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| Case Number: | CM13-0056155 | | |
| Date Assigned: | 12/30/2013 | Date of Injury: | 12/27/1999 |
| Decision Date: | 03/19/2014 | UR Denial Date: | 11/13/2013 |
| Priority: | Standard | Application Received: | 11/22/2013 |

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician 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 physician 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 61 year-old with a date of injury of 12/27/99. A progress report associated with the request for services, dated 10/31/13, identified subjective complaints of severe pain due to her lack of pain medications. The note states that she takes the pain meds to be functional. Her symptoms relate to the neck, low back, and bilateral shoulders and wrists. Objective findings included tenderness along the cervical and lumbar muscles. She had an antalgic gait. Diagnoses included cervical and lumbar disc disease; bilateral impingement syndrome of the shoulders; bilateral carpal tunnel syndrome; and depression. Treatment has included trigger point injections and oral medications including an NSAID, muscle relaxant, and opioid as well as topical analgesics for at least one year. The record states that the aforementioned medications help her to do activities of daily living and household chores. A Utilization Review determination was rendered on 11/13/13 recommending non-certification of "Percocet 10/325mg #90 + 1 refill for next ofv; Protonix 20mg #60 + 1 refill for next ofv; Terocin patches #20 + 1 refill for next ofv; Flexeril 7.5mg #60 + 1 refill for next ofv; Tramadol ER 150mg #60 + 1 refill for next visit; Naproxen Sodium 550mg #60 + 1 refill for next visit; Lidopro lotion 4oz qty: 2".

IMR ISSUES, DECISIONS AND RATIONALES

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

Percocet 10/325mg #90 #1 refill for next ofv: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain; Opioids-Oxycodone Page(s): 91-94; 94.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids
Page(s): 74-83.

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 patient has been on opioids well in excess of 16 weeks. In this case, though there is description of functional improvement related to a variety of her medications, there is no 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.

Protonix 20mg #60 + 1 refill for next ofv: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain-NSAIDs, (GI) Gastrointestinal symptoms, and cardiovascular ri.

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

Decision rationale: Protonix, 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. In this case, there is no documentation of any of the above risk factors. Therefore, the medical record does not document the medical necessity for Protonix.

Terocin patches #20 + 1 refill for next ofv: 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, 115. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics

Decision rationale: Terocin is a compounded agent consisting of menthol and the active ingredients capsaicin (an irritant found in chili peppers), lidocaine (a topical anesthetic) and methylsalicylate (an anti-inflammatory). The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain section states that topical analgesics are primarily recommended when other modalities could not be tolerated or have failed. They are primarily recommended for neuropathic pain. The Guidelines for Chronic Pain state that capsaicin topical is "Recommended only as an option in patients who have not responded or are intolerant to other treatments." It is noted that there are positive randomized trials with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific low back pain, but it should be considered experimental at very high doses. The Guidelines further note that although Capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in combination with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The Official Disability Guidelines (ODG) state that neither salicylates nor capsaicin have shown efficacy in the treatment of osteoarthritis. 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 demonstrated medical necessity for capsaicin in the compound. 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 demonstrated medical necessity for Lidocaine in the compound. The Guidelines do recommend topical salicylates as being significantly better than placebo in chronic pain. However, salicylate is a non-steroidal anti-inflammatory agent. The Guidelines note that this class of topicals has not been shown to have long-term effectiveness. In osteoarthritis, salicylates are superior to placebo for the first two weeks, with diminishing effect over another two-week period. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. The only FDA approved agent, diclofenac, has not been evaluated for treatment of the spine, hip or shoulder. They are not recommended for neuropathic pain as there is no evidence to support their use. The Official Disability Guidelines (ODG) states that salicylates have not shown any significant efficacy in the treatment of osteoarthritis. The Guidelines further state: "Any compounded product that co

Flexeril 7.5mg #60 + 1 refill for next ofv: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain-Muscle relaxants for pain.

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

Decision rationale: The Chronic Pain Guidelines state that cyclobenzaprine (Flexeril) is indicated as a short course of therapy. The Medical Treatment Utilization Schedule (MTUS) states that non-sedating 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. 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 patient has been on the therapy beyond a short course (12 months) and is being used in combination with other agents. Therefore, in this case, the medical record does not document the medical necessity for cyclobenzaprine (Flexeril).

Tramadol ER 150mg #60 + 1 refill for next visit: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids-Classification-Tramadol (Ultram) Page(s): 75.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-83; 113.

Decision rationale: Tramadol (Ultram) is a centrally acting synthetic opioid analgesic. 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 patient has been on opioids well in excess of 16 weeks. The Guidelines further specifically state that Tramadol is not recommended as a first-line oral analgesic. In this case, there is limited documentation of the elements of the pain assessment referenced above needed for necessity of therapy beyond 16 weeks where the evidence is otherwise unclear; likewise, that other first-line oral analgesics have been tried and failed. Therefore, there is no documented medical necessity for Tramadol.

Naproxen Sodium 550mg #60 + 1 refill for next visit: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain-NSAIDs Page(s): 67-73.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-73.

Decision rationale: Naproxen is a non-steroidal anti-inflammatory agent (NSAID). NSAIDs have been 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." They further state that there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. NSAIDs are also recommended as an option for short-term symptomatic relief on back pain. Again, no one NSAID was superior to another. There is inconsistent evidence for the long-term treatment of neuropathic pain with NSAIDs. Precautions are listed related to side effects. The most recent progress notes states that the patient has "severe pain". The original denial of services was based upon limited indication of NSAIDs beyond the short-term. However, in this case, the patient meets other criteria for therapy including the intensity of her pain and apparent maintenance of functional improvement with this therapy. Therefore, there is documentation in the record for the medical necessity of Naproxen.

Lidopro lotion 4oz. QTY: 2: 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 Topical Analgesics Page(s): 111-113; 115. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics

Decision rationale: Lidopro is a compounded agent consisting of menthol and the active ingredients capsaicin (an irritant found in chili peppers), lidocaine (a topical anesthetic) and methylsalicylate (an anti-inflammatory). The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain section states that topical analgesics are primarily recommended when other modalities could not be tolerated or have failed. They are primarily recommended for neuropathic pain. The Guidelines for Chronic Pain state that capsaicin topical is "Recommended only as an option in patients who have not responded or are intolerant to other treatments." It is noted that there are positive randomized trials with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific low back pain, but it should be considered experimental at very high doses. The Guidelines further note that although capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in combination with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The Official Disability Guidelines (ODG) state that neither salicylates nor capsaicin have shown efficacy in the treatment of osteoarthritis. 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 demonstrated medical necessity for capsaicin in the compound. 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 demonstrated medical necessity for lidocaine as a cream in the compound. The Guidelines do recommend topical salicylates as being significantly better than placebo in chronic pain. However, salicylate is a non-steroidal anti-inflammatory agent. The Guidelines note that this class of topicals has not been shown to have long-term effectiveness. In osteoarthritis, salicylates are superior to placebo for the first two weeks, with diminishing effect over another two-week period. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. The only FDA approved agent, diclofenac, has not been evaluated for treatment of the spine, hip or shoulder. They are not recommended for neuropathic pain as there is no evidence to support their use. The Official Disability Guidelines (ODG) states that salicylates have not shown any significant efficacy in the treatment of osteoarthritis. The Guidelines further state: "Any compounded prod