MAXIMUS Federal Services

Case Number:	CM14-0079679		
Date Assigned:	08/08/2014	Date of Injury:	04/13/2006
Decision Date:	09/17/2014	UR Denial Date:	04/29/2014
Priority:	Standard	Application Received:	05/30/2014

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 Physical Medicine & Rehabilitation, has a subspecialty in Pain 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:

The injured worker is a 27-year-old female who reported injury on 04/13/2006. The mechanism of injury, surgical history and prior treatments were not provided. The documentation of 02/11/2014, revealed the injured worker was diagnosed with cervical sprain/strain and lumbosacral sprain/strain with radiculopathy, particularly on the left lower extremity. The subjective complaints included stabbing low back pain radiating into the left lower extremity and her foot. The pain was noted to be 7/10 to 8/10 with weakness. The physical examination revealed decreased sensation over the left lower extremity at L4-5 dermatomes. The injured worker had decreased patellar reflexes as well as decreased Achilles reflex on the left compared to the right. The injured worker had a decrease in motor strength of 4/5 at the lower extremity. The injured worker had tenderness to palpation in the bilateral columns of the lumbar spine. The injured worker had sciatic notch tenderness on the left side. The injured worker had a positive straight leg raise at 65 degrees. The treatment plan included topical compounds and creams to reduce any injudicious use of prescription drugs, a urine drug screen, genetic testing, Terocin, Flurbi cream, Somnicin, Laxacin, Gabacyclotram, and Xolido, a spine surgical consultation, Vicodin 7.5/325 mg, and ibuprofen 800 mg, x-rays of the flexion and extension of the lumbar spine, and an updated MRI of the lumbar spine. The injured worker subsequently underwent an MRI of the lumbar spine on 03/25/2014, which revealed there was satisfactory range of motion in flexion and extension, no instability, and no fractures. There was no Request for Authorization submitted for review for the requested procedures.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin cream (no dosage or quantity given): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals; Topical Analgesic; Topical Capsaicin; Lidocaine Page(s): 105; 111; 28; 112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:http://www.drugs.com/search.php?searchterm=Terocin.

Decision rationale: The California MTUS guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. The guidelines indicate that topical lidocaine (Lidoderm) 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). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The guidelines recommend treatment with topical salicylates. Per Drugs.com, Terocin is a topical analgesic containing Capsaicin / Lidocaine / Menthol / Methyl Salicylate. The clinical documentation submitted for review failed to indicate the injured worker had trialed and failed antidepressants and anticonvulsants and had not responded or was intolerant to other treatments. The duration of use could not be established. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. The request as submitted failed to indicate the frequency, dosage, and quantity of Terocin cream being requested. Additionally, there was a lack of documentation indicating a necessity for 3 topical forms of lidocaine as this review was concurrently being reviewed with Xolido, which is a topical form of lidocaine. Given the above, the request for Terocin cream (no dosage or quantity given) is not medically necessary.

Flurbi Cream (no dosage or quantity given): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen; Topical analgesics; Lidocaine; Antidepressants Page(s): 72; 111; 112; 13. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Skolnick P (1999) Antidepressants for the new millennium. Eur J Pharmacol 375:31-40.

Decision rationale: The California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have

failed. Topical non-steroidal anti-inflammatory drugs (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. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Flurbiprofen is not currently Food and Drug Administration (FDA) approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. The guidelines indicate that topical lidocaine (Lidoderm) 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). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Per Skolnick, P. (1999) "while local peripheral administration of antidepressants has been demonstrated to produce analgesia in the formalin model of tonic pain; a number of actions, to include inhibition of noradrenaline (NA) and 5-HT reuptake, inhibition of NMDA, nicotinic, histamine, and 5-HT receptors, and block of ion channels and even combinations of these actions, may contribute to the local peripheral efficacy of antidepressant; therefore the contribution of these actions to analgesia by antidepressants, following either systemic or local administration, remains to be determined". The clinical documentation submitted for review failed to provide the injured worker had a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation indicating a necessity for 3 topical formulations of lidocaine. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. The request as submitted failed to indicate the frequency, quantity, and dosage. The duration of use could not be established. Given the above, the request for Flurbi cream (no dosage or quantity given) is not medically necessary.

Somnicin (no dosage or quantity given): 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 TreatmentOther Medical Treatment Guideline or Medical Evidence:http://sales.advancedrxmgt.com/sales-content/uploads/2012/04/Somnicin-Patient-Info-Sheet.pdf.

Decision rationale: The Official Disability Guidelines (ODG) indicates that non-pharmacologic treatment includes stimulus control, progressive muscle relaxation, and paradoxical intention and is a first line treatment for insomnia. Per advancedrxmgmt.com, the ingredients include Melatonin, 5-HTP, L-tryptophan, compound B-6 and Magnesium. Additionally, the Official Disability Guidelines, melatonin is recommended in the treatment of sleep disorders. A thorough search of the California MTUS, Official Disability Guidelines, and the National Guideline Clearinghouse failed to reveal guidelines or scientific evidence to L-tryptophan, pyridoxine, or magnesium in the management of insomnia. The duration of use could not be established. If the

medication was not utilized for the first instance, there was a lack of documentation of objective functional benefit received. The request as submitted failed to indicate the dosage, frequency, and quantity. Given the above, the request for Somnicin (no dosage or quantity given) is not medically necessary.

Laxacin (no dosage or quantity given): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Initiation of Opioid Therapy Page(s): 77.

Decision rationale: The California MTUS Guidelines recommend the prophylactic use of medications for constipation when initiating opioid therapy. The clinical documentation submitted for review indicated the injured worker was on opioid therapy. However, there was a lack of documentation indicating the injured worker had a necessity for medications for constipation. The duration of use could not be established. The request as submitted failed to indicate the frequency, quantity, and dosage. Given the above, the request for Laxacin (no dosage or quantity given) is not medically necessary.

Gabacyclotram:

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine; Topical Analgesics; Gabapentin; Tramadol Page(s): 41; 111; 113; 82. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA.gov.

Decision rationale: The California MTUS guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Gabapentin is not recommended. There is no peer-reviewed literature to support use. Other anti-epilepsy drugs: There is no evidence for use of any other anti-epilepsy drug as a topical product do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is not recommended. A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been Food and Drug Administration (FDA) approved. Additionally, per CA MTUS, the approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy. The clinical documentation submitted for review failed to indicate the injured worker had a trial of failure of anticonvulsants and antidepressants. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. The duration of use could not

be established. The request as submitted failed to indicate the frequency, quantity, and strength for the requested medication. Given the above, the request for Gabacyclotram is not medically necessary.

Xolido: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Topical Lidocaine Page(s): 111; 112.

Decision rationale: The California MTUS guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. 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. This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. They further indicate that research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia and that formulation that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The clinical documentation submitted for review failed to provide the injured worker had a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation indicating a necessity for 3 topical formulations including lidocaine. The duration of use could not be established. The request as submitted failed to indicate the frequency, strength, and quantity for the requested medication. Given the above, the request for Xolido is not medically necessary.