

<b>Case Number:</b>	CM15-0126815		
<b>Date Assigned:</b>	07/13/2015	<b>Date of Injury:</b>	06/04/2002
<b>Decision Date:</b>	09/04/2015	<b>UR Denial Date:</b>	06/12/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	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: New York

Certification(s)/Specialty: Pediatrics, Internal 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 68-year-old female, who sustained an industrial injury on 06-04-2002. According to a progress report dated 04-08-2015, there were no significant changes in her pain since the last visit on 02-10-2015. Right leg pain was the most bothersome. Pain radiated from the right buttock down to the heel and ankle. Ambulating was difficult at times. When pain was severe, she had to lie down on her stomach. Medications were working well. Fentanyl patch was on. The trial of Sonata was not improving her sleep. It actually kept her awake. She was otherwise stable but still complained of right sided leg pain. Average pain since the last visit was 4-5 on a scale of 1-10. Mood since last visit was rated 4-5. Functional level since last visit was rated 4-5. Sleep pattern noted complaints of poor sleep quality due to pain. Ambien CR made her sleep walk. She was only able to sleep 2 hours uninterrupted. She had difficulty falling and staying asleep. Current medications included Celebrex, Cymbalta, Fentanyl patch and Norco. Current assessment included chronic low back pain with left greater than right leg pain, degenerative disease with discogenic and facetogenic pain, myofascial pain/spasm, cervicgia with arm pain, cervicogenic headache, bilateral knee pain status left total knee arthroplasty, status post right total knee arthroplasty, depression secondary to chronic pain, osteoarthritis, hypertension and poor sleep hygiene. Diagnoses included lumbosacral spondylosis without myelopathy, spasm of muscle, lumbago, thoracic/lumbosacral neuritis/radiculitis unspecified, cervicgia, cervicocranial syndrome, degenerative lumbar-lumbosacral intervertebral disc and displacement of lumbar disc without myelopathy. The treatment plan included Celebrex 200 mg twice a day #60, Fentanyl patch 50 ugm 1 patch every 3 days #10, Norco 10-325 mg 1 by mouth four times a day #120, Cymbalta 60 mg 1 by mouth every bed time, and a trial of

Belsomra 10 mg 1 by mouth every bed time #30. Medications tried and failed included Vicodin ES, Lidoderm, Voltaren, Zanaflex, Ambien and Sonata. Urine drug screens performed on 07-13-2011, 04-25-2012 and 12-09-2013 were noted as consistent. According to a progress report dated 06-03-2015, the injured worker had a right L4, L5 transforaminal epidural on 05-13-2015 noting about a 75% improvement in her pain. She had been trying to walk more and felt much better. Her neck was doing better. The trial of Belsomra had improved her sleep quality. Average pain since the last visit was 2-10 on a scale of 1-10. Mood since last visit was rated 8. Functional level since last visit was rated 8. Medications were continued as previously. Currently under review is the request for Fentanyl Patch 50 ugm #10, Norco 10-325 mg #120 and Belsomra 10 mg #30. Documentation submitted for review shows that the dosage of Fentanyl and Norco had remained the same since 10-08-2014. Functional level and average pain had remained the same for the last six months up until 06-03-2015 following the transforaminal epidural. Documentation shows use of Norco and Fentanyl dating back to 2011.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **Fentanyl Patch 50 ugm #10: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic (fentanyl transdermal system) Fentanyl, Opioids, Opioid dosing Page(s): 44, 47, 78-86.

**Decision rationale:** CA MTUS Chronic Pain Medical Treatment Guidelines state that Duragesic (fentanyl transdermal system) is not recommended as a first-line therapy. Duragesic is the trade name of a fentanyl transdermal therapeutic system, which releases fentanyl, a potent opioid, slowly through the skin. It is manufactured by [REDACTED] and marketed by [REDACTED] (both subsidiaries of [REDACTED]). The FDA-approved product labeling states that Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means. MTUS Guidelines state that Fentanyl is an opioid analgesic with potency eight times that of morphine. Weaker opioids are less likely to produce adverse effects than stronger opioids such as Fentanyl. MTUS Guidelines state that prescriptions should be from a single practitioner taken as directed, and all prescriptions from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects. Pain assessment should include current pain, the least reported pain over the period since the last assessment, average pain, and the intensity of pain after taking the opioid, how long it takes for pain relief, how long pain relief lasts, improvement in pain and improvement in function. MTUS Guidelines recommend that dosing not exceed 120 mg oral morphine equivalents per day, and for patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose. In general, the total daily dose of opioid should not exceed 120 mg oral morphine equivalents. Documentation provided did not discuss the current pain level, least reported pain over the period since the last assessment, how long it takes for pain relief and how long pain relief lasts. 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. Documentation does not show that the injured worker's

pain cannot be managed by other means. There was no discussion of failure with first-line therapy. The combination of the injured worker's dosage of Norco and Fentanyl combined equal 160, which is not recommended. Medical necessity for the requested treatment was not established. The requested treatment is not medically necessary.

**Norco 10/325mg #120:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Opioids dosing Page(s): 78, 86.

**Decision rationale:** CA MTUS Chronic Pain Medical Treatment Guidelines state that prescriptions should be from a single practitioner taken as directed, and all prescriptions from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects. Pain assessment should include current pain, the least reported pain over the period since the last assessment, average pain, and the intensity of pain after taking the opioid, how long it takes for pain relief, how long pain relief lasts, improvement in pain and improvement in function. MTUS Guidelines recommend that dosing not exceed 120 mg oral morphine equivalents per day, and for patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose. In general, the total daily dose of opioid should not exceed 120 mg oral morphine equivalents. Documentation provided did not discuss the current pain level, least reported pain over the period since the last assessment, how long it takes for pain relief and how long pain relief lasts. 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. The combination of the injured worker's dosage of Norco and Fentanyl combined equal 160, which is not recommended. Medical necessity for the requested treatment was not established. The requested treatment is not medically necessary.

**Belsomra 10mg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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:** CA MTUS Guidelines do not address Belsomra. ODG also recommends that treatment of insomnia be based on the etiology. 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 medical illness. Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed and include sleep onset, sleep maintenance, sleep quality and next day functioning. Literature states that Belsomra is an orexin receptor antagonist that was approved by the FDA for the treatment insomnia. According to Official Disability Guidelines,

non- benzodiazepine sedative-hypnotics are considered first-line medications for insomnia. The injured worker had tried and failed Ambien. There was no discussion of any other agents tried and failed in first-line treatment. Although the treating physician noted improvement with sleep quality with use of Belsomra, there was no specific objective evidence of improvement of such as sleep onset, hours of sleep and next day functioning with use of Belsomra. Medical necessity for the requested treatment is not established. The requested treatment is not medically necessary.