MAXIMUS Federal Services

Case Number:	CM15-0138112		
Date Assigned:	07/28/2015	Date of Injury:	07/23/2004
Decision Date:	10/09/2015	UR Denial Date:	06/19/2015
Priority:	Standard	Application Received:	07/16/2015

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: Maryland, Texas, Virginia
Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

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 59-year-old male, who sustained an industrial injury on 7/23/2004. Diagnoses have included lumbar disc displacement without myelopathy and lumbar facet syndrome. Treatment to date has included lumbar epidural steroid injection, lumbar radiofrequency ablation, trigger point injections and medication. According to the progress report dated 6/10/2015, the injured worker complained of low back pain. The injured worker was noted to be very angry and demanding in demeanor. He requested Viagra due to sexual dysfunction. Objective findings revealed and antalgic gait. The injured worker used a cane. He had profound, reproducible axial back pain and buttocks pain with extension and rotation of the lumbar spine. Sensation was decreased in the left L3 dermatome. Spasm and guarding were noted in the lumbar spine. It was noted that Hysingla ER was discontinued due to ineffectiveness. He was to be prescribed Morphine. Authorization was requested for Docusate (DSS), Hysingla ER, Miralax powder packet, Viagra, Zolpidem-Ambien, Ketamine cream and Orphenadrine-Norflex ER.

IMR ISSUES, DECISIONS AND RATIONALES

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

DSS 250MG #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Opioid-induced constipation treatment and Other Medical Treatment Guidelines UpToDate.com, docusate and senna.

Decision rationale: Docusate and sennoside are stool softeners and laxatives, respectively. This patient is undergoing treatment with hydrocodone, which is an opioid. The length of time this patient has been on methadone is unknown. Opioids can commonly cause constipation and treatment to prevent constipation is recommended. ODG states that first line treatment should include "physical activity, appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber" and "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". Up-to-date states "Patients who respond poorly to fiber, or who do not tolerate it, may require laxatives other than bulk forming agents". Additionally, There is little evidence to support the use of surfactant agents in chronic constipation. Stool softeners such as docusate sodium (e.g., Colace) are intended to lower the surface tension of stool, thereby allowing water to more easily enter the stool. Although these agents have few side effects, they are less effective than other laxatives. The medical records fail to demonstrate that the patient has failed first line constipation treatments and did not indicate if fiber treatment was initiated. Additionally, no quantitative or qualitative description of bowel movement frequency/difficulty was provided either pre or post "constipation treatment education" by the physician, which is important to understand if first line constipation treatment was successful. As such, the request for DSS 250 mg #60 is not medically necessary at this time.

Hysingla ER 60mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids, specific drug list. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic), Shoulder, Pain, Opioids.

Decision rationale: ODG does not recommend the use of opioids for low back pain "except for short use for severe cases, not to exceed 2 weeks". The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "ongoing review and documentation of pain relief, functional status, appropriate medication 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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life". The treating physician does not fully document the least

reported pain over the period since last assessment, pain relief, increased level of function, or improved quality of life. Additionally, medical documents indicate that the patient has been on an opioid in excess of the recommended 2-week limit. The treating physician does not detail sufficient information to substantiate the need for continued opioid medication. Given the duration of use, the need for tapering and weaning is necessary. As such, the question for Hysingla ER 60mg #30 is not medically necessary.

Miralax powder packet 17gr #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Opioid-induced constipation treatment.

Decision rationale: Miralax is a Polyethylene glycol (PEG) osmotic laxative agent. This patient is undergoing treatment with opioids for chronic pain. The length of time this patient has been on opioid is unclear from the records, but appears to be undergoing treatment for chronic pain for several years. Opioids can commonly cause constipation and treatment to prevent constipation is recommended. ODG states that first line treatment should include "physical activity, appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber" and "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". Up-to-date recommends "other laxatives", such as sennosides (which the patient is taking), for patients who response poorly to fiber, or who do not tolerate it. The treating physician did document constipation side effects of opioid usage, but does not document attempt of the first line treatment mentioned above and the results of those treatments. Additionally, no quantitative or qualitative description of bowel movement frequency/difficulty was provided either pre or post "constipation treatment education" by the physician, which is important to understand if first line constipation treatment was successful. As such, the request for Miralax powder packet 17gr #30 is not medically necessary at this time.

Viagra 25mg #40: 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.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Epocrates, https://online.epocrates.com, Viagra.

Decision rationale: The MTUS and ODG as silent on the use of Viagra, or sildenafil. Other guidelines were used. According to epocrates, Viagra is utilized for the treatment of erectile dysfunction. The patient has not been diagnosed with erectile dysfunction. The medical records state that his sexual dysfunction is secondary to pain. As such, the request for Viagra is not medically necessary.

Zolpidem-ambien 5mg #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.

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

Decision rationale: The CA MTUS silent regarding this topic. ODG states that zolpidem is a prescription short acting non-benzodiazepine hypnotic, which is approved for short-term treatment of insomnia. In this case, the patient has been taking this medication for at least 6 months. There has been no discussion of the patient's sleep hygiene or the need for variance from the guidelines, such as "(a) Wake at the same time everyday; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping."Medical documents also do not include results of these first line treatments, if they were used in treatment of the patient's insomnia. ODG additionally states "The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning." Medical documents provided do not detail these components. As such, the request for Zolpidem-ambien 5mg #30 is not medically necessary at this time.

Ketamine 5% cream 60gr #2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams.

Decision rationale: TUS and ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of anti-depressants or anti-convulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Ketamine (Last Resort Topical) MTUS states regarding topical Ketamine, "Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted." Medical records do not indicate that all primary and secondary treatment options have been exhausted. There is no documentation of improvement in symptoms while taking this medication. As such, the request for Ketamine 5% cream 60gm #2 is not medically necessary.

Orphenadrine-Norfles ER 100mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: Norflex is classified as a muscle relaxant. MTUS states, "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." ODG recommends limited muscle relaxant usage to 2 weeks in duration. Additionally, MTUS states "Orphenadrine (Norflex, Banflex, Antiflex, Mio-Rel, Orphenate, generic available): This drug is similar to diphenhydramine, but has greater anticholinergic effects. The mode of action is not clearly understood. Effects are thought to be secondary to analgesic and anticholinergic properties. This drug was approved by the FDA in 1959. Side Effects: Anticholinergic effects (drowsiness, urinary retention, dry mouth). Side effects may limit use in the elderly. This medication has been reported in case studies to be abused for euphoria and to have mood-elevating effects. (Shariatmadari, 1975) Dosing: 100 mg twice a day; combination products are given three to four times a day. (See, 2008)." MTUS guidelines recommend against the long-term use of muscle relaxants. The patient has been on this muscle relaxant for at least 6 months. Guidelines recommend against long-term muscle relaxant usage. The treating physician has not detailed how NSAIDs is inferior to Norflex, per MTUS guidelines. As written, the prescription is still in excess of the recommended 2-week limit. The medical documents do not indicate extenuating circumstances to allow for exceptions to the guidelines. As such, the request for 1 Prescription for Orphenadrine-Norflex ER 100mg #90 is not medically necessary.