priority: | Standard | Application Received: | 06/30/2015 |

## 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 66 year old female who sustained an industrial injury on 01/06/1998. Current diagnoses include cervicalgia, thoracic lumbosacral nuritis/radiculitis, degenerative cervical intervertebral disc, degenerative lumbar/lumbosacral intervertebral disc, unspecified myalgia and myositis, and intervertebral lumbar disc disorder-myelopathy. Previous treatments included medications, physical therapy, weight loss program, and pool therapy. Report dated 06/09/2015 noted that the injured worker presented with complaints that included neck pain with left arm pain, headache, back spasm, bilateral hip pain with burning feet pain, muscle spasm, lumbar radiculopathy on the left, and poor sleep quality. Pain level was 7 out of 10 on a visual analog scale (VAS). Physical examination was positive for ongoing pain in the lumbar region with bilateral leg pain, positive straight leg raise left lower extremity, cervical pain; she uses a cane to help with ambulation, and has increased pain without full regimen of medications. The treatment plan included re-establishing informed consent for medical management and 4 A's, continue current medication regimen which included MetanX, restarted Elavil, continue Achiphex, continue Lidoderm patches, continue fentanyl patches, continue Percocet, continue Abstral, re-trial Belsomra and Fentora, follow up in 1 month or as needed, follow up with primary treating physician as needed, recommendation for future medical care with possible surgical options and continuing pain management, renew/continue weight loss program, continue pool therapy, home exercise and physical therapy, continue with medication management, restart all previously efficacious medications again, hold authorization for further decompression for cervical spine and left C-2, 3, 4, 5 mb, follow up for consult with new lumbar spine MRI done, and refer for rheumatology consultation. Disputed treatments include

MetanX #180, Aciphex 20mg, #30, Fentanyl Patches at 25ugm #10, Trial Belsomra 15mg, #30, Trial Fentora #28, and Lidoderm patches.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**MetanX #180:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Medical food, www.drugs.com.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic pain, Medical food.

**Decision rationale:** The MTUS / ACOEM did not address the use of MetanX, therefore other guidelines were consulted. Per the ODG, MetanX is not recommended for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Since the guidelines do not support use of medical food for chronic pain the request for MetanX #180 is not medically necessary.

**Aciphex 20mg, #30:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68-69.

**Decision rationale:** According to the California MTUS chronic pain medical treatment guidelines, there are specific guidelines for prescribing proton pump inhibitors (PPI). PPI's are recommended when patients are identified to have certain risks with the use of Non-steroidal anti-inflammatory drugs (NSAIDs). Risk factors include age > 65 years, history of peptic ulcer, GI bleeding or perforation, concurrent use of Aspirin, corticosteroids, and/or an anti-coagulant, and high dose/multiple NSAID. A history of ulcer complications is the most important predictor of future ulcer complications associated with NSAID use. The documentation provided did not indicate that the injured worker had gastrointestinal complaints, Therefore the request for Aciphex 20mg, #30 is not medically necessary.

**Fentanyl Patches at 25ugm #10:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Functional improvement, Fentanyl, Opioids section Page(s): 1, 47, 74-96.

**Decision rationale:** According to the California MTUS, Fentanyl is an opioid analgesic with a potency of eighty times that of Morphine. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs. According to ODG and MTUS, Fentanyl is a long-acting narcotic analgesic used to manage both acute and chronic pain. Fentanyl transdermal (Duragesic) patches are indicated for the management of persistent chronic pain, which is moderate to severe requiring continuous, around-the-clock opioid therapy. In this case, the treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. The CA MTUS Guidelines define functional improvement as "a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management and a reduction in the dependency on continued medical treatment." There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. Medical necessity of the requested medication has not been established. The request for Fentanyl Patches at 25ugm #10 is not medically necessary.

**Trial Belsomra 15mg, #30:** Overturned

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness and Stress, Suvorexant (Belsomra).

**Decision rationale:** The California MTUS is silent regarding Belsomra. The Official Disability Guidelines (ODG) do not recommended as a first-line treatment due to adverse effects. FDA approved a first-in-class insomnia drug suvorexant (Belsomra, Merck) after the manufacturer lowered the dosages to satisfy the agency's safety concerns. Originally the FDA had declined to approve suvorexant until the starting dose for most patients was 10 mg. The agency also said that proposed upper-limit doses of 30 mg for elderly patients and 40 mg for nonelderly patients were unsafe. Suvorexant, an orexin receptor antagonist, is the first drug of its kind to be approved for patients with insomnia. It alters the signaling of orexins, neurotransmitters responsible for regulating the sleep-wake cycle. Drowsiness was the most commonly reported adverse event for clinical trial participants taking suvorexant, which is classified as a Schedule IV controlled substance. In next-day driving tests, both male and female participants who took the 20-mg dose proved to be impaired drivers. The FDA advises physicians to caution patients

against next-day driving or other activities requiring full alertness. The documentation provided indicates that the injured worker has tried and failed Ambien CR. Therefore the request for a trial Belsomra 15mg, #30 is medically necessary.

**Trial Fentora #28:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Fentora (Fentanyl buccal tablets) Page(s): 47.

**Decision rationale:** The California MTUS chronic pain medical treatment guidelines do not recommend Fentora for musculoskelatal pain. "Fentora is an opioid painkiller currently approved for treatment of breakthrough pain in certain cancer patients. Cephalon had currently applied to the FDA for approval to market the drug for patients with other pain conditions such as chronic low back pain and chronic neuropathic pain, but approval was not obtained." The injured worker is not being treated for any type of cancer, and documentation supports that the injured worker is being treated for chronic pain complaints. Since this drug is not recommended for use of musculoskeletal pain or chronic pain, the request for a Trial Fentora #28 is not medically necessary.

**Lidoderm patches:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Functional improvement, Lidoderm (lidocaine patches), and Topical Analgesics Page(s): 1, 56-57, and 111-113.

**Decision rationale:** According to the California MTUS chronic pain medical treatment guidelines recommend specific guidelines for the use of Lidoderm patches. Guidelines recommend the use of topical lidocaine for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Guidelines also state that topical analgesics are recommended for neuropathic pain when trials of antidepressants and anti-convulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Also defined by the California MTUS, Functional improvement means decrease in work restrictions or improvement in activities of daily living (ADLs) plus decreased dependence on medical treatment. There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. Also the treating provider did not include the site of

application. Therefore the request for Lidoderm patches is not medically necessary.