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| Case Number: | CM13-0030167 | | |
| Date Assigned: | 03/03/2014 | Date of Injury: | 08/21/2007 |
| Decision Date: | 04/23/2014 | UR Denial Date: | 09/19/2013 |
| Priority: | Standard | Application Received: | 09/26/2013 |

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 Family Practice, 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:

This 56 yr. old female claimant sustained an injury on 8/21/07 involving the hips, back, wrists and shoulders. She underwent a L4-L5 decompressive laminectomy , carpal tunnel release and , left and right hip acetabuloplasty and femoralplasty. Her chronic pain had been managed with Norco, Tramadol, Lyrica ,and Zanaflex. She had been on Colace for several months dating back until at least March 2013. An evaluation note on 8/9/13 stated that the claimant had no side effects of medications. After a thorough examination, the claimant had a continued diagnosis of lumbar laminectomy syndrome and hip pain. The following medication regimen was continued: Colace, Zanaflex, Lyrica, Cymbalta, Lunesta and Ultram. A request had been made on 9/6/13 for continuation of Colace 100 mg #60 with 5 refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

PRESCRIPTION OF COLACE 100MG #60 WITH 5 REFILLS: Overturned

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 Opioids Page(s): 75-92.

Decision rationale: According to the MTUS guidelines, prophylactic treatment for constipation should be initiated when initiating Opioids. According to the ODG guidelines, prophylaxis for constipation is recommended if prescribing opioids has been determined to be appropriate. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. In first-line treatment, the guidelines indicate that when prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. In this case, the employee had been on long-term opioids such as Ultram and Norco. Colace is available in over the counter formulation. Based on the guidelines, prophylactic use of Colace along with opioids is medically necessary.

Ultram 50mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol Page(s): 93-94.

Decision rationale: According to the MTUS guidelines opioid analgesics and Tramadol have been suggested as a second-line treatment (alone or in combination with first-line drugs). A recent consensus guideline stated that opioids could be considered first-line therapy for the following circumstances: (1) prompt pain relief while titrating a first-line drug; (2) treatment of episodic exacerbations of severe pain; [&] (3) treatment of neuropathic cancer pain. Tramadol is a synthetic opioid affecting the central nervous system. The immediate release formulation is recommended at a dose of 50 to 100mg by mouth every 4 to 6 hours (not to exceed 400mg/day). This dose is recommended after titrating patients up from 100mg/day, with dosing being increased every 3 days as tolerated. For patients in need of immediate pain relief, which outweighs the risk of non-tolerability, the initial starting dose, may be 50mg to 100mg every 4 to 6 hours (max 400mg/day). Regarding Ultram ER®: the patient currently not on immediate release tramadol should be started at a dose of 100mg once daily. The dose should be titrated upwards by 100mg increments if needed (maximum dose 300mg/day). Patients currently on immediate release tramadol, calculate the 24-hour dose of IR and initiate a total daily dose of ER rounded to the next lowest 100mg increment (maximum dose 300mg/day). Ultram is not recommended as a first-line therapy for osteoarthritis. Short-term use: Tramadol is recommended on a trial basis for short-term use after there has been evidence of failure of first-line non-pharmacologic and medication options (such as acetaminophen or NSAIDs) and when there is evidence of moderate to severe pain. It is also recommended for a trial if there is evidence of contraindications for use of first-line medications. Weak opioids should

be considered at initiation of treatment with this class of drugs (such as Tramadol, Tramadol/acetaminophen, hydrocodone and codeine), and stronger opioids are only recommended for treatment of severe pain under exceptional circumstances (oxycodone, oxycodone, hydromorphone, fentanyl, morphine sulfate). Benefits of opioids are limited by frequent side effects (including nausea, constipation, dizziness, somnolence and vomiting). Long-term use: Tramadol is under study for long-term use as there are no long-term trials. There is therefore a lack of evidence to allow for a treatment recommendation. If used on a long-term basis, the criteria for use of opioids should be followed. In this case, the employee had used Tramadol for the long term. There is a lack of evidence to support continued use without evidence of failure of first-line therapies. Its continued use is not medically necessary.

neuropathy or postherpetic neuralgia. Morphine was the least effective treatment (reducing leg and back pain by 1-7% compared to placebo). Sample size and drop out rate was a limitation. (Khoromi, 2007) . Not recommended as a first-line therapy for osteoarthritis. Short-term use: Recommended on a trial basis for short-term use after there has been evidence of failure of first-line non-pharmacologic and medication options (such as acetaminophen or NSAIDs) and when there is evidence of moderate to severe pain. Also recommended for a trial if there is evidence of contraindications for use of first-line medications. Weak opioids should be considered at initiation of treatment with this class of drugs (such as Tramadol, Tramadol/acetaminophen, hydrocodone and codeine), and stronger opioids are only recommended for treatment of severe pain under exceptional circumstances (oxymorphone, oxycodone, hydromorphone, fentanyl, morphine sulfate). Benefits of opioids are limited by frequent side effects (including nausea, constipation, dizziness, somnolence and vomiting). (Stitik, 2006) (Avouac, 2007) (Zhang, 2008) Long-term use: Under study for long-term use as there are no long-term trials. There is therefore a lack of evidence to allow for a treatment recommendation. If used on a long-term basis, th