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| Case Number: | CM14-0218854 | | |
| Date Assigned: | 01/08/2015 | Date of Injury: | 08/07/2014 |
| Decision Date: | 03/11/2015 | UR Denial Date: | 12/20/2014 |
| Priority: | Standard | Application Received: | 12/30/2014 |

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. 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: Indiana

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 43-year-old male, who sustained an industrial injury on 8/7/2014. He has reported bilateral shoulder pain and stiffness of the neck, and upper and lower back pain. The diagnoses have included sub-acute traumatic moderate repetitive cervical spine sprain/strain, neck pain, sub-acute traumatic moderate repetitive thoracic spine sprain/strain; rule out herniated disc, upper back pain, sub-acute traumatic moderate repetitive lumbar spine sprain/strain; rule out herniated disc, lower back pain, sub-acute traumatic moderate repetitive bilateral shoulder sprain/strain; rule out ligamentous injury, anxiety/depression/stress with associated mood swings and irritability and nightly sleep disturbances. Treatment to date has included medications and physical therapy. Magnetic resonance imaging (MRI) of the cervical spine from 8/15/2014 revealed cervical spondylosis, mild central canal stenosis and moderate foraminal stenosis. Magnetic resonance imaging (MRI) of the right shoulder from 9/19/2014 revealed mild-moderate AC joint osteoarthritis. Per the PR2 from 11/10/2014, the injured worker complained of neck pain and shoulder pain. Treatment plan included Naproxen, Prevacid, Flextor patches and Flurbiprofen. Per the PR2 from 12/8/2014, the injured worker complained of neck pain 6-7/10, right shoulder pain 7-8/10, left shoulder pain 5/10, upper back pain 5/10, lower back pain 3-4/10 and nightly sleep disturbances. Physical exam revealed slight to moderate tenderness over the cervical spine, thoracic spine and lumbar spine with decreased range of motion. There was slight to moderate tenderness with palpation of the shoulders. Work status was temporarily totally disabled. On 12/20/2014, Utilization Review (UR) modified a request for Naproxen 550mg # 60 with 3 refills to Naproxen 550mg #60 with 0 refills, noting that the

guidelines may recommend a short course of nonsteroidal anti-inflammatory drugs in the treatment of pain. The ACOEM Guidelines were cited. Utilization Review non-certified a request for Prevacid 30mg #30 with 3 refills, noting that the patient did not express any current gastrointestinal distress and that guidelines do not recommend prescribing a proton pump inhibitor for patients taking nonsteroidal anti-inflammatory drugs for prophylactic purposes. UR cited MTUS. UR non-certified a request for Flexor patch 1.3% with 3 refills and Compound medication: Flurbiprofen/Lidocaine 240mg with 3 refills noting that the guidelines do not recommend it as a first line treatment and the patient had yet to attempt or fail the recently certified naproxen. Also, UR noted that the recent evaluation failed to identify any localized peripheral pain. UR cited ODG and MTUS.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naproxen 550mg # 60 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints, Chapter 9 Shoulder Complaints Page(s): 173-174, 204. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Naproxen

Decision rationale: MTUS specifies four recommendations regarding NSAID use: 1) Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. 2) Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. 3) 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. 4) Neuropathic pain: There is inconsistent evidence for the use of these medications to treat longterm 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. The medical documents do not indicate that the patient is being treated for osteoarthritis. Additionally, the treating physician does not document failure of primary (Tylenol) treatment. Progress notes do not indicate how long the patient has been on naproxen, but the MTUS guidelines recommend against long-term use. Dyesthesia pain is present, but as MTUS outlines, the evidence for NSAID use in neuropathic pain is inconsistent. As such, the request for Naproxen 550mg # 60 with 3 refills is not medically necessary.

Prevacid 30mg # 30 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs and GI distress Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, NSAIDs

Decision rationale: MTUS states "Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease : (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." ODG states If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011) . The medical documents provided do not establish the patient has having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. Additionally, there is no evidence provided to indicate the patient suffers from dyspepsia because of the present medication regimen. As such, the request for Prevacid 30mg # 30 with 3 refills is not medically necessary.

Flector Patch 1.3% with 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Topical Analgesics; NSAIDs

Decision rationale: MTUS 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 no indicate failure of antidepressants or anticonvulsants. 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. A Flector patch is composed of NSAIDs. MTUS states regarding topical NSAIDs, Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of

osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. The employee does not meet the above criteria for application of the product to a recommended body area, such as the knee. Therefore, the request for Flector patch is not medically necessary.

Compounded medication (Flurbiprofen / Lidocaine 240mg) with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints, Chapter 9 Shoulder Complaints Page(s): 173,174, 201, 204. Decision based on Non-MTUS Citation Official Disability Guidelines , Pain (Chronic)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain; compounded creams

Decision rationale: MTUS 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 antidepressants or anticonvulsants. 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. A Flector patch is composed of NSAIDs. MTUS states regarding topical NSAIDs, Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. The employee does not meet the above criteria for application of the product to a recommended body area, such as the knee. Therefore, the request for Flector patch is not medically necessary.