

<b>Case Number:</b>	CM13-0068348		
<b>Date Assigned:</b>	01/03/2014	<b>Date of Injury:</b>	03/20/2004
<b>Decision Date:</b>	05/23/2014	<b>UR Denial Date:</b>	12/05/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/19/2013

### 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. The expert reviewer is Board Certified in Preventive Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

According to the records made available for review, this is a 62-year-old male with a 3/20/04 date of injury. At the time (11/15/13) of request for authorization for Fentanyl patch 25mcg #10. There is documentation of subjective findings of ongoing low back pain, doing well on the current medication regiment with no major side effects. Objective findings include: absent reflexes at the Achilles and decreased strength in the lower extremities. The current diagnoses are chronic low back pain, failed back syndrome, depression, and anxiety. The treatments to date are medications (including Fentanyl patch, Norco, Lyrica, and Valium since at least 4/9/13). There is no (clear) documentation of persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means; that the patient has demonstrated opioid tolerance, and requires a total daily dose at least equivalent to Duragesic®@25 mcg/h; and no contraindications exist. In addition, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Fentanyl patch use to date.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**FENTANYL PATCH 25MCG #10:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Duragesic (fentanyl transdermal system),. Decision based on Non-MTUS Citation Title 8, California Code of Regulations, section 9792.20, non-MTUS: Official Disability Guidelines (ODG), Pain, Duragesic and Fentanyl, and Food and Drug Administration (FDA).

**Decision rationale:** The MTUS Chronic Pain Medical Treatment Guidelines identifies documentation of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means, as criteria necessary to support the medical necessity of Duragesic. The MTUS Chronic Pain Medical Treatment Guidelines identifies that Duragesic is not recommended as first-line therapy. The MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. The ODG identifies documentation that Duragesic is not for use in routine musculoskeletal pain. The FDA identifies documentation of persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means; that the patient is already receiving opioid therapy, has demonstrated opioid tolerance, and requires a total daily dose at least equivalent to Duragesic® 25 mcg/h; and no contraindications exist, as criteria necessary to support the medical necessity of Duragesic patch. Within the medical information available for review, there is documentation of diagnoses of chronic low back pain, failed back syndrome, depression, and anxiety. In addition, there is documentation of ongoing treatment with medications (including Fentanyl patch, Norco, Lyrica, and Valium). However, despite documentation of ongoing low back pain, there is no (clear) documentation of persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means; that the patient has demonstrated opioid tolerance, and requires a total daily dose at least equivalent to Duragesic® 25 mcg/h; and no contraindications exist. In addition, given documentation of ongoing treatment with Fentanyl patch, and despite documentation that patient is doing well on the current medication regimen with no major side effects, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Fentanyl patch use to date. Therefore, based on guidelines and a review of the evidence, the request for Fentanyl patch 25mcg #10 is not medically necessary.