

Case Number:	CM14-0009832		
Date Assigned:	02/21/2014	Date of Injury:	11/25/2008
Decision Date:	08/08/2014	UR Denial Date:	01/24/2014
Priority:	Standard	Application Received:	01/27/2014

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 Internal Medicine and Emergency Medicine and is licensed to practice in Florida. 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:

This patient is a 70 year-old with a date of injury of 11/25/08. Progress reports associated with the request for services, dated 09/05/13, 10/17/13, and 01/09/14, were mostly eligible. They identified subjective complaints of pain, weakness, and numbness in the low back. Objective findings included decreased sensation in the right calf and foot. Diagnoses were not listed. An independent typewritten evaluation on 11/25/13 listed diagnoses of lumbar disc disease with radiculopathy. Treatment has included 3 prior epidural injections, physical therapy, NSAIDs, oral and topical analgesics. A Utilization Review determination was rendered on 01/24/14 recommending non-certification of "Naproxen 550 mg quantity 60; Prilosec 20 mg quantity 50; Norco 10/325 mg quantity 180; Cyclobenzaprine 7.5 mg quantity 60; Flurbiprofen/Lidocaine cream twice a day quantity (1); Percocet 10/325 mg quantity 40; and transforaminal lumbar epidural steroid injection at L4, L5 and S1 quantity (1)".

IMR ISSUES, DECISIONS AND RATIONALES

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

NAPROXEN 550 MG QUANTITY 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI SYMPTOMS & CARDIOVASCULAR RISK Page(s): 67-73.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS and Acetaminophen Page(s): 67-73 & 12.

Decision rationale: Naproxen (Naprosyn) is a non-steroidal anti-inflammatory agent (NSAID). The Medical Treatment Utilization Schedule (MTUS) states that NSAIDs are recommended for use in osteoarthritis. It is noted that they are: "Recommended at the lowest dose for the shortest period in patients with moderate to severe pain." NSAIDs are also recommended as an option for short-term symptomatic relief on back pain. The Official Disability Guidelines (ODG) state that studies have found that NSAIDs have more side effects than acetaminophen or placebo, but less than muscle relaxants or narcotic analgesics. Another study concluded that NSAIDs should be recommended as a treatment option after acetaminophen. Since NSAIDs are recommended for the shortest period possible, there must be documented evidence of functional improvement to extend therapy beyond that. In this case, there is no documentation of the functional improvement related to naproxen and therefore no medical necessity.

PRILOSEC 20 MG QUANTITY 50: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI SYMPTOMS & CARDIOVASCULAR RISK Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 68-69.

Decision rationale: Prilosec (Omeprazole), a proton pump inhibitor, is a gastric antacid. It is sometimes used for prophylaxis against the GI side effects of NSAIDs based upon the patient's risk factors. The Medical Treatment Utilization Schedule (MTUS) notes that these risk factors include (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 NSAIDs. The use of non-selective NSAIDs without prophylaxis is considered "okay" in patients with no risk factors and no cardiovascular disease. The non-certification was based upon lack of any risk factors. However, the claimant has the risk factor of age greater than 65 years. Therefore, the medical record does document the medical necessity for Prilosec in that NSAID therapy appears to be ongoing.

NORCO 10/325 MG QUANTITY 180: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS Page(s): 89.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: Norco 10/325 is a combination drug containing acetaminophen and the opioid Hydrocodone. The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines related to on-going treatment of opioids state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid state that there should be

documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. The guidelines note that a recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or improved functional capacity (Eriksen 2006). The Chronic Pain Guidelines also state that with chronic low back pain, opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited." Additionally, "There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain (Martell - Annals, 2007)." The California MTUS Guidelines further state that opioid therapy is not recommended for the low back beyond 2 weeks. The patient appears to be on Norco in excess of 16 weeks. The Official Disability Guidelines (ODG) state: "While long-term opioid therapy may benefit some patients with severe suffering that has been refractory to other medical and psychological treatments, it is not generally effective achieving the original goals of complete pain relief and functional restoration." Therapy with Norco appears to be ongoing. The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. Therefore, the record does not demonstrate medical necessity for Norco.

CYCLOBENZAPRINE 7.5 MG QUANTITY 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines FLEXERIL Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine and Muscle Relaxants Page(s): 41-42 & 63-66.

Decision rationale: Cyclobenzaprine is an antispasmodic muscle relaxant. The Medical Treatment Utilization Schedule (MTUS) states muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations of low back pain. They note that in most low-back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also, there is no additional benefit shown in combination of NSAIDs. Likewise, the efficacy diminishes over time. The California MTUS states that Cyclobenzaprine is indicated as a short course of therapy. Limited, mixed evidence does not allow a recommendation for Cyclobenzaprine for chronic use. Though it is noted that Cyclobenzaprine is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. They further state that treatment should be brief and that addition of Cyclobenzaprine to other agents is not recommended. The Guidelines do note that Cyclobenzaprine has been shown to produce a moderate benefit in the treatment of fibromyalgia. The record does not show any evidence of fibromyalgia, and other indications for Cyclobenzaprine beyond a short course are not well supported. Likewise, it has not been prescribed in the setting of an acute exacerbation of symptoms. Therefore, based upon the Guidelines, the record does not document the further medical necessity for Cyclobenzaprine.

FLURBIPROFEN/LIDOCAINE CREAM TWICE A DAY QUANTITY (1): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS LIDOCAINE.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics.

Decision rationale: The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Flurbiprofen is an NSAID being used as a topical analgesic. The California MTUS Guidelines note that the efficacy of topical NSAIDs in clinical trials has been inconsistent and most studies are small and of short duration. Recommendations primarily relate to osteoarthritis where they have been shown to be superior to placebo during the first two weeks of treatment, but either not afterward, or with diminishing effect over another two week period. The Guidelines also state that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. They are indicated for relief of osteoarthritis pain in joints that lend themselves to treatment (ankle, elbow, foot, hand, knee, and wrist). The only FDA approved topical NSAID is Diclofenac. Lidocaine is a topical anesthetic. Lidocaine as a dermal patch has been used off-label for neuropathic pain. However, the guidelines note that no other form (creams, lotions, gels) are indicated. Further, the Guidelines note that Lidocaine showed no superiority over placebo for chronic muscle pain. Also, the FDA has issued warnings about the safety of these agents. The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, in this case, there is no documented functional improvement, or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation. Last, the strength and duration of the compound are not specified.

PERCOCET 10/325 MG QUANTITY 40: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS Page(s): 89.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: Percocet is a combination of the opioid Oxycodone and Acetaminophen. The California Medical Treatment Utilization Schedule (MTUS) Guidelines related to on-going treatment of opioids state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or

improved functional capacity (Eriksen 2006). The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. The Guidelines also state that with chronic low back pain, opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited." Additionally, "There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain (Martell - Annals, 2007)." The California MTUS Guidelines further state that opioid therapy is not recommended for the low back beyond 2 weeks. The patient has been on opioids in excess of 16 weeks. In this case, there is no description of functional improvement related to the medication, or documentation of the other elements of the pain assessment referenced above for necessity of therapy beyond 16 weeks, where the evidence is otherwise unclear. Therefore, there is no documented medical necessity for Percocet.

TRANSFORAMINAL LUMBAR EPIDURAL STEROID INJECTION AT L4 L5 AND S1 QUANTITY (1): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines EPIDURAL STEROID INJECTIONS Page(s): 46.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Epidural Steroid Injections Page(s): 46.

Decision rationale: The Medical Treatment Utilization Schedule Chronic Pain Guidelines note that epidural steroids injections (ESI) offer short-term relief from radicular pain, but do not affect impairment or need for surgery. Criteria for ESIs include radiculopathy documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing. Further, no more than one interlaminar level should be injected at one session. The Official Disability Guidelines (ODG) states that an epidural steroid injection "... offers no significant long-term benefit." Criteria include objective findings of radiculopathy corroborated by imaging studies and/or electrodiagnostic testing. They should be done using fluoroscopy. During the diagnostic phase, a maximum of one to two injections and the second block is not indicated without 30% or more improvement from the first. No more than two nerve roots should be injected using transforaminal blocks and no more than one interlaminar level during one session. If there is a documented response to the therapeutic blocks (50-70% pain relief for at least 6-8 weeks), then up to 4 blocks per region per year may be used. Current research does not support "series-of-three" injections. The claimant does not appear to have objective findings of a radiculopathy supported by imaging. Likewise, the efficacy of the previous epidural injections is not documented. Therefore, there is no documented medical necessity for an epidural steroid injection.