

<b>Case Number:</b>	CM15-0145281		
<b>Date Assigned:</b>	08/07/2015	<b>Date of Injury:</b>	10/19/1998
<b>Decision Date:</b>	09/30/2015	<b>UR Denial Date:</b>	07/02/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/28/2015

### 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, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 65 year old female, who sustained an industrial injury on October 19, 1998. The mechanism of injury was not found in the medical records. The injured worker has been treated for low back complaints. The diagnoses have included lumbago, thoracic or lumbosacral neuritis-radiculitis, limb pain, lumbar disc bulges and lumbar radiculopathy. Treatment and evaluation to date has included medications, radiological studies, MRI, transforaminal epidurogram, injections and physical therapy. Work status was not provided in the medical records. Current documentation dated June 23, 2015 notes that the injured worker reported worsening, constant low back pain with radiculopathy to the lower extremities. The injured worker also noted muscle spasms in the low back. Associated symptoms include tingling and shaking in the legs. The pain was rated a 7-8 out of 10 on the visual analogue scale. Examination of the low back revealed tenderness to palpation diffusely over the lumbar spine and sacroiliac joints. A straight leg raise test was positive on the right. There was severe pain noted over the facet joints as well as severe pain with radiculopathy. Significant weakness was noted in the lower extremities. No muscle wasting was noted. The treating physician's plan of care included requests for Duragesic patches 100 mcg every 72 hours # 10 times 6 months and Duragesic patches 12 mcg every 72 hours # 10 times 6 months.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Duragesic 12 mcg Qty 10 x 6 months, every 72 hrs: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opiates  
Page(s): 78, 93.

**Decision rationale:** Per MTUS CPMTG with regard to Duragesic: "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 p93 notes that Duragesic should only be used in patients who are currently on opioid therapy for which tolerance has developed. Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids "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 non-adherent) drug related behaviors. These domains have been summarized as the '4 A's' (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." Review of the available medical records reveals no documentation to support the medical necessity of Duragesic nor any documentation addressing the '4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Furthermore, efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. There is no documentation comprehensively addressing this concern in the records available for my review. As MTUS recommends to discontinue opioids if there is no overall improvement in function, medical necessity cannot be affirmed. Furthermore, the request for 6-month supply is not appropriate, as it does not allow for timely reassessment of medication efficacy.

**Duragesic 100 mcg Qty 10 x 6 months, every 72 hrs: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opiates  
Page(s): 78, 93.

**Decision rationale:** Per MTUS CPMTG with regard to Duragesic: "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 p93 notes that Duragesic should only be used in patients who are currently on opioid therapy for which tolerance has developed. Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids "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 non-adherent) drug related behaviors. These domains have been summarized as the '4 A's' (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." Review of the available medical records reveals no documentation to support the medical necessity of Duragesic nor any documentation addressing the '4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Furthermore, efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. There is no documentation comprehensively addressing this concern in the records available for my review. As MTUS recommends to discontinue opioids if there is no overall improvement in function, medical necessity cannot be affirmed. Furthermore, the request for 6-month supply is not appropriate, as it does not allow for timely reassessment of medication efficacy.