

Case Number:	CM14-0215668		
Date Assigned:	01/05/2015	Date of Injury:	12/17/1999
Decision Date:	03/10/2015	UR Denial Date:	12/22/2014
Priority:	Standard	Application Received:	12/23/2014

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. 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: Maryland, District of Columbia
 Certification(s)/Specialty: Internal 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 employee was a 60 year old female who sustained an industrial injury on 12/17/1999. The pain management note from 12/09/14 was reviewed. She noted no significant changes in the left shoulder pain. She continued to have difficulty using the left arm due to the pain. her medications were working fair. It helped her function better. Fentora helped her with severe pain when she can't stand the pain. Her pain was 7/10 and functional level was 5-6/10. She complained of poor sleep quality. She was not working. Current medications included Aciphex, Celebrex, Fentanyl patch, Fentora tablets, Morphine IR. On exam, she had painful range of motion of shoulder. Her diagnoses included severe left shoulder pain status post surgery twice, CRPS I/II, poor pain control due to analgesic side effects/intolerance, poor sleep hygiene, chronic low back pain, cervical disc lesions. She had failed Exalgo, Dilaudid, Nucynta, Vicodin, Celebrex, Subsys, Lyrica, Methadone, Cymbalta, Neurontin, Subsys, percocet, Opana IR and TN1. Urine drug screen was sent on 08/19/14. The request was for Fentanyl patch, Fentora tablet, Aciphex, Celebrex, MS IR, PC 5001 cream.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fentanyl patch 50mcg #15: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, ongoing management Page(s): 78.

Decision rationale: According to MTUS Chronic Pain Guidelines, four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on Opioids: pain relief, adverse effects, physical and psychosocial functioning and potential aberrant behaviors. The employee was being treated for chronic pain syndrome and had been on Fentanyl, Fentora, MS IR and Celebrex. She had ongoing pain at 7/10 in intensity suggesting possible opioid induced analgesia or tolerance. She was not working and had ongoing pain. There is no discussion on the results of the most recent UDS from August 2014. Given the lack of efforts to rule out unsafe usage and the ongoing severe pain at 7/10, and possible opioid tolerance, the criteria for continued use of Fentanyl patch and Morphine sulphate IR have not been met.

Fentora 400mcg tablet #28: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Fentora Page(s): 47.

Decision rationale: According to MTUS, Chronic Pain Medical treatment guidelines, Fentora is currently not recommended for musculoskeletal pain. Fentora is an opioid painkiller currently approved for the treatment of breakthrough pain in certain cancer patients. Cephalon had applied to the FDA for approval to market the drug for patients with other pain conditions such as chronic lowback pain and chronic neuropathic pain, but approval was not obtained. The employee was being treated with multiple pain medications with ongoing pain level of 7/10. She was also not working. There was no current urine drug screen within 6 months. Hence the request was Fentora is not medically necessary or appropriate.

Aciphex 20mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk Page(s): 68.

Decision rationale: The chronic pain guidelines indicate Aciphex as a proton pump inhibitor indicated in the treatment of NSAID-induced dyspepsia. The review of the medical records does not indicate that there is a diagnosis of dyspepsia, NSAID-induced or otherwise. The limited information given suggests that employee is being given the proton pump inhibitor for protective purposes without actual symptoms of dyspepsia. Employee does not have need for prophylactic

use of proton pump inhibitor due to lack of evidence in the clinical notes. There is no documentation to support that employee was using multiple NSAIDs in conjunction with corticosteroids and is also not greater than 65. Request for Aciphex is not medically necessary and appropriate.

Celebrex 200mg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Celebrex Page(s): 22.

Decision rationale: According to MTUS, COX 2 inhibitors like Celebrex may be considered if the patient has a risk for GI complications, but not for the majority of patients. The employee had no documented GI risk factors including advanced age, prior GI bleeding, multiple NSAID use or NSAID use with anticoagulant or antiplatelet agent. Hence, the request for Celebrex instead of a non selective NSAID is not medically necessary or appropriate.

Ms - IR 15mg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, on-going management Page(s): 78.

Decision rationale: According to MTUS Chronic Pain Guidelines, four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on Opioids: pain relief, adverse effects, physical and psychosocial functioning and potential aberrant behaviors. The employee was being treated for chronic pain syndrome and had been on Fentanyl, Fentora, MS IR and Celebrex. She had ongoing pain at 7/10 in intensity suggesting possible opioid induced analgesia or tolerance. She was not working and had ongoing pain. There is no discussion on the results of the most recent UDS from August 2014. Given the lack of efforts to rule out unsafe usage and the ongoing severe pain at 7/10, and possible opioid tolerance, the criteria for continued use of Fentanyl patch and Morphine sulphate IR have not been met.

PC 5001 cream, 300gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 112-113.

Decision rationale: According to the MTUS, compounded product that contains at least one drug or drug class that is not recommended is not recommended. In addition, the guidelines add that the topical analgesics are largely experimental in use with few RCTs to determine their efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The employee had CRPS and had failed multiple medications. But the requested cream's ingredients are not available for review. An internet search and Lexicomp database search came up empty. Hence the request for PC5001 cream is not medically necessary or appropriate.