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| Case Number: | CM15-0011327 | | |
| Date Assigned: | 01/28/2015 | Date of Injury: | 06/18/1989 |
| Decision Date: | 03/27/2015 | UR Denial Date: | 12/24/2014 |
| Priority: | Standard | Application Received: | 01/20/2015 |

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: New York

Certification(s)/Specialty: Anesthesiology

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 injured worker is a 51 year old female, who sustained an industrial injury on 06/18/1989. She reported slipping while walking and tried to catch herself and subsequently fell wrenching her back. Diagnoses include cervical radiculopathy, post lumbar laminectomy syndrome, and radiculopathy. Treatment to date has included medication regimen, magnetic resonance imaging of the lumbar, thoracic, and cervical spine, urine toxicology, multiple radiofrequency medial branch neurotomies at lumbar two to three and lumbar five, status post instrumented interbody fusion of lumbar four to five, epidural blocks, and use of a gym . In a progress note dated 12/15/2014 the injured worker reports a pain level of six on a scale of one to ten with pain medication and a nine out of ten without pain medication to the back and leg along with a poor quality of sleep. The treating physician requested the below listed medications, with the medical records noting the injured worker to have been on the medications of Celebrex, Bethanechol, and Morphine Sulfate IR for treatment of symptoms and Relpax specifically for headaches. The documentation did not indicate the specific reasons for Zanaflex, Kadian, and MiraLax. On 12/24/2014 Utilization Review non-certified the requested treatments for Zanaflex 4mg capsules with a quantity of 30, Morphine Sulfate IR 30mg tablets with a quantity of 300, Kadian 60mg capsules 24 hour for a quantity of 180, Celebrex 100mg capsules with a quantity of 60, Relpax 40mg tablets with a quantity of 9, and Bethanechol with a quantity of 60 and modified the requested medication MiraLax 17gram/dose powder with a quantity of 5 with 5 refills to MiraLax 17gram/dose powder with a quantity of 5 for 0 refills, noting the California Medical Treatment Utilization Schedule, Chronic Pain Medical Treatment Guidelines; American College

of Occupational and Environmental Medicine Practice Guidelines, 2nd Edition (2004); National Library of Medicine; and the Official Disability Guidelines, Pain Chapter.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zanaflex 4mg #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CA MTUS, Muscle relaxants Page(s): 63, 66.

Decision rationale: Zanaflex (Tizanidine) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. It is indicated for the treatment of chronic myofascial pain and considered an adjunct treatment for fibromyalgia. According to CA MTUS Guidelines (2009), muscle relaxants have not been considered any more effective than non-steroidal antiinflammatory drugs (NSAIDs) for pain or overall improvement. There is also no additional benefit shown in combination with NSAIDs. In addition, sedation is the most commonly reported adverse effect of muscle relaxant medications. In this case, this medication is not recommended long-term for the treatment of musculoskeletal pain. Medical necessity of the requested item has not been established. The requested medication is not medically necessary.

Morphine Sulfate IR 30mg #300: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CA MTUS (2009), Opioids Page(s): 91-97. Decision based on Non-MTUS Citation Opioids

Decision rationale: According to ODG, chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs. When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added. According to ODG and MTUS, Morphine Sulfate IR is an opioid analgesic, and is in a class of drugs that has a primary indication to relieve symptoms related to pain. Opioid drugs are available in various dosage forms and strengths. They are considered the most powerful class of analgesics that may be used to manage both acute and chronic pain. These medications are generally classified according to potency and duration of dosage duration. The treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. In this case, there is no documentation of the medication's pain relief effectiveness, functional status, or response to ongoing opioid

analgesic therapy. Medical necessity of the opioid analgesic has not been established. The requested medication is not medically necessary.

Kadian 60mg #180: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CA MTUS (2009), Opioids Page(s): 91-97. Decision based on Non-MTUS Citation Opioids

Decision rationale: According to ODG, chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs. When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added. According to ODG and MTUS, Kadian (Morphine Sulfate ER) is an opioid analgesic, and is in a class of drugs that has a primary indication to relieve symptoms related to pain. Opioid drugs are available in various dosage forms and strengths. They are considered the most powerful class of analgesics that may be used to manage both acute and chronic pain. These medications are generally classified according to potency and duration of dosage duration. The treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. In this case, there is no documentation of the medication's pain relief effectiveness, functional status, or response to ongoing opioid analgesic therapy. Medical necessity of the opioid analgesic has not been established. The requested medication is not medically necessary.

MiraLax 17 gram/dose powder # 5 5 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Library of Medicine: Polyethylene glycol 3350 Official Disability Guidelines

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medscape Internal Medicine (2014), Miralax

Decision rationale: Miralax is in a class of medicines called osmotic laxatives. It works by causing water to be retained in the stool. This softens the stool and increases the number of bowel movements. Opioid-induced constipation is a common adverse effect of long-term opioid use because of the binding of opioids to peripheral opioid receptors in the gastrointestinal tract, resulting in absorption of electrolytes and reduction in small intestine fluid. According to ODG, if opioids are determined to be appropriate for the treatment of pain then prophylactic treatment of constipation should be initiated. In this case, with non-approval of opioid use, the medical necessity of Miralax is not established. The requested medication is not medically necessary.

Celebrex 100mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CA MTUS (2009) Page(s): 30. Decision based on Non-MTUS Citation Anti-inflammatory Medications

Decision rationale: Celebrex is the brand-name for celecoxib. Celecoxib is a nonsteroidal anti-inflammatory drug (NSAID) that is a COX-2 selective inhibitor, a drug that directly targets COX-2, an enzyme responsible for inflammation and pain. Unlike other NSAIDs, celecoxib does not appear to interfere with the antiplatelet activity of aspirin and is bleeding neutral when patients are being considered for surgical intervention or interventional pain procedures. Celebrex may be considered if the patient has a risk of GI complications, but not for the majority of patients. Generic NSAIDs and COX-2 inhibitors have similar efficacy and risks when used for less than 3 months. In this case, there is no documentation indicating that the patient cannot tolerate NSAIDs. In this case, medical necessity of the requested medication has not been established. The requested medication is not medically necessary.

Relpax 40mg #9: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medscape Internal Medicine (2014)

Decision rationale: Relpax (Eletriptan) is a second-generation triptan drug used for the treatment of migraine headaches. It is used as an abortive migraine medication, blocking a migraine attack already in progress. In this case, there is no documentation indicating the patient has a diagnosis of migraine headaches. Medical necessity for the requested medication has not been established. The requested medication is not medically necessary.

Bethanechol #60: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medscape Internal Medicine (2014)

Decision rationale: Bethanechol is a parasympathomimetic choline carbamate that selectively stimulates muscarinic receptors without any effect on nicotinic receptors. The medication is used in the treatment of neurogenic bladder and to treat urinary retention resulting from general anesthesia. It is also used for the treatment of diabetic neuropathy of the bladder, for side effects of antidepressants and to treat gastrointestinal atony. Bethanechol should be used to treat these

disorders only after mechanical obstruction is ruled out as a possible cause. In this case, there has not been a neurological consult or urodynamic study to support the potential etiology of urinary dysfunction to support the use of this medication. Medical necessity for Bethanechol has not been established. The requested medication is not medically necessary.