

Case Number:	CM15-0003121		
Date Assigned:	01/14/2015	Date of Injury:	09/07/1995
Decision Date:	03/13/2015	UR Denial Date:	12/08/2014
Priority:	Standard	Application Received:	01/07/2015

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: Physical Medicine & Rehabilitation

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 59 year old male was injured 9/7/95 in an industrial accident. Current complaints include left shoulder, arm and leg pain and low back pain. The pain intensity is 10/10 without medications and 5/10 with medications. His medications are oxycodone hydrochloride and Opana oxymorphone hydrochloride. Laboratory evaluations were inconsistent with prescribed medications. Diagnoses include failed back surgery syndrome; chronic lumbar radiculopathy; spondylolisthesis, lumbar spine; chronic regional pain syndrome, left upper extremity status post trauma, extensive surgeries; status post implant and explant of spinal cord stimulator; opioid dependence; status post-surgical attachment of middle finger and colon cancer Stage II T3. Due to the cancer diagnosis the injured worker had radiation therapy. Diagnostic studies were not available. The treating provider prescribed Abstral 600 mcg #32 for pain. On 12/8/14 Utilization Review non-certified the request for Abstral 600 mcg based on the injured worker already receiving oxycodone for breakthrough pain and he is not being treated for cancer pain. MTUS Chronic Pain Treatment Guidelines were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Abstral 600mcg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 47 & 76-80. Decision based on Non-MTUS Citation ODG, Pain

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CRITERIA FOR USE OF OPIOIDS Page(s): 76-78, 88-89. Decision based on Non-MTUS Citation Drug Formulary, Abstral

Decision rationale: The patient presents with pain and weakness in his lower back and left leg. The request is for ABSTRAL 600MCG #32. The patient is currently taking Oxycontin, Xycodone Hydrochloride and Abstral. The patient has been utilizing Abstral since 09/04/14. Per 11/26/14 progress report, the increased Abstral worked well, but on 10/30/14 progress report, Abstral -400mcg is not at effective dosing. The treater increased Abstral from 400mc 600mcg. The patient started Abstral 200mcg on 09/04/14. The patient has completed radiation therapy on 12/16/14. Regarding chronic opiate use, MTUS guidelines page and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4A's --analgesia, ADLs, adverse side effects, and adverse behavior--, as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. ODG guidelines, under Drug Formulary, specifically discuss Abstral 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, not for use in routine musculoskeletal pain. On Jan 7, 2011, the FDA approved an immediate-release transmucosal tablet formulation of fentanyl Abstral; [REDACTED] -- 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. In this case, while the patient has a diagnosis of colon cancer, there is discussion from the treater that this medication is being used for the patient's cancer pain. There is no description of pain from the patient's cancer. It would appear that this medication is being used for the patient's musculoskeletal pain for which the use of Abstral or sublingual Fentanyl is not recommended per ODG guidelines. The request IS NOT medically necessary.