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| Case Number: | CM14-0180795 | | |
| Date Assigned: | 11/04/2014 | Date of Injury: | 06/08/2014 |
| Decision Date: | 12/16/2014 | UR Denial Date: | 10/27/2014 |
| Priority: | Standard | Application Received: | 10/29/2014 |

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. The expert reviewer is Board Certified in Internal Medicine and is licensed to practice in District of Columbia and Virginia. 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/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 is a 41 year old patient who sustained injury on Oct 29 2014. She developed lower back and hip pain after a fall on a wet floor. She had ongoing issues with pain in the lower back with radiation to both hips. The patient had an MRI of the Lumbar spine on Jul 17, 2014 which showed no anomalies. The patient was prescribed flexeril, diclofenac, and tramadol.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cyclobenzaprine 7.5mg #60: Upheld

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): 41-42.

Decision rationale: Per MTUS, Cyclobenzaprine (Flexeril) Recommended as an option, using a short course of therapy. See Medications for chronic pain for other preferred options. Cyclobenzaprine (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. There is also a post-op use. The addition of cyclobenzaprine to other

agents is not recommended. (Clinical Pharmacology, 2008) Cyclobenzaprine-treated patients with fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. (Tofferi, 2004) Note: Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. See Antidepressants. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. (Kinkade, 2007) Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is marketed as Flexeril by [REDACTED]. Per guidelines, treatment should be on a trial basis for no longer than 2 weeks. It is unclear what the duration of this medication was and it would not be medically indicated. Therefore, the request is not medically necessary.

Diclofenac 100mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)..

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 70-72.

Decision rationale: Per MTUS, Combination (NSAID/GI protectant): Arthrotec (diclofenac/misoprostol) 50mg/200mcg, 75mg/20mcg. [Black Box Warning]: Do not administer Arthrotec /misoprostol to pregnant women because it can cause abortion. Mechanism of action: Combines a diclofenac (an NSAID) with misoprostol, an agent that inhibits basal and nocturnal gastric acid secretion and has some mucosal protective properties. Misoprostol is available as Cytotec . Uses: Indicated for the treatment of the signs and symptoms of osteoarthritis in patients at high risk for developing NSAID-induced gastric or duodenal ulcers and their complications. These two products are available as separate medications if you need to individualize therapy. Side Effects: See diclofenac. Misoprostol side effects: (vs. diclofenac alone). The following symptoms were increased over and above that found for diclofenac alone with the addition of misoprostol: abdominal pain (21% with Arthrotec and 15% with diclofenac); Diarrhea (19% with Arthrotec vs. 11% with diclofenac); Dyspepsia (14% for Arthrotec vs. 11% for diclofenac); Nausea/vomiting (11% for Arthrotec vs. 6% for diclofenac); Flatulence (9% for Arthrotec vs. 4% for diclofenac). Diarrhea and abdominal pain usually resolve in 2 to 7 days. Dosing: The recommended dose for OA is diclofenac 50mg/misoprostol 200mcg t.i.d. In patients that may not tolerate this dose, 50mg/200mcg b.i.d and 75mg/200mcg b.i.d. may be prescribed, but are somewhat less effective in ulcer prevention. (Arthrotec Package Insert) (Bocanegra, 1998) Nonselective NSAIDs: (Inhibits COX-1 and COX-2) Mechanism of action: Inhibits prostaglandin synthesis by decreasing the activity of the enzymes COX-1 and COX-2, which results in decreased formation of prostaglandins involved in the physiologic response of pain and inflammation. Side Effects: See Disease-state warnings above. Other common side effects include the following. CNS: headache, dizziness, insomnia; Skin: rash including life-threatening skin reactions (Stevens-Johnson syndrome) **Discontinue if rash develops**; GI: abdominal cramps, nausea/vomiting, diarrhea, constipation, flatulence; Otic: Tinnitus; Hematologic: Anemia. Specific NSAIDs are listed below: Diclofenac Sodium (Voltaren , Voltaren-XR) generic available: (Voltaren , diclofenac sodium enteric-coated tablet Package Insert), (Voltaren -XR, diclofenac sodium extended-release tablets Package Insert), Diclofenac Potassium

(Cataflam, generic available): (Cataflam, diclofenac potassium immediate-release tablets Package Insert) Different formulations of diclofenac are not necessarily bioequivalent. Dosing: Cataflam: Osteoarthritis: Adults: 50 mg PO 2--3 times daily. Dosages > 150 mg/day PO are not recommended. Pain: 50mg PO 3 times per day (max dose is 150mg/day). An initial dose of 100 mg PO followed by 50-mg doses may provide better relief. Voltaren: Osteoarthritis: 50 mg PO 2-3 times daily or 75 mg PO twice daily. Dosages > 150 mg/day PO are not recommended. Ankylosing spondylitis: 25 mg PO 4 times a day with an extra 25-mg dose at bedtime if necessary. Voltaren-XR: 100 m g PO once daily for chronic therapy. Voltaren-XR should only be used as chronic maintenance therapy. Diflunisal(Dolobid, generic available): Dosing: Mild to moderate pain (arthralgia, bone pain, myalgia); 1 gm initially, followed by 500mg every 12 hours; some patients may require 500mg PO every 8 hour s (Max 1500mg/day). Osteoarthritis: 250-500mg PO twice daily (Max 1500mg/day). (Dolubid Package Insert)Etodolac(Lodine, Lodine XL, generic available): Dosing: Lodine: Osteoarthritis: 300mg PO 2-3 times daily or 400 - 500mg twice daily (doses > 1000mg/day have not been evaluated). Lodine-XL: Osteoarthritis: 400 to 1000 mg once daily. A therapeutic response may not be seen for 1-2 weeks. There is no objective measure of improvement in patient's pain, Therefore the request is not medically necessary.

Tramadol 50mg # 60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 83.

Decision rationale: Per MTUS, 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). This is recommended for short term usage. The patient had been on this medication previously and this would not be recommended for long term usage and a weaning process should be initiated. Therefore, the request is not medically necessary.