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| Case Number: | CM15-0107890 | | |
| Date Assigned: | 06/17/2015 | Date of Injury: | 10/25/2006 |
| Decision Date: | 08/11/2015 | UR Denial Date: | 02/23/2015 |
| Priority: | Standard | Application Received: | 03/19/2015 |

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: Internal 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 61 year old female, who sustained an industrial injury on 10/25/06. Initial complaints were not reviewed. The injured worker was diagnosed as having cervical stenosis; cervical kyphosis; cervical degenerative spondylolisthesis. Treatment to date has included status post left shoulder arthroscopy; with rotator cuff repair; extensive debridement of the glenohumeral joint including circumferential labrum; subacromial decompression with acromioplasty (8/4/14); radiofrequency ablation lumbar medial branches (2/16/15); cervical epidural steroid injections; status post right thumb trigger release with right wrist de Quervain's release; status post right carpal tunnel release. Diagnostics included MRI cervical spine (1/8/15); x-rays cervical spine (11/20/14). Currently, the PR-2 notes dated 2/16/15 (Operative Record) indicated the injured has spinal surgery for an anterior cervical disc fusion (ACDF) C4-7 with allograft, fluoroscopy, microscope, neuromonitoring SSEP with 2 day stay inpatient on 4/20/15. A PR-2 note dated 1/12/15 indicated she complained of severe neck pain and is miserable taking pain medications every day. The pain radiates across her neck and shoulders. On physical examination she has restricted range of motion of the cervical spine; positive Hoffman's sign bilaterally with mildly poor fast finger movements; no clonus; no hyperreflexia distally. She has good strength throughout the upper extremities except some mild weakness in the wrist extensors and flexors. X-rays; (two views) of the cervical spine taken on this date, shows severe disc disease at C5-C6 and C6-C7. There is anterolisthesis at C3-C4 and C4-C5 and C4-C5 definitely is a significant step-off. A MRI of the cervical spine shows kyphotic alignment at C5-C6 C4-C5 and severe foraminal stenosis at C5-C6, C6-C7. Mild stenosis is noted at C4-C5. The provider

has requested authorization for medications: Celebrex 200mg; Citalopram Hydrobromido 20mg; Estradiol 1mg; Losartan Potassium-HCTZ 50 12.5mg; Norco 10/325mg (1-2 tabs PO every 4-6 hours PRN); Savella 50mg; Synthroid 88mcg; Toprol XL 100mg; Voltaren 1% (apply 2-4grams to affected area every 6 hours) and Zolpidem Tartrate 10mg.

IMR ISSUES, DECISIONS AND RATIONALES

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

Celebrex 200mg: 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 Celebrex Page(s): 30. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Anti-inflammatory medications.

Decision rationale: Celebrex (Celecoxib) is a selective nonsteroidal anti-inflammatory drug (NSAID) that is a COX-2 selective inhibitor, a drug that directly targets COX-2, an enzyme responsible for inflammation and pain. Unlike other NSAIDs, Celebrex does not appear to interfere with the antiplatelet activity of aspirin and is bleeding neutral when patients are being considered for surgical intervention or interventional pain procedures. Celebrex may be considered if the patient has a risk of GI complications, but not for the majority of patients. Generic NSAIDs and COX-2 inhibitors have similar efficacy and risks when used for less than 3 months. In this case, the submitted Medical Records do not mention prior use of this medicine by the injured worker and there is no compelling evidence presented by the treating provider that indicates selective NSAID is indicated for this injured worker. No mention that injured worker has GI risk factors. The medical necessity of the requested medication has not been established, therefore, the requested medication is not medically necessary.

Citalopram Hydrobromido 20mg: 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 Specific Antidepressants Page(s): s 13-16.

Decision rationale: Citalopram (Celexa) is a selective serotonin re-uptake inhibitor (SSRI). SSRIs are not recommended as a treatment for chronic pain, but may have a role in treating secondary depression. It has been suggested that the main role of SSRIs may be in addressing psychological symptoms associated with chronic pain, but more information is needed regarding the role of SSRIs and pain. In addition, SSRIs have not been shown to be effective for low back pain. In this case, the submitted Medical Records do not mention prior use of this medicine by the injured worker and there is also no narrative presented by the treating provider that indicates

the need for Citalopram in this injured worker. The medical necessity of the requested medication has not been established. The requested medication is not medically necessary.

Estradiol 1mg: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation U.S Food and Drug Administration (FDA), Estradiol.

Decision rationale: Estradiol is an estrogen indicated for treatment of Moderate to Severe Vasomotor Symptoms due to Menopause, treatment of Moderate to Severe Symptoms of Vulvar and Vaginal Atrophy due to Menopause, treatment of Hypoestrogenism due to Hypogonadism, Castration or Primary Ovarian Failure, and prevention of Postmenopausal Osteoporosis. Treating provider's note dated July 2nd, 2014 documents that injured worker has history of hysterectomy and Estradiol is listed as one of the medicines in her current list of medications. With the submitted information, the determination for requested treatment Estradiol is medically necessary and appropriate.

Losartan Potassium-HCTZ 50-12.5mg: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate, Losartan Potassium and HCTZ.

Decision rationale: CA MTUS and Official Disability Guidelines (ODG) do not address this; therefore, the determination is based on reviewing the information in Uptodate. Losartan Potassium is an Angiotensin II Receptor Blocker indicated for treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria, and treatment of hypertension, alone or in combination with other antihypertensive agents. Treating provider's note dated July 2nd, 2014 lists Losartan as one of the medicines in her current list of medications, but there is no documentation that injured worker has history of hypertension. Also there are no blood pressure recordings and no rationale provided for the requested treatment. HCTZ is recommended for management of mild-to-moderate hypertension. In this case, the submitted Medical Records do not mention prior use of this medicine by the injured worker and there is also no narrative presented by the treating provider that indicates the need for HCTZ in this injured worker. There is no documentation that injured worker has history of hypertension, therefore, requested treatment Losartan Potassium-HCTZ 50-12.5mg is not medically necessary and appropriate.

Norco 10/325mg (1-2 tabs PO q4-6 PRN): 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): s 76-81. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter--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. Per MTUS initiating therapy with opioids for (a) Intermittent pain: Start with a short-acting opioid trying one medication at a time. (b) Continuous pain: extended-release opioids are recommended. Patients on this modality may require a dose of "rescue" Opioids. The need for extra opioid can be a guide to determine the sustained release dose required (c) Only change 1 drug at a time (d) Prophylactic treatment of constipation should be initiated. In the submitted records for review, the treating provider's notes do not describe the treatment plan for initiating therapy with opioids; therefore the requested treatment is not medically necessary and appropriate.

Savella 50mg: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: ODG state Savella is not recommended for chronic pain. FDA has now approved Milnacipran (Savella) for the management of fibromyalgia. Milnacipran should be prescribed with caution in patients with a history of seizure disorder, mania, or controlled narrow-angle glaucoma and should ordinarily not be prescribed in patients with substantial alcohol use or evidence of chronic liver disease (FDA, 2009). As there is little to no evidence that the cause of fibromyalgia is related to industrial injuries, the use of Savella should be restricted to documented cases of fibromyalgia as part of an appropriate treatment plan. Treating provider's note dated July 2nd, 2014 lists Savella is as one of the medicines in her current list of medications, but there is no documentation that injured worker has history of fibromyalgia. The functional benefit of this medication is not described in the submitted Medical records; therefore, the requested treatment is not medically necessary and appropriate.

Synthroid 88mcg: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate, Synthroid.

Decision rationale: Synthroid is used for replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. Specific indications include primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) hypothyroidism and subclinical hypothyroidism. Primary hypothyroidism may result from functional deficiency, primary atrophy, partial or total congenital absence of the thyroid gland, or from the effects of surgery, radiation, or drugs, with or without the presence of goiter. Treating provider's note dated July 2nd, 2014 documents that injured worker has history of thyroid resection and Synthroid is listed as one of the medicines in her current list of medications. With the submitted information, the determination for requested treatment Synthroid is medically necessary and appropriate.

Toprol XL 100mg: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate, Toprol XL.

Decision rationale: CA MTUS and Official Disability Guidelines (ODG) do not address this; therefore, the determination is based on reviewing the information in UpToDate. Toprol XL an extended release Beta-1 Selective Beta-Blocker, recommended for treatment of angina pectoris or hypertension; to reduce mortality/hospitalization in patients with heart failure (HF). In this case, the submitted Medical Records do not mention prior use of this medicine by the injured worker, and there is also no narrative presented by the treating provider that indicates the need for Toprol XL, in this injured worker. The requested treatment is not medically necessary and appropriate.

Voltaren 1% (apply 2-4 grams to affected area every 6 hours): 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 Topical Analgesics Page(s): s 111 to 113.

Decision rationale: According to the California MTUS Guidelines, Voltaren Gel 1% (Diclofenac) is indicated for the relief of osteoarthritis in joints that lend themselves to topical treatment, such as the ankle, elbow, foot, hand, knee, and wrist. It has not been evaluated for treatment of the spine, hip, or shoulder. The submitted documentation does not indicate that the injured worker had a diagnosis of osteoarthritis. There is also no documentation of intolerance to other previous oral medications. Medical necessity for the requested topical gel has been not established. The requested 1% Voltaren Gel is not medically necessary.

Zolpidem Tartrate 10mg: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter-- Insomnia Treatment.

Decision rationale: Zolpidem is a prescription short-acting non-benzodiazepine hypnotic, which is indicated for the short-term treatment of insomnia with difficulty of sleep onset (7-10 days). Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Zolpidem can be habit-forming, and may impair function and memory more than opioid analgesics. There is also concern that it may increase pain and depression over the long-term. The treatment of insomnia should be based on the etiology, and pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. In this case, the injured worker has chronic pain, the submitted Medical Records do not mention prior use of this medicine by the injured worker, and there is also no narrative presented by the treating provider that indicates the need for Zolpidem in this injured worker. The requested medication is not medically necessary.