

Case Number:	CM14-0051064		
Date Assigned:	06/23/2014	Date of Injury:	11/18/2004
Decision Date:	08/22/2014	UR Denial Date:	03/06/2014
Priority:	Standard	Application Received:	03/20/2014

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 Occupational Medicine, and is licensed to practice in California. 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 claimant injured her low back on 11/18/04. She has chronic pain. Her medications are under review. The prescription for Exalgo, gabapentin, and Norco were modified to one prescription each. Dilaudid and Celebrex were not certified. The dates are 02/06/14 through 05/02/14. Doctor stated these medications work for her and she is able to care for herself at home. She appears depressed as a consequence of her chronic pain and a psychiatric consultation was recommended. Surgery was also being recommended. She stated on 09/27/12 that the fentanyl patch was not doing much. She did feel that the Dilaudid that she used for breakthrough pain seemed to work well. It was 9/10 for pain relief. She wanted to wean off the patches. She did try to decrease from 150 g to 125 g a day but she got withdrawal symptoms. She was on sertraline and her mood was fair. Her pain was averaging 5/10 and ranged from 4-10/10. She was using fentanyl, Dilaudid, Norco, ibuprofen, sertraline, Relpax, and gabapentin. She was in no obvious distress but moved slowly. She appeared uncomfortable during transitions. She had tenderness and intact sensation. Straight leg raise was positive bilaterally at 20. Exalgo was recommended. It would be in place of the patch. She was to stay on the other medications. On 11/01/12, she had back pain radiating down her left leg. She had a selective nerve root block in 2009 that helped by 70%. She was to remain on Dilaudid and Norco for pain. Her pain level was 9. Weaning off the fentanyl was planned along with a selective nerve root block. She underwent an epidural steroid injection on 12/12/12. On 01/31/13, she was evaluated by nurse practitioner [REDACTED] and said the Exalgo had just been approved. She had the same pain. MRI had shown disc degeneration at 2 levels. She continued to show improvement after the selective nerve block and a repeat was recommended. She was still using Dilaudid, Norco, gabapentin, ibuprofen, and Relpax. On 02/21/13, she reported finding the Exalgo very effective for pain relief and was taking three 16 mg tablets daily. She was using Dilaudid more than four

16 mg [sic] milligram tablets. Her selective nerve root block was working about 70% for leg pain. She could do more things around the house with the Exalgo. She was doing home exercises. Exalgo was continued and a functional restoration program was recommended. Ibuprofen was discontinued and she was given a trial of Celebrex. On 03/14/13, she continued to feel that the Exalgo was working well. She was still taking between 4-6 Dilaudid 4 mg tablets per day and Norco for pain control. She underwent an epidural steroid injection on 04/03/13. She noticed increased pain after the injection with radiation down the leg and this was reported on 04/18/13. On 08/08/13, she reported having a functional capacity evaluation the day before. Retraining was her goal. She was still using Norco and Dilaudid for pain and hoped to decrease the amount. Her medications were the same. There is no mention of Exalgo. Scoliosis x-rays were done on that date. The FCE report dated 10/18/13 indicated that she would require modification of her job. On 11/14/13, she still had daily pain averaging 6/10. She remained on Dilaudid. Exalgo was then mentioned in the list. She was started back on it that day. Weaning had not been successful. On 12/12/13, the report states that the Exalgo was not approved. She was taking Dilaudid almost 7 every day including a Norco. On 01/02/14, she was able to pick up the Exalgo on 12/20. She took 2 per day but got sedated so she decreased it to 1 in the morning but she still needed Dilaudid during the day. Her mood was more depressed due to her pain. She had done several visits of cognitive behavior therapy. On 01/29/14, she underwent another epidural steroid injection. On 02/19/14, she reported some worsening pain. This injection hurt more than the others.

IMR ISSUES, DECISIONS AND RATIONALES

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

Unknown prescription of Exalgo: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Formulary: Exalgo.

Decision rationale: The ODG Formulary states Exalgo (hydromorphone) is a once-a-day extended release opioid formulation for the management of moderate to severe pain in opioid-tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time, with an FDA black box warning, and is not recommended as a first line drug. The MTUS outlines several components of initiating and continuing opioid treatment and states a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals. In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or nonsteroidal anti-inflammatory drugs. MTUS further explains, 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.

There is also no indication that periodic monitoring of the claimant's pattern of use and a response to this medication, including assessment of pain relief and functional benefit, has been or will be done. Additionally, the 4A's analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors should be followed and documented per the guidelines. There is no evidence that a signed pain agreement is on file at the provider's office and no evidence that a pain diary has been recommended. Also, there is no evidence that urine drug screens have been monitored periodically and compared to her reported prescriptions and patterns of use. The request is not medically necessary.

1 prescription of Dilaudid 4mg #180: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Pain Page(s): 110.

Decision rationale: The MTUS outlines several components of initiating and continuing opioid treatment and states a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals. In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or nonsteroidal anti-inflammatory drugs. MTUS further explains, 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. The 4A's analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors should be followed and documented per the guidelines. Because she takes a number of medications, it is difficult to assess the specific benefit to her of the use of this medication. There is no evidence that a signed pain agreement is on file at the provider's office and no evidence that a pain diary has been recommended. As such, the medical necessity of the ongoing use of Dilaudid is not medically necessary.

Unknown prescription of Gabapentin: Upheld

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

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

Decision rationale: The history and documentation do not objectively support the request for ongoing use of gabapentin if the recommended prescription is unknown. The MTUS support gabapentin as a first line drug for neuropathic pain and state gabapentin is an anti-epilepsy drug (AEDs - also referred to as anti-convulsants), which has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. However, in this case, it is unclear what objective evidence of

benefit, including improved functionality, the claimant has been receiving from it since her pain levels have remained significantly elevated despite multiple medications. Additionally, MTUS and ODG state relief of pain with the use of medications is generally temporary and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain, the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication to be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medication should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within one week. A record of pain and function with the medication should be recorded. (Mens 2005) Additionally, the medical records provided do not provide objective findings of improvement in physical examination findings based on the use of this medication. As such, this request for gabapentin, unknown prescription, is not medically necessary.

Unknown prescription of Norco: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Pain Page(s): 110.

Decision rationale: The history and documentation do not objectively support the request for the opioid, Norco, prescription unknown. The MTUS outlines several components of initiating and continuing opioid treatment and states a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals. In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or nonsteroidal anti-inflammatory drugs. The claimant has been given ibuprofen and then Celebrex with no description of benefit or lack thereof. MTUS further explains, 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. There is also no indication that periodic monitoring of the claimant's pattern of use and a response to this medication, including assessment of pain relief and functional benefit, has been or will be done. Additionally, the 4A's analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors should be followed and documented per the guidelines. The claimant's pattern of use of Norco is unclear other than she takes it prn. There is no evidence that a signed pain agreement is on file at the provider's office and no evidence that a pain diary has been recommended. As such, the request for Norco is not medically necessary.

Unknown prescription of Celebrex: Upheld

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 NSAIDs Page(s): p. 102.

Decision rationale: The history and documentation do not objectively support the request for Celebrex for the claimant's ongoing pain. The CA MTUS p. 102 state re: Back Pain -Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008). Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. (Namaka, 2004) (Gore, 2006) Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006). In this case, there is no documentation of side effects or lack of benefit from ibuprofen that she was taking. The MTUS and ODG state relief of pain with the use of medications is generally temporary and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain, the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication to be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medication should show effects within 1 to 3 days. A record of pain and function with the medication should be recorded. (Mens 2005) In this case, the claimant's pattern of use of medications, including other first-line drugs such as acetaminophen and anti-inflammatories and the response to them, including relief of symptoms and documentation of functional improvement, have not been described. In addition, the actual prescription is unknown. As such the request for Celebrex is not medically necessary.