

<b>Case Number:</b>	CM15-0077343		
<b>Date Assigned:</b>	04/24/2015	<b>Date of Injury:</b>	03/21/1991
<b>Decision Date:</b>	06/02/2015	<b>UR Denial Date:</b>	03/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/10/2015

### 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: California

Certification(s)/Specialty: 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 (IW) is a 57 year old male who sustained an industrial injury on 03/21/1991. He reported back pain. The injured worker was diagnosed as having other symptoms referable to back; thoracic or lumbosacral neuritis or radiculitis, unspecified; lumbosacral spondylosis without myelopathy; displacement of lumbar intervertebral disc without myelopathy; intervertebral lumbar disc disorder with myelopathy lumbar region; headache; unspecified sleep disturbance; posttraumatic stress disorder; displacement of intervertebral disc site unspecified, without myelopathy; degeneration of thoracic or thoracolumbar intervertebral disc. Treatment to date has included medications, education, and physical therapy with home therapy. Currently, the injured worker complains of back pain with occasional shooting pain into the neck causing headaches and some radiation of the pain into the left lower extremity. Medication refills are requested including request for Duragesic 100mcg (fentanyl transdermal system) CII patch #15 with no refills.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Duragesic 100mcg (fentanyl transdermal system) CII patch #15 with no refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chapter 3 Initial Approaches to Treatment Page(s): 47-48, 308-310, Chronic Pain Treatment Guidelines Opioids Page 74-96. Duragesic (Fentanyl transdermal system), pages 44, 47, 93. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Duragesic (Fentanyl transdermal system). FDA Prescribing Information Duragesic <http://www.drugs.com/pro/duragesic.html>.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address opioids. The lowest possible dose should be prescribed to improve pain and function. MTUS Chronic Pain Medical Treatment Guidelines recommends that opioid dosing not exceed 120 mg oral morphine equivalents per day. Immediate discontinuation has been suggested for evidence of illegal activity including diversion. Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the 4 A's (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). Frequent evaluation of clinical history and frequent review of medications are recommended. Periodic review of the ongoing chronic pain treatment plan for the injured worker is essential. Patients with pain who are managed with controlled substances should be seen regularly. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) Chapter 3 states that opioids appear to be no more effective than safer analgesics for managing most musculoskeletal symptoms. Opioids should be used only if needed for severe pain and only for a short time. ACOEM guidelines indicate that the long-term use of opioids is not recommended for low back conditions. Medical records document the long-term use of opioids. Per MTUS, the lowest possible dose of opioid should be prescribed. ACOEM guidelines indicate that the long-term use of opioids is not recommended for low back conditions. MTUS Chronic Pain Medical Treatment Guidelines indicates that Duragesic (Fentanyl transdermal system) is not recommended as a first-line therapy. Duragesic releases Fentanyl, a potent opioid. Fentanyl is an opioid analgesic with a potency eighty times that of morphine. Duragesic is indicated for the management of persistent chronic pain, which is moderate to severe requiring continuous, around-the-clock opioid therapy, and the pain cannot be managed by other means. FDA Prescribing Information indicates that Duragesic is indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Patients considered opioid-tolerant are those who are taking, for one week or longer, at least 60 mg of morphine daily, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily, or an equianalgesic dose of another opioid. Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve Duragesic for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Official Disability Guidelines (ODG) indicates that Duragesic (Fentanyl transdermal system) is not recommended as a first-line therapy. Due to the significant side effects, Duragesic is not for use in routine musculoskeletal pain. The date of injury was 03-21-1991. The progress report dated 3/3/15 documented subjective complaints of

back pain, and prescriptions for Norco 10/325 mg #210, Soma 350 mg #90, Klonopin 1 mg #60, and Duragesic 100 mcg/hr #15. The patient reported marijuana use. There was no documentation that alternative treatment options were inadequate. The patient's opioid regimen exceeds the MTUS recommended limit of 120 mg morphine equivalents per day. Per MTUS, the lowest possible dose of opioid should be prescribed. Medical records document the long-term use of opioids. ACOEM guidelines indicate that the long-term use of opioids is not recommended for back conditions. Therefore, the request for Duragesic is not medically necessary.