

Case Number:	CM15-0119538		
Date Assigned:	06/30/2015	Date of Injury:	02/11/2008
Decision Date:	08/25/2015	UR Denial Date:	06/17/2015
Priority:	Standard	Application Received:	06/22/2015

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
 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 54 year old male sustained an industrial injury to the back and left shoulder on 2/11/08. Previous treatment included left carpal tunnel release (6/24/13), left shoulder superior labral anterior posterior repair (11/29/10) left shoulder rotator cuff repair revision (8/24/12), physical therapy, functional restoration program and medications. In a PR-2 dated 5/11/15, the injured worker complained of ongoing low back pain with radiation to the right lower extremity, right ankle pain and left shoulder pain. The injured worker reported approximately 30% decrease in pain with the use of Norco, allowing him to increase his activity. The injured worker was requesting a temporary one month increase in medications due to an impending increase in activity because of many scheduled physician appointments. Physical exam was remarkable for normal muscle tone without atrophy to bilateral lower and upper extremities without tenderness to palpation. The injured worker walked with an antalgic gait using a cane for assistance with ambulation. Current diagnoses included pain in shoulder joint, cervical disc displacement, neck pain, sacrum disorders, sciatica and lumbar disc displacement without myelopathy. The treatment plan included prescriptions for Cialis, Norco, Protonix and Naproxen Sodium.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cialis 10mg #10: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.drugs.com/pro/cialis.html, Erectile Dysfunction.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation AETNA Guidelines Clinical Policy Bulletin No. 0007.

Decision rationale: Based on the 05/11/15 progress report provided by treating physician, the patient presents with low back and neck pain, lower extremity radiculopathy, and shoulder pain. The patient is status post left shoulder surgery 11/29/10, rotator cuff repair revision 08/24/12, and left carpal tunnel release 06/24/13. The request is for CIALIS 10MG #10. Patient's diagnosis per Request for Authorization form dated 06/11/15 includes pain in joint shoulder, status post arthroscopy, now with recurrent tear by MRI. The patient ambulates with antalgic gait assisted by cane. Treatment to date has included surgery, imaging studies, physical therapy, functional restoration program and medications. Patient's medications include Cialis, Viagra, Norco, Protonix and Naproxen Sodium. The patient is permanent and stationary, per 05/11/15 report. The MTUS and ACOEM Guidelines do not discuss Cialis specifically. AETNA Guidelines Clinical Policy Bulletin No. 0007 regarding erectile dysfunction states that a comprehensive physical/examination and lab workup for the diagnosis of erectile dysfunction (ED) including medical, sexual, and psychosocial evaluation is required including documentation of hypogonadism that may contribute to the patient's ED. AETNA also does not support performance enhancing drugs such as Viagra or Cialis. Cialis has been included in patient's medications, per treater reports dated 05/11/15, 06/09/15, and 07/16/15. It is not known when this medication was initiated. Per Appeal report dated 07/16/15, treater states the patient "did state that he had erectile dysfunction secondary to his chronic pain. Patient reported that he had a decrease in sex drive and decreased ability to obtain erections satisfactory for sexual intercourse...Patient did find Cialis to be beneficial and denied any side effects with this medication." In this case, treater has discussed patient's ED and benefit from medication, but there is no medical evaluation regarding ED, in terms of etiology, severity, etc. In addition, there are no laboratory tests documenting patient's testosterone levels. Furthermore, some guidelines such as the AETNA consider life-enhancing medications not medically necessary. Therefore, the request for Cialis IS NOT medically necessary.

Hydrocodone-Acetaminophen 10/325mg #105: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids ongoing management.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain CRITERIA FOR USE OF OPIOIDS Page(s): 60, 61, 88, 89, 76-78.

Decision rationale: Based on the 05/11/15 progress report provided by treating physician, the patient presents with low back and neck pain, lower extremity radiculopathy, and shoulder pain. The patient is status post left shoulder surgery 11/29/10, rotator cuff repair revision 08/24/12, and left carpal tunnel release 06/24/13. The request is for HYDROCODONE-

ACETAMINOPHEN 10/325MG #105. Patient's diagnosis per Request for Authorization form dated 06/11/15 includes pain in joint shoulder, status post arthroscopy, now with recurrent tear by MRI. The patient ambulates with antalgic gait assisted by cane. Treatment to date has included surgery, imaging studies, physical therapy, functional restoration program and medications. Patient's medications include Cialis, Viagra, Norco, Protonix and Naproxen Sodium. The patient is permanent and stationary, per 05/11/15 report. MTUS Guidelines pages 88 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 4As (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. MTUS p77 states, "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." MTUS p90 states, "Hydrocodone has a recommended maximum dose of 60mg/24hrs." Per 05/11/15 report, treater states the patient "does receive excellent pain relief from the use of Norco. He reports approximately 30% pain decrease, allowing him to increase his activity... no side effects with the use of his medications." Per Appeal report dated 07/16/15, treater states "Norco brings his pain down from 10/10 on VAS down to 6/10... [the patient] is able to go out and do his errands such as grocery shopping with less pain, and can carry out his daily activities more easily. It also helps with his left shoulder pain so that he can better tolerate reaching and lifting...the patient recently had his urine drug screen conducted on 03/23/15 which is positive for Hydrocodone and consistent with the prescription. There have been no signs or issues of abuse or aberrant behavior or diversion with this patient... DEA CURES report dated 07/31/14 indicates that the patient has been receiving opioids only from our office...patient signed an opioid pain contract with us on 03/23/15...The patient is currently stable on his medication as prescribed." In this case, the 4A's have been addressed, adequate documentation has been provided including numeric scales and functional measures that show significant improvement. The request appears to be in accordance with guidelines. Therefore, this request IS medically necessary.

Pantoprazole (Protonix) 20mg #60: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 69.

Decision rationale: Based on the 05/11/15 progress report provided by treating physician, the patient presents with low back and neck pain, lower extremity radiculopathy, and shoulder pain. The patient is status post left shoulder surgery 11/29/10, rotator cuff repair revision 08/24/12, and left carpal tunnel release 06/24/13. The request is for PANTOPROZOLE (PROTONIX) 20MG #60. Patient's diagnosis per Request for Authorization form dated 06/11/15 includes pain in joint shoulder, status post arthroscopy, now with recurrent tear by MRI. The patient ambulates with antalgic gait assisted by cane. Treatment to date has included surgery, imaging studies, physical therapy, functional restoration program and medications. Patient's medications

include Cialis, Viagra, Norco, Protonix and Naproxen Sodium. The patient is permanent and stationary, per 05/11/15 report. MTUS pg 69 states, "Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." "Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI." Protonix and Naproxen have been included in patient's medications, per progress reports dated 03/23/15, 05/11/15, and 07/16/15. It is not known when Protonix was initiated. Per Appeal report dated 07/16/15, treater states "Patient does report GI upset with the use of Naproxen... The concurrent use of Protonix along with oral medications prevents the GI side-effects...The patient is currently stable on his medication as prescribed." MTUS allows it for prophylactic use along with oral NSAIDs when appropriate GI risk is present. Treater has documented patient's GI risk

assessment and benefit from medication. The request to continue PPI prophylactic therapy appears reasonable. Therefore, the request IS medically necessary.

Naproxen Sodium 550mg #60: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications Page(s): 22.

Decision rationale: Based on the 05/11/15 progress report provided by treating physician, the patient presents with low back and neck pain, lower extremity radiculopathy, and shoulder pain. The patient is status post left shoulder surgery 11/29/10, rotator cuff repair revision 08/24/12, and left carpal tunnel release 06/24/13. The request is for NAPROXEN SODIUM 550MG #60. Patient's diagnosis per Request for Authorization form dated 06/11/15 includes pain in joint shoulder, status post arthroscopy, now with recurrent tear by MRI. The patient ambulates with antalgic gait assisted by cane. Treatment to date has included surgery, imaging studies, physical therapy, functional restoration program and medications. Patient's medications include Cialis, Viagra, Norco, Protonix and Naproxen Sodium. The patient is permanent and stationary, per 05/11/15 report. MTUS Chronic Pain Medical Treatment Guidelines, pg 22 for Anti-inflammatory medications states: Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in chronic LBP and of antidepressants in chronic LBP. MTUS p60 also states, "A record of pain and function with the medication should be recorded," when medications are used for chronic pain. Naproxen have been included in patient's medications, per progress reports dated 03/23/15, 05/11/15, and 07/16/15. Per Appeal report dated 07/16/15, treater states "...Chronic patients do have good days and bad days where their pain waxes and wanes. This patient utilizes Naproxen to help with these flare ups. Please note that the patient is using Naproxen for anti-inflammation and pain relief... the medication is helping him and adequately relieving his pain...The patient is currently stable on his

medication as prescribed." Given patient's continued pain and documentation of functional improvement, the request for Naproxen appears reasonable and in accordance with guidelines. Therefore, the request IS medically necessary.