

<b>Case Number:</b>	CM14-0027369		
<b>Date Assigned:</b>	06/13/2014	<b>Date of Injury:</b>	10/07/2003
<b>Decision Date:</b>	07/16/2014	<b>UR Denial Date:</b>	02/07/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/04/2014

### 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 Internal and Emergency Medicine and is licensed to practice in Florida. 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:

This patient is a 55 year-old with a date of injury of 10/07/03. A progress report associated with the request for services, dated 01/30/14, identified subjective complaints of neck pain as well as right knee and left arm. Objective findings included decreased range-of-motion of the cervical spine. There was decreased sensation in the left upper extremity. Motor function was normal. Diagnoses included cervical disc disease and failed back syndrome. Treatment has included a cervical fusion, epidural injections, physical therapy, and medication (methadone, Norco, Fentanyl patches). A Utilization Review determination was rendered on 02/07/14 recommending non-certification of "Subsys 400mcg/spray sub-lingual #60 (dispensed)".

### IMR ISSUES, DECISIONS AND RATIONALES

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

**SUBSYS 400MCG/SPRAY SUB-LINGUAL #60 (DISPENSED):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Short-acting/Long-acting Opioids.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 181, Chronic Pain Treatment Guidelines Functional Improvement Measures; Opioids Page(s): 48; 74-96. Decision based on Non-MTUS Citation [www.subsyspray.com](http://www.subsyspray.com).

**Decision rationale:** SUBSYS spray is a sublingual release form of fentanyl, which is classified as an opioid analgesic. The California Medical Treatment Utilization Schedule (MTUS) Guidelines related to on-going treatment of opioids state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or improved functional capacity (Eriksen 2006). The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. The Guidelines also state that with chronic low back pain, opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited." Additionally, "There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain (Martell - Annals, 2007)." The MTUS further states that opioids are not recommended for neck complaints for more than 2 weeks. The patient has been on opioids well in excess of 16 weeks. Manufacturer indications for SUBSYS states that it is an opioid agonist indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients must remain on around-the-clock opioids when taking SUBSYS. In this case, there is no documentation of the other elements of the pain assessment referenced above or necessity of therapy beyond 16 weeks or specific functional improvement. The claimant's total daily morphine-equivalents of opioid therapy exceed recommendations. Last, SUBSYS is not indicated for the claimant's type of pain. Therefore, the record does not document the medical necessity for SUBSYS. Therefore, the request is not medically necessary.