

Case Number:	CM15-0089180		
Date Assigned:	05/13/2015	Date of Injury:	04/08/2013
Decision Date:	09/23/2015	UR Denial Date:	05/04/2015
Priority:	Standard	Application Received:	05/08/2015

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 43 year old female who sustained an industrial injury on 04/08/2013. Mechanism of injury was not documented; she sustained an injury to her knee. Diagnoses include lumbar radiculopathy, lumbar spinal stenosis, lumbar facet syndrome, right shoulder tendinitis and status post left knee surgery on 10/30/2014. Treatment to date has included diagnostic studies, surgery, medications, and physical therapy. A physician progress note dated 04/22/2015 documents the injured worker complains of low back pain rated as 6 out of 10 radiating to the bilateral lower extremities with numbness and tingling, constant right shoulder pain rated a 6 out of 10 and constant left knee/calf pain rated as 5 out of 10. The injured worker denies any side effects or gastrointestinal symptoms with the use of oral and topical medications. Her pain level without medications is 7 out of 10, and with medications her pain is 3-4 out of 10. Topical creams, patches and oral medications help decrease pain and allow the injured worker to stand longer. Right shoulder range of motion-flexion 120 degrees, extension 25 degrees, abduction 120 degrees, adduction 20 degrees, internal rotation 60 degrees. There is tenderness long the trapezius muscle on the right with spasms. Lumbar range of motion is restricted, and Straight Leg Raise is positive on the left. There is tenderness along the lumbar spine and spasms along the paravertebral muscles bilaterally. She ambulates with an antalgic gait and uses one crutch. Left knee range of motion-flexion 110 degrees, extension is 0. There is patellar grinding on the left. There is tenderness to palpation noted over the medial and lateral joint line, and over the patella. The treatment plan is for topical creams, for pain and inflammation, and the efficacy of these medications will be reviewed upon the injured worker's return visit, medication for

treatment of arthritic pain, and medications for insomnia, anxiety, and muscle relaxation, to continue to follow up with her physician status post left knee surgery, and follow up in 4-6 weeks. Treatment requested is for Calypxo Cream 113gm, Flurbi Cream LA 10gm, Flurbiprofen 20%-Lidocaine 5%-Amitriptyline 4%, Gabacyclotram 180mg, Gabapentin 10%-Cyclobenzaprine 6%- Tramadol 10%, Retrospective request for MEDS x 1 Genicin #90 capsules glucosamine sodium 500mg, Somnicin #30 capsules-melatonin 2mg, and Terocin 120ml, Capsaicin 0.025% methyl Salicylate 25%-menthol 10%-Lidocaine 2.5%.

IMR ISSUES, DECISIONS AND RATIONALES

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

Calypxo Cream 113gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical NSAIDs Page(s): 111.

Decision rationale: The patient complains pain in the left knee, rated at 2/10, radiating to the left lower extremity along with anxiety, insomnia and stomach cramps, as per progress report dated 04/15/15. The request is for CALYPXO CREAM 113gm. There is no RFA for this case, and the patient's date of injury is 04/08/13. The patient is status post left knee arthroscopy on 10/03/14, as per progress report dated 04/15/15. Diagnoses included clinical evidence of positive examination, r/o medial meniscal tear. Diagnoses, as per progress report dated 03/17/15, included lumbar radiculopathy, lumbar spinal stenosis, lumbar facet syndrome, and right shoulder tendinitis. Medications included Terocin lotion, Gabacyclotram cream, Flurbi (NAP) cream, Genicin and Somnicin. The patient is temporarily totally disabled, as per the same progress report. Calypxo cream contains Methyl salicylate and Menthol. Regarding topical NSAIDs MTUS page 111 and Topical Analgesics section states, "Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use." In this case, a prescription for Calypxo cream is only mentioned in progress report dated 01/22/15. Prior progress report dated 05/29/14 documents the use of Methoderm gel which has a similar composition. In progress report dated 01/22/15, the treater states that the cream provides "temporary relief of minor aches and pains associated with simple backaches, arthritis, bruises, sprains and cramps." The treater, however, does not document its efficacy in terms of improvement in function and reduction in pain. Additionally, while the Calypxo can be used for arthritis, topical NSAIDs are not indicated for spinal, shoulder conditions, which the patient also presents with. Hence, the request IS NOT medically necessary.

Terocin 120ml, Capsaicin 0.025% methyl Salicylate 25%-menthol 10%-Lidocaine 2.5%:
Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

Decision rationale: The patient complains pain in the left knee, rated at 2/10, radiating to the left lower extremity along with anxiety, insomnia and stomach cramps, as per progress report dated 04/15/15. The request is for TEROGIN 120ml, CAPSAICIN 0.025% METHYL SALICYLATE 25%-MENTHOL 10%-LIDOCAINE 2.5%. There is no RFA for this case, and the patient's date of injury is 04/08/13. The patient is status post left knee arthroscopy on 10/03/14, as per progress report dated 04/15/15. Diagnoses included clinical evidence of positive examination, r/o medial meniscal tear. Diagnoses, as per progress report dated 03/17/15, included lumbar radiculopathy, lumbar spinal stenosis, lumbar facet syndrome, and right shoulder tendinitis. Medications included Terocin lotion, Gabacyclotram cream, Flurbi (NAP) cream, Genicin and Somnicin. The patient is temporarily totally disabled, as per the same progress report. The MTUS guidelines p111 and Topical Analgesics section on topical lidocaine states: "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). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain." MTUS further states: "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, a prescription for Terocin lotion is first noted in progress report dated 03/27/14, and the patient has been using it consistently since then. It is not clear when the topical was prescribed for the first time. In progress report dated 03/17/15, the treater states medications help reduce the pain from 7/10 to 3-4/10. As per the report, "topical creams and patches help decrease pain and use of oral medications, and allow the patient to stand longer." The treater, however, does not indicate where and how this topical will be used. Additionally, Terocin contains Lidocaine and MTUS supports the use of this component only in the form of a patch. The Guidelines also provide clear discussion regarding topical compounded creams on pg 111. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Additionally, the treater does not indicate where and how the cream will be used. Hence, the request IS NOT medically necessary.

Flurbi Cream LA 10gm, Flurbiprofen 20%-Lidocaine 5%-Amitriptyline 4%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

Decision rationale: The patient complains pain in the left knee, rated at 2/10, radiating to the left lower extremity along with anxiety, insomnia and stomach cramps, as per progress report dated

04/15/15. The request is for FLURBI CREAM LA 10gm, FLURBIPROFEN 20%-LIDOCAINE 5%-AMITRITYLINE 4%. There is no RFA for this case, and the patient's date of injury is 04/08/13. The patient is status post left knee arthroscopy on 10/03/14, as per progress report dated 04/15/15. Diagnoses included clinical evidence of positive examination, r/o medial meniscal tear. Diagnoses, as per progress report dated 03/17/15, included lumbar radiculopathy, lumbar spinal stenosis, lumbar facet syndrome, and right shoulder tendinitis. Medications included Terocin lotion, Gabacyclotram cream, Flurbi (NAP) cream, Genicin and Somnicin. The patient is temporarily totally disabled, as per the same progress report. MTUS Chronic pain guidelines have the following regarding topical creams on page 111 and Topical Analgesics section: Non-steroidal antiinflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. In this case, a prescription for Flurbi cream LA is first noted in progress report dated 03/27/14, and the patient has been using it consistently since then. It is not clear when the topical was prescribed for the first time. In progress report dated 03/17/15, the treater states medications help reduce the pain from 7/10 to 3-4/10. As per the report, "topical creams and patches help decrease pain and use of oral medications, and allow the patient to stand longer." The topical formulation contains Lidocaine and MTUS supports the use of this component only in the form of a patch. Additionally, topical NSAIDs are approved for arthritis pain but they are not indicated for spinal, shoulder conditions, and the treater does not indicate where and how this topical will be used. The Guidelines also provide clear discussion regarding topical compounded creams on pg 111. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Additionally, the treater does not indicate where and how the cream will be used. Hence, the request IS NOT medically necessary.

Gabacyclotram 180mg, Gabapenting 10%-Cyclobenzaprine 6%- Tramadol 10%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

Decision rationale: The patient complains pain in the left knee, rated at 2/10, radiating to the left lower extremity along with anxiety, insomnia and stomach cramps, as per progress report dated 04/15/15. The request is for GABACYCLOTRAM 180mg, GABAPENTIN 10%-CYCLOBENZAPRINE 6%- TRAMADOL 10%. There is no RFA for this case, and the patient's date of injury is 04/08/13. The patient is status post left knee arthroscopy on 10/03/14, as per progress report dated 04/15/15. Diagnoses included clinical evidence of positive examination, r/o medial meniscal tear. Diagnoses, as per progress report dated 03/17/15, included lumbar radiculopathy, lumbar spinal stenosis, lumbar facet syndrome, and right shoulder tendinitis.

Medications included Terocin lotion, Gabacyclotram cream, Flurbi (NAP) cream, Genicin and Somnicin. The patient is temporarily totally disabled, as per the same progress report. MTUS guidelines on page 111 and Topical Analgesics section, state that "Gabapentin: Not recommended. There is no peer-reviewed literature to support use." Additionally, the guidelines state that there is no evidence for use of any muscle relaxants such as cyclobenzaprine as a topical product. MTUS Guidelines also provide clear discussion regarding topical compounded creams on pg 111. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, a prescription for Gabacyclotram is first noted in progress report dated 03/27/14, and the patient has been using it consistently since then. It is not clear when the topical was prescribed for the first time. In progress report dated 03/17/15, the treater states medications help reduce the pain from 7/10 to 3-4/10. As per the report, "topical creams and patches help decrease pain and use of oral medications, and allow the patient to stand longer." The treater, however, does not indicate where and how this topical will be used. Additionally, this topical formulation contains Gabapentin and Cyclobenzaprine which are not recommended by MTUS. MTUS Guidelines also provide clear discussion regarding topical compounded creams on pg 111. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. This request IS NOT medically necessary.

Retrospective request for MEDS x 1 Genicin #90 capsules glucosamine sodium 500mg:
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 Glucosamine (and Chondroitin Sulfate) Page(s): 50.

Decision rationale: The patient complains pain in the left knee, rated at 2/10, radiating to the left lower extremity along with anxiety, insomnia and stomach cramps, as per progress report dated 04/15/15. The request is for RETROSPECTIVE REQUEST FOR MEDS x 1 GENICIN #90 CAPSULES GLUCOSAMINE SODIUM 500mg. There is no RFA for this case, and the patient's date of injury is 04/08/13. The patient is status post left knee arthroscopy on 10/03/14, as per progress report dated 04/15/15. Diagnoses included clinical evidence of positive examination, r/o medial meniscal tear. Diagnoses, as per progress report dated 03/17/15, included lumbar radiculopathy, lumbar spinal stenosis, lumbar facet syndrome, and right shoulder tendinitis. Medications included Terocin lotion, Gabacyclotram cream, Flurbi (NAP) cream, Genicin and Somnicin. The patient is temporarily totally disabled, as per the same progress report. MTUS Chronic Pain Medical Treatment Guidelines, page 50 under Glucosamine (and Chondroitin Sulfate) states: "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)." In this case, a prescription for Genicin is first noted in progress report dated 03/27/14, and the patient has been using it consistently since then. It is not clear when the medication was prescribed for the first time. In

progress report dated 03/17/15, the treater states medications help reduce the pain from 7/10 to 3-4/10. MTUS supports the use of Glucosamine in patients with moderate arthritis pain. While this patient suffers from left knee pain due to possible medial meniscal tear, there is no diagnosis of arthritis for which the medication is indicated. Hence, the request IS NOT medically necessary.

Somnicin #30 capsules melatonin 2mg: 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 under somnicin.

Decision rationale: The patient complains pain in the left knee, rated at 2/10, radiating to the left lower extremity along with anxiety, insomnia and stomach cramps, as per progress report dated 04/15/15. The request is for SOMNICIN #30 CAPSULES MELATONIN 2mg. There is no RFA for this case, and the patient's date of injury is 04/08/13. The patient is status post left knee arthroscopy on 10/03/14, as per progress report dated 04/15/15. Diagnoses included clinical evidence of positive examination, r/o medial meniscal tear. Diagnoses, as per progress report dated 03/17/15, included lumbar radiculopathy, lumbar spinal stenosis, lumbar facet syndrome, and right shoulder tendinitis. Medications included Terocin lotion, Gabacyclotram cream, Flurbi (NAP) cream, Genicin and Somnicin. The patient is temporarily totally disabled, as per the same progress report. The MTUS and ACOEM Guidelines do not address this request. However, ODG Guidelines under the Pain Chapter on Somnicin states: "Not recommended." Somnicin, a nutritional supplement, contains melatonin, magnesium oxide, oxitriptan (the L form of 5-hydroxytryptophan), 5-hydroxytryptophan, tryptophan and Vitamin B6 (pyridoxine). It is postulated as a treatment for insomnia, anxiety and depression. Melatonin appears to reduce sleep onset latency and is used for delayed sleep phase syndrome. In this case, a prescription for Somnicin is first noted in progress report dated 03/27/14, and the patient has been using it consistently since then. It is not clear when the medication was prescribed for the first time. The patient does suffer from anxiety and insomnia, as per progress report dated 04/15/15. The treater, however, does not document the efficacy of Somnicin in this patient. Additionally, ODG does not support this medication at this time owing to a lack of clinical studies showing evidence for the efficacy of this particular formulation as a sleep aid. Therefore, the request IS NOT medically necessary.