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| <b>Case Number:</b>   | CM15-0201902 |                              |            |
| <b>Date Assigned:</b> | 10/16/2015   | <b>Date of Injury:</b>       | 04/04/2012 |
| <b>Decision Date:</b> | 12/18/2015   | <b>UR Denial Date:</b>       | 09/16/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 10/14/2015 |

### 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 53 year old female, who sustained an industrial injury on 4-4-2012. Medical records indicate the worker is undergoing treatment for cervical and thoracic sprain-strain and headache. A recent progress report dated 9-3-2015, reported the injured worker complained of neck and upper back pain. Physical examination revealed tenderness to palpation in the upper trapezius and bilateral thoracic paraspinal muscles. Cervical magnetic resonance imaging showed cervical 4-6 level 2-3mm disc bulge. Treatment to date has included physical therapy, Diclofenac, Orphenadrine, Pantoprazole, Trazodone, Norco (since at least 4-15-2015) and compounded medications. On 9-3-2015, the Request for Authorization requested Diclofenac sodium 100mg #60, Orphenadrine 100mg #90, Pantoprazole 20mg #60, Norco 10-325mg #90, Trazodone 150mg #30, Compound: (HS) AGBH 240gms: Amitriptyline, gabapentin, bupivacaine, hyaluronic acid and Compound FBD 240gms: Flurbiprofen, Baclofen, Dexamethasone, Menthol, Camphor, Capsaicin. On 9-16-2015, the Utilization Review noncertified the request for Pantoprazole 20mg #60, Norco 10-325mg #90, Compound: (HS) AGBH 240gms: Amitriptyline, gabapentin, bupivacaine, hyaluronic acid and Compound FBD 240gms: Flurbiprofen, Baclofen, Dexamethasone, Menthol, Camphor, Capsaicin. Certified Diclofenac sodium 100mg #60, Orphenadrine 100mg #90 and Trazodone 150mg #30.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Pantoprazole 20mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Proton pump inhibitors (PPIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) PPIs.

**Decision rationale:** According to CA MTUS (2009), proton pump inhibitors (PPIs), such as Protonix (Pantoprazole), are recommended for patients at risk for gastrointestinal events or taking NSAIDs with documented GI distress symptoms. There is no documentation indicating the patient has any GI symptoms or GI risk factors. Risk factors include: age >65; history of peptic ulcer disease; GI bleeding, concurrent use of aspirin, corticosteroids; and/or anticoagulants or high-dose/multiple NSAIDs. There is no documentation of any reported GI complaints. Based on the available information provided for review, the medical necessity for Protonix has not been established. The requested medication is not medically necessary.

**Norco 10/325mg #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain, Opioids, criteria for use, Opioids, dosing.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Opioids.

**Decision rationale:** According to the CA MTUS and ODG, Norco 10/325mg (Hydrocodone/Acetaminophen) is a short-acting opioid analgesic indicated for moderate to moderately severe pain, and is used to manage both acute and chronic pain. 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 insufficient evidence that the opioids were prescribed according to the CA MTUS guidelines, which recommend prescribing according to function, with specific functional goals, return to work, random drug testing, an opioid contract, and documentation of a prior failure of non-opioid therapy. In addition, the MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. In this case, there is no documentation of significant pain relief or increased functional benefit from the opioid use, taken since at least 9/3/2015. Medical necessity of the requested medication has not been established. Of note, discontinuation of an opioid analgesic should include a taper to avoid withdrawal symptoms. The requested medication is not medically necessary.

**Compound: (HS) AGBH 240gms - Amitriptyline, gabapentin, bupivacaine, hyaluronic acid: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. The requested topical analgesic compound for this patient contains: Amitriptyline, gabapentin, bupivacaine, and hyaluronic acid. Topical Gabapentin is not recommended by the guidelines, since there is no peer-reviewed literature to support its use. Bupivacaine is an amide local anesthetic, and lidocaine is in the same drug class. The guidelines state that topical lidocaine, only in the form of the Lidoderm patch, is indicated for neuropathic pain. Topical lidocaine other than Lidoderm is not recommended per the MTUS. Medical necessity for the requested topical compounded medication has not been established. The requested topical compound is not medically necessary.

**Compound FBD 240gms - Flurbiprofen, Baclofen, Dexamethasone, Menthol, Camphor, Capsaicin: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. The requested topical analgesic compound for this patient contains: Flurbiprofen, Baclofen, Dexamethasone, Menthol, Camphor, and Capsaicin. Flurbiprofen, used as a topical NSAID, has been shown in a meta-analysis to be superior to placebo during the first two weeks of treatment for osteoarthritis but either, not afterward, or with diminishing effect over another two-week period. There are no clinical studies to support

the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). The guidelines note that Capsaicin is only recommended when other, conventional treatments have failed. In addition, a new alert from the FDA warns that topical over-the-counter (OTC) pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. Medical necessity for the requested compounded topical agent has not been established. The requested topical analgesic compound is not medically necessary.