

Case Number:	CM14-0036881		
Date Assigned:	06/25/2014	Date of Injury:	06/28/2003
Decision Date:	07/25/2014	UR Denial Date:	02/26/2014
Priority:	Standard	Application Received:	03/26/2014

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 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 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:

The claimant was injured on 06/28/03. Her medications, blinded pain cocktail, Lyrica, Zanaflex, Ambien, and Amitiza are under review. She saw [REDACTED] on 09/11/13 and stated her pain was controlled at 4-5/10 with Opana ER, Lyrica, and Norco. She was able to do her ADLs. Her spasms were better with baclofen. She wanted to delay beginning [REDACTED]. She had decreased range of motion and tenderness of her cervical spine. Her upper extremity range of motion was functional. Her strength was 4/5. She was prescribed Opana ER, Lyrica, Norco, baclofen, and Lunesta. She was on Opana ER prior to that also. On 12/17/13, she reported she had completed [REDACTED] and was currently on blinded cocktail for pain control. Her pain level was 8/10 with current medications. She could walk 2 blocks 3 times a day and stand or sit for 30 minutes. She had increased overall activity since completing [REDACTED]. She was still using medications to control pain. She used Lunesta for sleep. She was to continue the blinded pain cocktail but the dose is not clear. On 01/22/14, she saw [REDACTED] and she was doing well with the pain cocktail, Lyrica, and baclofen for pain control. She had pain at level 9/10 without and 2/10 with current medications. She was able to walk 3 blocks 3 times per day. She could stand or sit 45 minutes and lift less than 10 pounds. She had increased motivation since [REDACTED]. Lyrica was helpful for neuropathic pain, baclofen controlled her spasms, and she had not been able to sleep since the Lunesta was not approved. She reported constipation as a side effect of her medications. She was alert and smiling and oriented. Neck range of motion was limited in all directions. She had no tenderness to palpation. She had tight muscles in her shoulders. Again her upper extremity strength was 4/5. The pain medication was decreased including blinded pain cocktail from M8 to M6 and she was prescribed Lyrica and baclofen and Ambien instead of Lunesta. She was given Senokot. On 02/06/14, Ambien, Lyrica, baclofen, and

Senokot were denied. There is mention of a blinded pain cocktail-methadone. On 03/05/14, she was seen again and her pain was the same. She stated Lyrica helped the neuropathic pain, she was not sure she was taking Zanaflex for spasms. She was using Ambien. She had severe constipation that improved with Amitiza. Pristiq improved her mood. She could use a computer for 30 minutes and complete simple household tasks and her ADLs. Physical examination was unchanged. She had tight muscles and decreased range of motion. The blinded pain cocktail was decreased from M7 to M6. She was seen by [REDACTED] on 02/19/14. She had pain and stated Lyrica was beneficial for neuropathic pain. Baclofen did not help spasms. Ambien was helpful for sleep but not as effective as Lunesta. Her constipation was improved with Amitiza. Pristiq had improved her mood. She was more active. She was awake, alert, and smiling. She had limited range of motion of her neck in all directions. There was no tenderness over the cervical spinous processes. There were tight muscles in the shoulders and her extremity range of motion was functional. Strength in the upper extremities was 4/5 bilaterally and there were no other physical examination findings listed. Her diagnoses include nonspecific myalgia and myositis, cervicgia, and cervical postlaminectomy syndrome. Treatment measures were to increase the blinded pain cocktail from M6 to M7, Lyrica 150 mg #90, Zanaflex 4 mg #90, Ambien 10 mg #30, and Amitiza 24 g #60. The contents of the blinded pain cocktail are unknown.

IMR ISSUES, DECISIONS AND RATIONALES

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

Increase blinded pain cocktail (M6 to M7): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Use, page 102; methadone, page 95 Page(s): 102; 95.

Decision rationale: The history and documentation do not objectively support the request for an increase of the blinded pain cocktail from M6 to M7. The contents of the pain cocktail are not stated, including whether or not it contains opioids. There is a brief mention of methadone but again the contents are unknown. Of note, assuming that the cocktail contains opioids/methadone, 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." Regarding the use of methadone, if it is contained in this pain cocktail, the MTUS states, "methadone [may be] recommended as a second-line drug for moderate to severe pain if the potential benefit outweighs the risk. The FDA reports that they have received reports of severe morbidity and mortality with this medication. This appears, in part, secondary to the long half-life of the drug (8-59 hours). Pain relief, on the other hand, only lasts from 4-8 hours. Methadone should only be prescribed by providers experienced in using it." 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 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 injured worker'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 according to the guidelines. The injured worker's pattern of use of this pain cocktail is unclear other than the injured worker reporting taking it. 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. It is not clear, other than walking, that the injured worker has been involved in an ongoing exercise program for the cervical spine and shoulder region. As such, the medical necessity of an increase in this blinded pain cocktail has not been clearly demonstrated.

Lyrica 150mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anti-epilepsy drugs for pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines : Pregabalin, page 131; Anti-epilepsy drugs, page 46 Page(s): 131; 46.

Decision rationale: The history and documentation do not objectively support the request for the medication, Lyrica. The MTUS guidelines indicate "pregabalin (Lyrica) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered a first-line treatment for both. Pregabalin was also approved to treat fibromyalgia." None of these diagnoses have been described. Also, the MTUS indicates 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." A record of pain and function with the medication should be recorded. The medical documentation provided does not establish the need for long-term/chronic usage of Lyrica based solely on findings of decreased range of motion and tenderness. The medical records provided do not provide objective findings of a chronic neuropathic condition or symptoms/findings. In this case, the injured worker's pattern of use of this medication and trials of other first-line drugs such as acetaminophen and anti-inflammatories and the response to them, including relief of symptoms and documentation of functional improvement, or lack thereof, have not been documented. It is not clear, other than walking, that the injured worker has been involved in an ongoing exercise program for the cervical spine and shoulder region. As such, this request for Lyrica 150 mg #90 is not medically necessary.

Zanaflex 4mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants Page(s): 97.

Decision rationale: The history and documentation do not objectively support the request for the medication, Zanaflex. Regarding muscle relaxants (for pain), the MTUS guidelines "recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement." There is no evidence of significant spasm or relief of significant spasm based on the use of this medication. Also, MTUS guidelines indicate that 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." A record of pain and function with the medication should be recorded. The medical documentation provided does not establish the need for long-term/chronic usage of a muscle relaxant based solely on findings of decreased range of motion and tenderness. The medical records provided do not provide objective findings of a chronic spastic condition or symptoms/findings. In this case, the injured worker's pattern of use of this medication and trials of other first-line drugs such as acetaminophen and anti-inflammatories and the response to them, including relief of symptoms and documentation of functional improvement, or lack thereof, have not been documented. It is not clear, other than walking, that the injured worker has been involved in an ongoing exercise program for the cervical spine and shoulder region. As such, this request for Zanaflex 4mg #90 is not medically necessary.

Ambien 10mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, zolpidem/ambien.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines : Antidepressants page 43, antineuropathic medications page 48, cyclobenzaprine for fibromyalgia page 74 Page(s): 43, 48, 74.

Decision rationale: The history and documentation do not objectively support the request for continued use of Ambien 10 mg. The MTUS guidelines indicate that sleep is important to recovery and some medications such as antidepressants, antineuropathic, and muscle relaxant medications may be considered to help with sleep. The ODG indicates, regarding Ambien (zolpidem), "zolpidem is a prescription short-acting non-benzodiazepine hypnotic, which is approved for the short-term (usually two to six weeks) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various

medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term." Trials of medications should include the following: (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. In addition, good sleep hygiene efforts should be included in the treatment and monitoring plan. Sleep medications may be recommended only for short periods of time in conjunction with other efforts to improve sleep patterns. There is no evidence of a full evaluation of the injured worker's sleep complaints, instruction or monitoring of sleep hygiene, or documentation of patterns of use of Ambien along with evidence of functional benefit/improvement. The medical necessity of the continued use of Ambien 10mg has not been clearly demonstrated.

Amitiza 24mcg #60: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: PDR, 2014, Amitiza.

Decision rationale: The history and documentation do not objectively support the request for Amitiza. The medical necessity of Amitiza has not been clearly demonstrated. The PDR recommends Amitiza for chronic idiopathic constipation and for constipation due to the chronic use of opioids/methadone. Before prescribing any medication for a chronic condition, 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. A record of symptom relief and functional benefit from the medication should be recorded." The medical documentation provided does not establish the need for long-term/chronic usage of Amitiza, especially if the opioids are weaned. In this case, the injured worker's pattern of use of this medication and trials of bowel hygiene, dietary adjustment, etc. have not been described. As such, this request for Amitiza 24 mcg #60 is not medically necessary.