

Case Number:	CM14-0161430		
Date Assigned:	10/06/2014	Date of Injury:	07/08/2013
Decision Date:	01/08/2015	UR Denial Date:	08/29/2014
Priority:	Standard	Application Received:	10/01/2014

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 Occupational Medicine 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 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 52-year-old female with a 7/8/13 date of injury. The mechanism of injury occurred when she fell off a chair and fell onto the right side of her body. According to the most recent progress report provided for review, dated 6/18/14, the patient complained of constant neck pain radiating to her upper extremities rated as a 7/10, constant mid back pain rated as a 6/10, constant low back pain radiating to the lower extremities rated as an 8/10, and left shoulder pain rated as an 8/10. She has had significant benefit with chiropractic care. The provider has requested chiropractic manipulation for the cervical spine along with medications. Objective findings: limited cervical/shoulder/lumbar/thoracic range of motion. Diagnostic impression: cervical sprain/strain, brachial neuritis or radiculitis, cervical disc protrusion, thoracic sprain/strain, lumbar radiculopathy, left shoulder sprain/strain. Treatment to date: medication management, activity modification, physical therapy, acupuncture, cervical ESI, chiropractic treatment. A UR decision dated 8/29/14 denied the requests for cyclobenzaprine, Norco, Terocin pain patch, Terocin lotion, Genicin, Somnicin, Flurbi (NAP) cream, Gabacyclotram, chiropractic manipulation, and Toradol/B-12 injection. Regarding cyclobenzaprine, there is no indication of spasm on exam. Long-term use of this muscle relaxant is not supported due to side effect potential. Regarding Norco, there are no urine drug screens documented to verify compliance and support ongoing use. Regarding Terocin pain patch and Terocin lotion, salicylate is the main ingredient, but is available over the counter. Adding other agents to it to form Terocin confers no proven added benefit, just added cost. Regarding Genicin, this is a form of glucosamine. Glucosamine is supported for knee osteoarthritis, which is not documented here. Regarding Somnicin, this is a medial food compound sleep aide. There is no indication of sleep hygiene being addressed and this agent has no proven benefit over standard traditional prescription meds to treat insomnia. Regarding Flurbi (NAP) cream, there is no indication why the patient could

not take these medications orally. Regarding Gabapentin (Gabapentin/cyclobenzaprine/tramadol), there is no indication why the patient could not take these medications orally as intended and the patient is already on oral cyclobenzaprine. Regarding chiropractic treatment, her pain scores remained essentially unchanged as do her medication requirements and medications are actually added at every visit. There is no indication of functional benefit from prior chiropractic treatment to warrant continuation. Regarding Toradol/B-12 injections, there is no indication that the pain is anymore significant when this was given to warrant it being done. There is no lab work to indicate she is deficient in B-12 and needs supplementation.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cyclobenzaprine 10mg, #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Page(s): 64.

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

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, Cyclobenzaprine is recommended as an option, using a short course of therapy. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief. There is also a post-op use. The addition of cyclobenzaprine to other agents is not recommended. However, according to the records provided for review, this patient has been taking cyclobenzaprine since at least 7/15/13, if not earlier. Guidelines do not support the long-term use of muscle relaxants. In addition, there is no documentation that the patient has had an acute exacerbation of his pain. Therefore, the request is not medically necessary.

Norco 10/325mg, #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 72, 99.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opiates Page(s): 78-81.

Decision rationale: The Chronic Pain Medical Treatment Guidelines do not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest possible dose; and unless there is ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. However, in the reports reviewed, there is no documentation of significant pain reduction or improved activities of daily living. Guidelines do not support the continued use of opioid medications without documentation of functional improvement. In addition, there is no documentation of lack of

aberrant behavior or adverse side effects, an opioid pain contract, or CURES monitoring. Therefore, the request is not medically necessary.

Terocin Pain Patches, #20,: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112. Decision based on Non-MTUS Citation National Library of Medicine Daily Med Database (<http://dailymed.nlm.nih.gov>)

Decision rationale: The Chronic Pain Medical Treatment Guidelines states that topical lidocaine in the formulation of a dermal patch has been designated for orphans status by the FDA for neuropathic pain. In addition, guidelines states that topical lidocaine may be recommended 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). However, in the present case, there is no documentation of the designated area for treatment as well as number of planned patches and duration for use (number of hours per day). In addition, there is no discussion in the reports reviewed regarding the patient failing treatment with a first-line agent such as gabapentin. Furthermore, there is no documentation that the patient is unable to take oral medications. In fact, her medication regimen consisted of several oral medications. Therefore, the request is not medically necessary.

Terocin, 120ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 105, 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation FDA (Terocin Lotion)

Decision rationale: An online search revealed that Terocin is a Topical Pain Relief Lotion containing Methyl Salicylate 25%, Capsaicin 0.025%, Menthol 10%, and Lidocaine 2.50%. The Chronic Pain Medical Treatment Guidelines do not recommend compound medications including lidocaine (in creams, lotion or gels), for topical applications. In addition, guidelines states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. While guidelines would support a capsaicin formulation, the above compounded topical medication is not recommended. Guidelines do not support the use of lidocaine in a topical cream/lotion formulation. A specific rationale identifying why Terocin would be required in this patient despite lack of guidelines support was not provided. Therefore, the request is not medically necessary.

Genicin Capsules, #90,: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Page(s): 50. Decision based on Non-MTUS Citation FDA (Genicin)

Decision rationale: An online search revealed that Genicin is a brand-name formulation of glucosamine. The Chronic Pain Medical Treatment Guidelines states that Glucosamine and Chondroitin Sulfate are recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. However, in the present case, there is no documentation that this patient has a diagnosis of arthritis. A specific rationale identifying why this patient requires this medication was not provided. Therefore, the request is not medically necessary.

Somnicin Capsules, #30,: 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 - Medical Foods; as well as the Non-MTUS website Rx Wiki (<http://www.rxwiki.com/somnicin>)

Decision rationale: The California MTUS Guidelines do not address this issue. An online search identifies that Somnicin contains melatonin, 5-htp, l-tryptophan, vitamin B6, and magnesium and is used for insomnia and sleeping problems. Therefore, Somnicin would be classified as a medical food. The Official Disability Guidelines states that medical foods may be considered if they are labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. However, in the present case, in the medical records provided for review, there is no indication that the patient has any specific nutritional deficit, which would be addressed with the currently requested substance. There is no indication that the patient has any specific disease state, which has distinctive nutritional requirements, as recommended by guidelines. In addition, there is no documentation that the patient suffers from insomnia. There is no documentation that the provider has addressed non-pharmacologic methods for sleep disturbances, such as proper sleep hygiene. Therefore, the request is not medically necessary.

Flurbi (NAP) Cream, 180 grams,: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 105, 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 25, 28, 111-113.

Decision rationale: The Chronic Pain Medical Treatment Guidelines state that ketoprofen, lidocaine (in creams, lotion or gels), capsaicin in anything greater than a 0.025% formulation, baclofen, Boswellia Serrata Resin, and other muscle relaxants, and gabapentin and other antiepilepsy drugs are not recommended for topical applications. In addition, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. According to the medical records provided for review, Flurbi (NAP) cream contains flurbiprofen, lidocaine, and amitriptyline. However, guidelines do not support the use of the NSAID, flurbiprofen, lidocaine, or amitriptyline in a topical cream/lotion formulation. There is no documentation that this patient is unable to tolerate oral medications. In fact, her medication regimen consisted of several oral medications. A specific rationale identifying why this topical compounded medication would be required in this patient despite lack of guideline support was not provided. Therefore, the request is not medically necessary.

GabaCycloTram, 180mgs,: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 105, 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 25, 28, 111-113.

Decision rationale: The Chronic Pain Medical Treatment Guidelines state that ketoprofen, lidocaine (in creams, lotion or gels), capsaicin in anything greater than a 0.025% formulation, baclofen, Boswellia Serrata Resin, and other muscle relaxants, and gabapentin and other antiepilepsy drugs are not recommended for topical applications. In addition, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. According to the medical records provided for review, Gabacyclotram is a topical formulation containing gabapentin, cyclobenzaprine, and tramadol. However, guidelines do not support these ingredients in a topical cream/lotion formulation. There is no documentation that this patient is unable to tolerate oral medications. In fact, her medication regimen consisted of several oral medications. A specific rationale identifying why this topical compounded medication would be required in this patient despite lack of guideline support was not provided. Therefore, the request is not medically necessary.

Chiropractic Manipulation (8-sessions): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manual Therapy and Manipulation Page(s): 58-60.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 173, Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back Chapter - Manipulation

Decision rationale: The California MTUS Guidelines states that using cervical manipulation may be an option for patients with neck pain or cervicogenic headache, but there is insufficient evidence to support manipulation of patients with cervical radiculopathy. In addition, the Official

Disability Guidelines supports a trial of 6 visits and with evidence of objective functional improvement, up to a total of up to 18 visits. In the present case, it is noted that the patient has had significant benefit from previous chiropractic treatment. However, there is no documentation of objective functional improvement from previous treatment. There is no documentation that treatment has allowed her to decrease her medication use or improve her activities of daily living. In addition, it is unclear how many total number sessions she has completed. Therefore, the request is not medically necessary.

Toradol/B-12 Injection: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 72. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter - Ketorolac, Vitamin B

Decision rationale: The FDA states that Ketorolac is indicated for the short-term (up to 5 days in adults), management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation treatment following IV or IM dosing of Ketorolac tromethamine. The California MTUS Guidelines do not specifically address the issue of Vitamin B-12. The Official Disability Guidelines states that Vitamin B-12 is not recommended. Vitamin B-12 is frequently used for treating peripheral neuropathy but its efficacy is not clear. However, in the present case, a specific rationale for Vitamin B-12 injection was not identified. There is no documentation that this patient has failed first-line analgesic medications to support the medical necessity of a Toradol injection. In addition, there is no documentation that the patient has had an acute exacerbation of her pain. Furthermore, there is no documentation that the patient is unable to tolerate oral medications. In fact, the patient's medication regimen consisted of several oral medications. Therefore, the request is not medically necessary.