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| Case Number: | CM13-0017790 | | |
| Date Assigned: | 12/11/2013 | Date of Injury: | 11/27/2001 |
| Decision Date: | 02/07/2014 | UR Denial Date: | 08/07/2013 |
| Priority: | Standard | Application Received: | 08/13/2013 |

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 Medicine and is licensed to practice in North Carolina. 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 patient is an 81 year old female with a reported injury date of November 27, 2001. Her diagnosis (with ICD codes) include spinal stenosis (724.02), post laminectomy syndrome-lumbar (722.83), lumbar disc with myelopathy (722.73), lumbosacral neuritis NOS (724.4) and neurogenic urinary incontinence (596.54). Her other medical problems included arthritis, hypertension, hypothyroidism, gastric ulcers and constipation. Pertinent past surgical history includes lumbar fusion in 2003, 2007, 2009 and 2011, lumbar laminectomy in 2003, and sacral and thoracic spinal fusion procedures in 2009. Past medical treatments include chiropractic care, epidural steroid injection, physical therapy, TENS units, ice treatments and spinal cord stimulation trial. The most recent physician note dated July 23, 2013 noted more pain over the left buttock region and increased pain in her lumbar spine and neck but with the remainder of her pain being stable. Her medications listed during this office visit included MS Contin, Percocet, pristiq, lyrica, Prilosec, Lidoderm, ramipril, Glucotrol xl, naproxen, premarin, synthroid, oracea and Zofran ODT. The treatment plan during this office visit was noted to "continue with current medication as prescribed without change." A utilization review decision was rendered on August 7, 2013 recommending non-certification for flexeril, anaprox and Prilosec.

IMR ISSUES, DECISIONS AND RATIONALES

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

Refill of Flexeril: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain). Antispasmodics: Cyclobenzaprine (Flex.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-42.

Decision rationale: According to the California Medical Treatment Utilization Schedule (MTUS), under the chronic pain medical treatment guidelines section, cyclobenzaprine (flexeril) is recommended as an option using a short course of therapy. "Flexeril is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001). Treatment should be brief...Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP (low back pain)." Also in the MTUS chronic pain medical treatment guidelines it recommends "non-sedating muscle relaxants with caution as a second line option for short-term treatment of acute exacerbation in patients with chronic LBP...However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time.." Thus the continued long-term use of flexeril would not be recommended.

Anaprox 550 mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Osteoarthritis (including knee and hip): Recommended at the lowest.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 67-73.

Decision rationale: According to the California MTUS under the chronic pain medical treatment guidelines under the NSAIDs subsection, "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. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications." The MTUS also addresses NSAID use in patients who are at risk for gastrointestinal events in the same section (as this patient has a history of ulcerative disease): "Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. 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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDs to develop gastroduodenal lesions. Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g,ibuprofen, naproxen, etc.) 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 (200 \hat{I} / $\hat{4}$ g 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). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxen plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007). The addition of anaprox to naproxen would be contraindicated per these guidelines.

Refill of Prilosec: 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 Page(s): 68.

Decision rationale: According to the MTUS when assessing gastrointestinal risk associated with NSAID use for chronic pain "Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. 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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) 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 (200 \hat{I} / $\hat{4}$ g 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). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxen plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007). While long term use of PPIs are noted to have an increased risk of hip fractures per the MTUS, this patient certainly falls in the intermediate risk category and per the MTUS guidelines recommendations "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 (200 \hat{I} / $\hat{4}$ g four times daily) or (2) a Cox-2 selective agent." Therefore Prilosec given her use of Naproxen would be deemed medically necessary.