

<b>Case Number:</b>	CM15-0079489		
<b>Date Assigned:</b>	04/30/2015	<b>Date of Injury:</b>	01/23/2001
<b>Decision Date:</b>	06/02/2015	<b>UR Denial Date:</b>	03/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/24/2015

### 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: Montana

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 35 year old female, who sustained an industrial injury on January 23, 2001. She reported neck pain, shoulder pain and mood disorder. The injured worker was diagnosed as having cervical radiculopathy, status post cervical fusion, shoulder pain and mood disorder. Treatment to date has included radiographic imaging, diagnostic studies, surgical intervention with C5-7 fusion of the cervical spine, acupuncture, trigger point injections, medications and work restrictions. Currently, the injured worker complains of continued neck pain. Medications were requested, including; Fentanyl 25mcg #5, Dilaudid 4mg #4, and Reglan 10mg #7.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Fentanyl 25mcg, #5:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Fentanyl; Opioids, specific drug list - Fentanyl transdermal (Duragesic; generic available); Opioids, long-term assessment.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Fentanyl Page(s): 75-85 and 93. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Duragesic (Fentanyl transdermal).

**Decision rationale:** The MTUS states that fentanyl (Duragesic) transdermal is indicated for management of persistent chronic pain, which is moderate to severe requiring continuous, around-the-clock opioid therapy. The pain cannot be managed by other means such as nonsteroidal anti-inflammatory drugs. Duragesic patches should only be used in patients who are currently on opioid therapy for which tolerance has developed. The patches should be applied to intact skin only and are worn for a 72 hour period. The ODG guidelines state that Duragesic patches are 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, due to the significant side effects, not for use in routine musculoskeletal pain. Ongoing use of opioid medication requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: the least reported pain over the period since the last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. In this case there is adequate documentation for pain that cannot be managed by other means. Percocet was discontinued secondary to side effects and Fentanyl was prescribed as a second-line agent. The treatment note on 4/2/15 indicated pain relief with no side effects with the new medication. Dilaudid is used minimally for breakthrough pain and the records indicate that it will be gradually weaned with adequate pain control from Fentanyl. At the next visit the treating physician must document a pain assessment that should include: the least reported pain over the period since the last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. There is a pain agreement and urine drug testing has been performed. The request for fentanyl (Duragesic) 25 g #5 is consistent with the MTUS and ODG guidelines and is medically necessary.

**Dilaudid 4mg, #4:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list - Hydromorphone (Dilaudid; generic available).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 75-85 and 93. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Dilaudid.

**Decision rationale:** The MTUS notes that opioids are not recommended as first line therapy for neuropathic pain. Opioids are suggested for neuropathic pain that has not responded to first line recommendations including antidepressants and anticonvulsants. The MTUS states that reasonable alternatives to opioid use should be attempted. There should be a trial of non-opioid analgesics. When subjective complaints do not correlate with clinical studies a second opinion with a pain specialist and a psychological assessment should be obtained. The lowest possible

dose should be prescribed to improve pain and function. The MTUS states that opioids are not recommended as first line therapy for neuropathic pain. Opioids are suggested for neuropathic pain that has not responded to first line recommendations including antidepressants and anticonvulsants. The MTUS states that reasonable alternatives to opioid use should be attempted. There should be a trial of non-opioid analgesics. When subjective complaints do not correlate with clinical studies a second opinion with a pain specialist and a psychological assessment should be obtained. The lowest possible dose should be prescribed to improve pain and function. Hydromorphone (Dilaudid; generic available): 2mg, 4mg, 8mg. Side Effects: Respiratory depression and apnea are of major concern. Patients may experience some circulatory depression, respiratory arrest, shock and cardiac arrest. The more common side effects are dizziness, sedation, nausea, vomiting, sweating, dry mouth and itching. (Product Information, Abbott Labs 2006) Analgesic dose: Usual starting dose is 2mg to 4mg PO every 4 to 6 hours. A gradual increase may be required, if tolerance develops. Ongoing use of Dilaudid requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: the least reported pain over the period since the last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. In this case the Dilaudid is used for breakthrough pain as part of a treatment regimen for severe chronic pain. The treatment notes indicate that it is used, on average, 1/2 tablet per week. The records indicate that the treating physician hopes to wean the injured worker off the Dilaudid after adequate pain control is established with Fentanyl. The request for Dilaudid 4mg, #4 is medically necessary.

**Reglan 10mg, #7:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation American Gastroenterological Association medical position statement on the management of gastroesophageal reflux disease.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Reglan product information; Epocrates, Reglan; Drugs.com, Reglan.

**Decision rationale:** The MTUS does not address the use of Reglan (metoclopramide). Product information notes that it is indicated for short-term to treatment of heartburn caused by gastroesophageal reflux in people who have used other medications without relief of symptoms. Reglan (metoclopramide) increases muscle contractions in the upper digestive tract. This speeds up the rate at which the stomach empties into the intestines. Other indications include diabetic gastroparesis, small bowel intubation and nausea and vomiting post-operatively and associated with chemotherapy. In this case the records document that Reglan is prescribed for side effects associated with use of Percocet. The treatment note on 3/19/15 indicates that Percocet was discontinued and Fentanyl was prescribed. The treatment note on 4/2/15 documents that there are no side effects from the current medications. The request for Reglan 10mg #7 is not medically necessary.