

Case Number:	CM15-0142344		
Date Assigned:	08/03/2015	Date of Injury:	12/03/1997
Decision Date:	09/29/2015	UR Denial Date:	07/16/2015
Priority:	Standard	Application Received:	07/22/2015

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, District of Columbia, Maryland
 Certification(s)/Specialty: Anesthesiology, Pain Management

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 a 55 year old male who sustained an industrial injury on 12/03/1997. Documentation shows that the injured worker suffered injury to the back and psyche from a cumulative trauma injury. According to a progress report dated 06/23/2015, chief complaints included back pain and left leg pain. The injured worker had rescue pain, but directly related to the left sciatica, which was unresponsive to intrathecal therapy, due to his surgical candidacy. Duragesic patches had not been approved on an industrial basis. Quality of left sciatica pain was described as throbbing, sharp, burning and aching. Severity was moderate. Escalating activities of daily living aggravated the underlying symptoms. Reducing activities of daily living improved the injured worker's symptoms. Past medical history included discography resulting in staphylococcus infection requiring a 20-day hospitalization and intrathecal pump implantation. Current medications included Fentanyl 100 mcg per hour one patch changed every 48 hours #15 and Hydrocodone/APAP 10-325 mg one tablet three times a day #90. There were no known medical allergies. Physical examination demonstrated well-healed lumbosacral and subcostal wounds. Range of motion of the lumbosacral spine was decreased. Diagnoses included degeneration lumbar disk, lumbar stenosis (foraminal), lumbago and sciatica. The provider noted that the injured worker continued to require Duragesic and Hydrocodone/APAP as currently prescribed, pending recommendations for disc replacement operation. Total pain-related impairment score was noted as moderately severe impairment. The treatment plan included continuation of intrathecal Fentanyl at 84.89 micrograms per day and Duragesic at 100 micrograms per hour, each patch changed every 48 hours #15. Authorization was being

requested for Hydrocodone/APAP 10-325 mg one tablet three times a day #90. The injured worker was on temporary total disability as of 08/20/2014 until (named provider) had the opportunity for L4-L5 and L5-S1 disc replacement arthroplasty. The provider noted that the injured worker had an opioid agreement. He was also noted to have intractable pain. The injured worker fell in to the high-risk category on the basis of the continued requirement of Duragesic. The goal was to proceed with intrathecal monotherapy only without the utilization of adjunctive oral opioids. Currently under review is the request for Fentanyl patches 100 micrograms #15.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fentanyl patches 100mcg #15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic Page(s): 44.

Decision rationale: Per MTUS CPMTG with regard to Duragesic: "Not recommended as a first-line therapy. Duragesic is the trade name of a fentanyl transdermal therapeutic system, which releases fentanyl, a potent opioid, slowly through the skin. It is manufactured by [REDACTED] and marketed by [REDACTED] (both subsidiaries of [REDACTED]). The FDA-approved product labeling states that Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means." Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug related behaviors. These domains have been summarized as the '4 A's' (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." Review of the available medical records reveals no documentation to support the medical necessity of fentanyl patch nor any documentation addressing the '4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Furthermore, efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. The medical records submitted for review contained no UDS reports. It was noted that the injured worker had an opioid agreement on file. With regard to medication history, the injured worker has been using fentanyl patches since at least 12/2014. It was noted that the goal of treatment was to proceed with intrathecal monotherapy only without the utilization of adjunctive oral opioids. As MTUS recommends discontinuing opioids if there is no overall improvement in function, medical necessity cannot be affirmed. The request is not medically necessary.

