

Case Number:	CM15-0167994		
Date Assigned:	09/14/2015	Date of Injury:	06/15/2000
Decision Date:	10/15/2015	UR Denial Date:	08/25/2015
Priority:	Standard	Application Received:	08/26/2015

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: Texas, New York, California
 Certification(s)/Specialty: Preventive Medicine, Occupational 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 applicant is a represented [REDACTED] ([REDACTED]) employee who has filed a claim for chronic pain syndrome reportedly associated with an industrial injury of June 15, 2000. In a Utilization Review report dated August 20, 2015, the claims administrator failed to approve a request for Subsys sublingual nasal spray. The claims administrator referenced a July 28, 2015 office visit in its determination. The applicant's attorney subsequently appealed. On said July 20, 2015 progress note, the applicant reported progressive worsening low back pain with derivative complaints of depression. The applicant had undergone earlier failed lumbar spine surgery, it was reported. The applicant was using a walker to move about. The applicant medications included morphine, Desyrel, Valium, Prilosec, Lexapro, methadone, and Miralax, it was reported. Electrodiagnostic testing of bilateral lower extremities, Duragesic patches, morphine, Valium, Desyrel, and Subsys sublingual spray were endorsed. The applicant was off of work and using Social Security Disability Insurance benefits, it was reported.

IMR ISSUES, DECISIONS AND RATIONALES

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

Subsys 1200mg Sublingual Spray DOS 7/28/2015 DS: 30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Subsys (Fentanyl Transmucosal Spray).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Introduction. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Subsys® (fentanyl sublingual spray) and Other Medical Treatment Guidelines U.S. Food and Drug Administration SUBSYS 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.

Decision rationale: No, the request for Subsys sublingual nasal spray was not medically necessary, medically appropriate, or indicated here. Page 78 of the MTUS Chronic Pain Medical Treatment Guidelines stipulates that the lowest possible dose of opioid should be prescribed to improve pain and function. Here, the attending provider's July 28, 2015 progress note, failed to furnish a clear or compelling rationale for concomitant usage of multiple different opioid agents to include morphine, methadone, Duragesic, and Subsys spray. It was not stated why the applicant needed to use Subsys spray when the applicant was already reportedly using immediate release morphine for reported breakthrough pain. Pages 7 and 8 of the MTUS Chronic Pain Medical Treatment Guidelines further stipulates that an attending provider using a drug for non-FDA labeled purposes has the responsibility to be well informed regarding usage of the same. The Food and Drug Administration (FDA) notes that Subsys is an opioid agonist indicated in the treatment of breakthrough pain in cancer patients who had developed tolerance to opioid therapy for underlying persistent cancer pain complaints. Here, however, there was no mention of the claimant is having issues with cancer which would have supported provision of Subsys. In a similar vein, ODG's Chronic Pain Chapter Subsys topic also notes that Subsys is not recommended for musculoskeletal pain, as was present here. The July 20, 2015 request for Subsys, thus, was at odds with page 78 of the MTUS Chronic Pain Medical Treatment Guidelines, the FDA label and with the ODG position on the same. Therefore, the request was not medically necessary.