



## 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 Internal Medicine and Pulmonary Diseases and is licensed to practice in California. 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.

### DOCUMENTS REVIEWED

The following relevant documents received from the interested parties and the documents provided with the application were reviewed and considered. These documents included:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

### CLINICAL CASE SUMMARY

The physician reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The patient is a 37-year-old male with a reported date of injury on 7/10/2008; the mechanism of injury was a lifting injury. The patient reported frequent right shoulder pain located over the scapular aspect of the shoulder with occasional radiation to the cervical spine associated with stiffness. The patient reported achy, burning pain with soreness, pin/needle sensation in the left shoulder, difficulty with physical activities, a positive Speed's test in the right shoulder, and a score of 6 out of 24 on the Epworth Sleepiness Scale. Sensation was within normal limits to light touch in all dermatomal distributions over the upper and lower extremities, strength in the upper extremities was intact, and the patient had negative impingement, drop arm, supraspinatus, and Yergason's testing in bilateral upper extremities and a negative Speed's test on the left. The patient had diagnoses of status post right shoulder surgery x2 and status post left shoulder surgery. The physician's treatment plan consisted of omeprazole 20 mg, Vicodin 5/500 mg, Terocin lotion, flurbi cream, gabacyclotram cream, Genicin, Somnicin, and a speciality drug metabolism test.

### IMR DECISION(S) AND RATIONALE(S)

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

**1. The prescription for omeprazole 20mg is not medically necessary and appropriate.**

The Claims Administrator based its decision on the Chronic Pain Medical Treatment Guidelines, which are part of the MTUS.

The Physician Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, pages 68-69, which are a part of the MTUS.

The Physician Reviewer's decision rationale:

The California MTUS guidelines recommend the use of a proton pump inhibitor (such as omeprazole) for patients at intermediate risk for gastrointestinal events with no cardiovascular disease and patient at high risk for gastrointestinal events with no cardiovascular disease. The guidelines note to 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). The provider noted the employee was provided omeprazole which is a proton pump inhibitor medication to be taken as directed for the treatment of gastrointestinal irritation. The employee was utilizing the medication Naproxen sodium. Within the provided documentation, it was unclear if the employee was at risk for gastrointestinal events. Within the provided documentation, the employee was not noted to have a history of peptic ulcer, GI bleeding, or perforation. The employee is not over 65 years of age. Within the provided documentation, there is a lack of information pertaining to the employee's level of risk for gastrointestinal events. **The request for omeprazole is not medically necessary and appropriate.**

## **2. Vicodin 5/500mg is not medically necessary and appropriate.**

The Claims Administrator based its decision on the Chronic Pain Medical Treatment Guidelines, which are part of the MTUS.

The Physician Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, page 78, which is a part of the MTUS.

The Physician Reviewer's decision rationale:

The California MTUS guidelines recommend patients utilizing opioid medication should obtain prescriptions from a single practitioner, medications should be taken as directed, and all prescriptions should come from a single pharmacy. Providers should prescribe the lowest possible dose should be prescribed to improve pain and function. The provider should conduct ongoing review with documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment.

Within the medical records provided for review, the requesting physician did not include an adequate documented assessment of the employee's pain including the least reported pain over the period since the last assessment, average pain, intensity of the pain after taking the opioid, how long it takes for pain relief, and how long pain relief lasts. Additionally, the requesting physician did not include adequate documentation of significant objective functional improvement with the use of the medication. Within the provided documentation, there was not an assessment indicating the employee had side effects with the medication or a lack thereof. **The request for Vicodin is not medically necessary and appropriate.**

## **3. Terocin lotion is not medically necessary and appropriate.**

The Claims Administrator based its decision on the Chronic Pain Medical Treatment Guidelines, which are a part of the MTUS.

The Physician Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, pages 105 and 111-113, which are a part of the MTUS.

The Physician Reviewer's decision rationale:

Terocin lotion is comprised of capsaicin, Lidocaine, menthol, and methyl salicylate. The California MTUS guidelines state any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. The California MTUS Guidelines note topical salicylate is significantly better than placebo in chronic pain. The California MTUS Guidelines recommend the use of capsaicin for patients with osteoarthritis, postherpetic neuralgia, diabetic neuropathy, and post mastectomy pain. The guidelines recommend the use of capsaicin only as an option in patients who have not responded or are intolerant to other treatments. The guidelines recommend the use of Lidocaine for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm®) has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain.

Within the provided medical records, it did not appear the employee had a diagnosis of osteoarthritis, postherpetic neuralgia or diabetic neuropathy which would indicate the employee's need for topical capsaicin. The guidelines do not recommend lidocaine in the form of creams, lotions, or gels. Additionally, the guidelines note any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. **The request for Terocin lotion is not medically necessary and appropriate.**

#### **4. Flurbi cream is not medically necessary and appropriate.**

The Claims Administrator based its decision on the Chronic Pain Medical Treatment Guidelines, which are a part of the MTUS.

The Physician Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, pages 111-113, which is a part of the MTUS.

The Physician Reviewer's decision rationale:

The California MTUS guidelines note topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first two weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. The guidelines note these medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) The guidelines recommend the use of topical NSAIDs for 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 and use with neuropathic pain is not recommended as there is no evidence to support use.

Within the medical records provided for review, it did not appear the employee had a diagnosis of osteoarthritis and/or tendonitis in particular, that of the knee and/or elbow. Additionally, the guidelines recommend the use of topical flurbiprofen for short-term use; it was unclear within the provided documentation how long the employee had been utilizing the medication. **The request for Flurbi cream is not medically necessary and appropriate.**

#### **5. Gabacyclotram cream is not medically necessary and appropriate.**

The Claims Administrator based its decision on the Chronic Pain Medical Treatment Guidelines, which are part of the MTUS.

The Physician Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, pages 111-113, which are a part of the MTUS.

The Physician Reviewer's decision rationale:

The California MTUS guidelines state any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. The guidelines note the topical use of gabapentin is not recommended as there is no peer-reviewed literature to support use. The guidelines also note there is no evidence for use of any other muscle relaxant as a topical product. The guidelines do not recommend the use of gabapentin or muscle relaxants as topical agents. The guidelines also note any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. **The request for gabacyclotram cream is not medically necessary and appropriate.**

#### **6. Genicin is not medically necessary and appropriate.**

The Claims Administrator based its decision on the Official Disability Guidelines, which are not a part of the MTUS.

The Physician Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, page 50, which is a part of the MTUS.

The Physician Reviewer's decision rationale:

The California MTUS guidelines note glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). A randomized, doubleblind placebo controlled trial, with 212 patients, found that patients on placebo had progressive joint-space narrowing, but there was no significant joint-space loss in patients on glucosamine sulphate. Within the provided documentation, it did not appear the employee had a diagnosis of osteoarthritis specifically of the knee. **The request for Genicin is not medically necessary and appropriate.**

#### **7. Somnicin is not medically necessary and appropriate.**

The Claims Administrator did not cite any evidence based criteria for its decision.

The Physician Reviewer found that no section of the MTUS was applicable. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Physician Reviewer based his/her decision on the Official Disability Guidelines (ODG) Head and Chronic Pain Chapters.

The Physician Reviewer's decision rationale:

Somincin is comprised of Melatonin 2 mg, 5-HTP (5-hydroxytryptopan) 50 mg, L-tryptophan 100 mg, Vitamin B6 (pyridoxine) 10 mg, Magnesium 50 mg and is noted to be used for patients with insomnia and depression. The ODG noted vitamin B is not recommended. Vitamin B is frequently used for treating peripheral neuropathy but its efficacy is not clear. A recent meta-analysis concluded that there are only limited data in randomized trials testing the efficacy of vitamin B for treating peripheral neuropathy and the evidence is insufficient to determine whether vitamin B is beneficial or harmful. The ODG noted Melatonin is recommended in treating sleep disorder post-traumatic brain injury (TBI). The provider noted the employee had a score of 6 out of 24 on the Epworth Sleepiness Scale. Per the provided medical records, it did not appear the employee had significant insomnia or depression. Additionally, the guidelines do not recommend the use of vitamin B (which is part of the medication Somnicin) as its efficacy is unclear. Additionally, the guidelines recommend melatonin (which is a component of the medication Somnicin) in treating a sleep disorder post TBI. Per the provided documentation, it did not appear the patient experienced a TBI. **The request for Somnicin is not medically necessary and appropriate.**

**8. A specialty drug metabolism test for right shoulder pain is not medically necessary and appropriate.**

The Claims Administrator did not cite any evidence based criteria for its decision.

The Physician Reviewer found that no section of the MTUS was applicable. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Physician Reviewer based his/her decision on the ODG, Chronic Pain chapter.

The Physician Reviewer's decision rationale:

The ODG note genetic testing for potential opioid abuse is not recommended. While there appears to be a strong genetic component to addictive behavior, current research is experimental in terms of testing for this and studies are inconsistent, with inadequate statistics and large phenotype range. More work is needed to verify the role of variants suggested to be associated with addiction and for clearer understanding of their role in different populations. The provider noted the test was ordered in order to identify the genetic risk factors of narcotic abuse, tolerance, and dependence to improve the employee's outcome and continue or avoid costs from unnecessary high dose narcotic usage. The guidelines note genetic testing for potential opioid abuse is not recommended. **The request for specialty drug metabolism test is not medically necessary and appropriate.**

/dso

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