

Case Number:	CM14-0075231		
Date Assigned:	07/16/2014	Date of Injury:	04/25/2014
Decision Date:	08/19/2014	UR Denial Date:	04/30/2014
Priority:	Standard	Application Received:	05/22/2014

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 Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Oklahoma and Texas. 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:

The injured worker is a 53-year-old female who reported an injury on 04/25/1993, who reportedly sustained injury to her lower back. She was constantly required to stand, lift, and walk. She intermittently knelt, twisted, bent, pulled, pushed, stooped, squatted, reached, and performed repetitive hand work. The injured worker's treatment history included physical therapy, MRIs, x-rays, medications, and pain management. The injured worker was evaluated on 01/27/2014, and it was documented the injured worker had back pain that was constant described as sharp, aching, throbbing, and shooting. The provider noted the injured worker stated her pain was 8/10 on average, 6/10 at best and 9/10 at worst. It was noted that the injured worker's pain level with opioid medications was improved by 100%. The physical examination of the lumbar spine revealed tenderness on the right and left lumbar paravertebral region at the L4-5 and L5-S1 levels, and tenderness was absent in the bilateral sacroiliac joint. Tenderness was present in the lumbar paravertebral region. Extension, right lateral rotation, left lateral rotation, was positive for back pain. Range of motion of the lumbar spine was restricted. Range of motion, right/left lateral flexion was 10 degrees, and forward flexion was 35 degrees and extension was 5 degrees. Straight Leg raise test was negative bilaterally. Strength was 5/5 in both lower extremities. Tenderness noted over thoracic paraspinal muscles. T4-8 range of motion of the thoracic spine was noted to be restricted with pain on extension. Tenderness noted on cervical spine paravertebral regions bilaterally and multiple trigger points with jump sign and radiation of pain at C3-4, C4-5, and C5-6 level. The Spurling test was positive on the right for neck as well as radiculopathy. The Spurling test was positive on the left for neck pain and radiculopathy. Medications included Tegaderm, Dilaudid 8 mg, promethazine 25 mg, subsys 800 mcg/spray, fentanyl 75 mcg, HR transdermal patch, Lidoderm 5% patch, Soma 350 mg, Colace

100 mg, Senokot 8.6 mg. Diagnoses included degenerative disc disease, lumbar, lumbar disc disorder, herniation disc, cervical, and degenerative, disc disease cervical. The request for authorization dated on 06/19/204 was for fentanyl 75 mcg/hour transdermal patch, Lidoderm 5% (700 mg/patch), Soma 350 mg and Subsys 800 mcg/spray sublingual. However, the rationale was not submitted for this review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fentanyl 75mcg/hr transdermal patch every 72 hours PRN for 30 days #15: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Fentanyl Page(s): 47.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic (Fentanyl Transdermal System) & Fentanyl, page(s) 44& 47 Page(s): 44 &47.

Decision rationale: The requested is not medically necessary. The California MTUS guidelines do not recommend Duragesic fentanyl transdermal system 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. 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. 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. The documents submitted for review lacked evidence of conservative care outcome measures of physical therapy and home exercise regimen for the injured worker. In addition, the request failed to indicate location where the Fentanyl patch should applied on the injured worker. Therefore the request for fentanyl 75 mcg/transdermal patch every 72 hours as needed for 30 days #15 is not medically necessary.

Lidoderm 5% (700mg/patch) adhesive patch 2 once a day PRN 30 days #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch) Page(s): 56,57.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, page(s) 111 Page(s): 111.

Decision rationale: The requested is not medically necessary. The California MTUS guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. The guidelines also state that any compounded product contains at least one drug (or drug class) that is not recommended. The guidelines state that there are no other commercially approved topical formulation of lidocaine (whether creams, lotions, or gels) that are indicated for neuropathic pain other than Lidoderm. The proposed gel contains methyl salicylate and menthol. The documentation submitted failed to indicate the injured worker's conservative care measures such as, physical therapy and pain medicine management outcome.

In addition, request did not provide location where the patch will be applied. As such, the request for Lidoderm 5 % (700 mg/patch) adhesive patch 2 once a day prn 30 days # 60 is not medically necessary.

Soma 350mg tablet once a day PRN for 30 day #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.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma) & Muscle Relaxants, page(s) 29 & 63 Page(s): 29 & 63.

Decision rationale: The requested is not medically necessary. The California MTUS Chronic Pain Medical Guidelines recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule-IV controlled substance). Carisoprodol is now scheduled in several states but not on a federal level. It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. Abuse has been noted for sedative and relaxant effects. In regular abusers the main concern is the accumulation of meprobamate. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs. The documents submitted indicated the injured worker received prior conservative care however, the outcome measurements were not provided. Furthermore, the documentation failed to indicate how long the injured worker has been on Soma. In addition, the guidelines do not recommend Soma to be used for long-term-use. Given the above, the request for Soma 350 mg tablet once a day as needed for 30 day # 30 is not medically necessary.

Subsys 800mcg/spray sublingual 1 dose as directed PRN for 28 days #60: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Subsys (Fentanyl sublingual spray).

Decision rationale: The requested is not medically necessary. According to the ODG subsys (fentanyl sublingual spray) are not recommended for musculoskeletal pain. The FDA has approved subsys fentanyl sublingual spray, from insys therapeutics, only for breakthrough cancer pain. Breakthrough cancer pain is characterized by sudden, often unpredictable, episodes of intense pain which can peak in severity at three to five minutes despite background pain medication. Subsys is approved 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. The documents submitted indicated the injured worker received prior conservative care however, the

outcome measurements were not provided. Given the above, the request for Subsys 800 mcg/spray sublingual 1 dose as directed as needed for 28 days # 60 is not medically necessary.