

<b>Case Number:</b>	CM15-0038283		
<b>Date Assigned:</b>	03/06/2015	<b>Date of Injury:</b>	09/29/1998
<b>Decision Date:</b>	04/14/2015	<b>UR Denial Date:</b>	02/13/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/02/2015

### 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: New Jersey, Michigan, California  
 Certification(s)/Specialty: Neurology, Neuromuscular 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 an 80 year old male, who sustained an industrial injury on 9/29/98. He has reported pain in the back. The diagnoses have included lumbar degenerative disc disease, lumbar spondylosis and post laminectomy syndrome. Treatment to date has included MRI, spinal cord stimulator and pain medications. As of the PR2 dated 2/2/15, the injured worker reports right sacroiliac joint pain that is resolved with Abstral. The treating physician requested Abstral Sub 400ucg #32 x 1 refill. On 2/13/15 Utilization Review non-certified a request for Abstral Sub 400ucg #32 x 1 refill. On 3/1/15, the injured worker submitted an application for IMR for review of Abstral Sub 400ucg #32 x 1 refill.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Abstral sub 400ugm QD to BID prn severe breakthrough pain #32: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, dosing, When to continue Opioids. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter, Opioids, criteria for use.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Fentanyl <http://www.odg-twc.com/index.html>.

**Decision rationale:** According to ODG guidelines, Fentanyl "Not recommended for musculoskeletal pain. Fentanyl is an opioid analgesic with a potency eighty times that of morphine. Weaker opioids are less likely to produce adverse effects than stronger opioids such as fentanyl. Due to significant side effects, it is not for use in routine musculoskeletal pain. For more information and references, see Opioids for general guidelines, as well as specific Fentanyl listing for more information and references. See also Actiq (fentanyl lollipop); Duragesic (fentanyl transdermal system); Fentora (fentanyl buccal tablet); Onsolis (fentanyl buccal film). On Jan 7, 2011, the FDA approved an immediate-release transmucosal tablet formulation of fentanyl (Abstral; ProStraken, Inc) for the management of breakthrough cancer pain. Because Abstral is subject to abuse and misuse, the product was approved with a risk evaluation and mitigation strategy (REMS) that includes a restricted distribution program requiring registration of prescribers, pharmacies, and patients. It is not recommended as a first-line agent for musculoskeletal pain. (FDA, 2011) The DEA has issued a nationwide alert about the dangers of fentanyl, saying that drug incidents and overdoses related to fentanyl are occurring at an alarming rate throughout the U.S. and represent a significant threat to public health and safety. According to the National Forensic Laboratory Information System, state and local laboratories reported 3,344 fentanyl submissions in 2014, up from 942 in 2013. Fentanyl is the most potent opioid available for use in medical treatment, 50 to 100 times more potent than morphine, and 30 to 50 times more potent than heroin. Fentanyl is extremely dangerous to law enforcement and anyone else who may come into contact with it. (DEA, 2015)" There is no documentation of the need for high dose of opioids. There is no justification for the use of high dose of opioids including fentanyl. There is no documentation of monitoring for side effects and compliance of the patient with his medications. Therefore, the request for Abstral sub 400ugm QD to BID prn severe breakthrough pain #32 is not medically necessary.