

Case Number:	CM14-0026501		
Date Assigned:	06/13/2014	Date of Injury:	12/04/2012
Decision Date:	07/23/2014	UR Denial Date:	02/19/2014
Priority:	Standard	Application Received:	03/03/2014

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 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 59-year-old male who reported an injury on 12/04/2012. The mechanism of injury was not provided in the documentation. The MRI of the lumbar spine dated 02/25/2013 revealed unroofing of the disc with posterior annular tear and disc protrusion at L5-S1, no evidence of spinal stenosis, moderate bilateral neural foraminal narrowing at L5-S1, mild bilateral facet arthropathy at L4-5, moderate bilateral facet arthropathy at L5-S1, disc desiccation at L2-3 and L5-S1, and a grade I retrolisthesis at L5 on S1. Per the evaluation dated 01/15/2014, the injured worker was reported to have decreased range of motion to the lumbar spine, decreased strength at 3-/5, and tenderness to the lumbosacral region. Per the clinical note the injured worker reported continued constant low back pain which was sharp and burning and rated 8/10, constant left leg pain rated 8/10, constant left knee pain, left leg numbness and cramping, and a pins and needles sensation. Prior treatments included medications and imaging studies. The injured worker had diagnoses including radiculopathy with disc herniation of the lumbosacral area with spondylolisthesis. The Request for authorization for medical treatment for the Xolido, Terocin, flurbi lido, amitriptyline, gabacyclotram, Somnicin, and Laxacin was not provided in the documentation, nor was the provider's rationale for the medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

XOLIDO (LIDOCAINE): Upheld

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

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

Decision rationale: Per the California MTUS Guidelines, topical analgesics are recommended as an option; however, they 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. Any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended for use. Topical lidocaine in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulation of lidocaine, whether it is creams, lotions, or gels, are indicated for neuropathic pain. There is a lack of documentation indicating the injured worker has neuropathic pain. There is a lack of documentation regarding oral medications and the efficacy of those medications. There is also a lack of documentation regarding trials of antidepressants and anticonvulsants prior to the request for the topical agent and the efficacy of those medications. The guidelines do not recommend the use of Lidocaine for topical application in the form of creams, lotions, or gels. Additionally, the request does not indicate the frequency at which the medication is prescribed in order to determine the necessity of the medication. Therefore, the request is not medically necessary.

TEROCIN (METHYL SALICYLATE, CAPSAICIN, MENTHOL, AND LIDOCAINE), QTY: 240 ML: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate topicals, Topical analgesics Page(s): 105 and 111-112.

Decision rationale: Terocin lotion contains methyl salicylate, capsaicin, menthol, and lidocaine. Per the California MTUS Guidelines, topical analgesics are recommended as an option, although they 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. Any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended for use. Topical lidocaine in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine, whether it is creams, lotions, or gels, are indicated for neuropathic pain. Capsaicin is recommended only as an option in patients who have not responded to, or are intolerant of, other treatments. There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Topical salicylate is recommended as significantly better than placebo in chronic pain. There is a lack of documentation regarding the previous use of this medication and its efficacy. As Lidocaine is not recommended for topical application in forms other than Lidoderm, the medication would not be

indicated. Additionally, the request does not indicate the frequency at which the medication is prescribed and the site at which it is to be applied in order to determine the necessity of its use. Therefore, the request is not medically necessary.

FLURBI (FLURBIPROFEN, LIDOCAINE, AMITRIPTYLINE), QTY: 180 GM: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-112. Decision based on Non-MTUS Citation David J. Kopsky MD and Jan M. Keppel Hesselink MD, MSc, PhD, 2012. High Doses of Topical Amitriptyline in Neuropathic Pain: Two Cases and Literature Review. Pain Practice, Volume 12, Issue 2, pages 148-153.

Decision rationale: Per the California MTUS Guidelines, topical analgesics are recommended as an option; however, they 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. Any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended for use. The guidelines recommend topical Nonsteroidal anti-inflammatory drugs (NSAIDs) for osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment 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. Topical lidocaine in the formulation of a dermal patch has been designated for orphan status by the FDA. No other commercially approved topical formulations of lidocaine, whether creams, lotions, or gels, are indicated for neuropathic pain. In an article authored by Kopsky and Hesselink it is noted that high dose topical amitriptyline might be a useful adjunct to treat severe and intractable neuropathic pain, although previous trials were inconsistent in reporting efficacy of topical amitriptyline cream. The effect of an antidepressant such as amitriptyline in combination with other classes of drugs has not been well-researched. There is a lack of documentation regarding the use of this medication and the efficacy of the medication. There is a lack of documentation regarding a failed trial of antidepressants and anticonvulsants. The documentation provided does not indicate the injured worker has a diagnosis for which topical NSAID use would be indicated. Studies indicate the effect of an antidepressant such as amitriptyline in combination with other classes of drugs has not been well-researched. In addition, the request did not include frequency information or site of application for the medication. Additionally, the request does not indicate the frequency at which the medication is prescribed and the site at which it is to be applied in order to determine the necessity of the medication. Therefore, the request is not medically necessary.

GABACYCLOTRAM (GABAPENTIN, CYCLOBENZAPRINE, TRAMADOL), QTY: 180GM: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 113. Decision based on Non-MTUS Citation Effectiveness of topical administration of opioids in palliative care: a systematic review. B LeBon, G Zeppetella, J Higginson - Journal of pain and symptoms, 2009 - Elsevier.

Decision rationale: Per the California MTUS Guidelines, topical analgesics are recommended as an option; however, they 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. Any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended for use. There is no peer reviewed literature to support the use of Gabapentin as a topical agent and it is not recommended. There is no evidence for the use of other muscle relaxants, such as cyclobenzaprine for topical application. Peer reviewed literature states that there is a deficiency of higher quality evidence on topical opioids, and that more robust primary studies are required to inform practice reviews. There is a lack of documentation regarding a failed trial of antidepressants and anticonvulsants. The request does not indicate the frequency at which the medication is prescribed and the site at which it is to be applied in order to determine the necessity of the medication. Therefore, the request is not medically necessary.

SOMNICIN (HYDROXYTRYPTOPHEN, MAGNESIUM, MELATONIN, PYRIDOXINE, TRYPTOPHAN- FOR ANXIETY/ INSOMNIA), QTY: 30: Upheld

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

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

Decision rationale: Somnicin is comprised of Melatonin 2 mg, 5-HTP (5-hydroxytryptophan) 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 Official Disability Guidelines note 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 Official Disability Guidelines note Melatonin is recommended in treating sleep disorder post traumatic brain injury (TBI). Hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, sleep disorders and depression. Per the Official Disability Guidelines, medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician, and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements based on recognized scientific principles are established by medical evaluation. To be considered, the product must meet the following criteria: the product must be a food for oral

or tube feeding, the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements, and the product must have been used under medical supervision. There is a lack of documentation regarding the use of this medication and the efficacy of the medication. There is a lack of documentation regarding assessment and consideration of alternative treatments. The guidelines do not recommend vitamin B and there is no indication that the injured worker has suffered a traumatic brain injury. Additionally, the request does not indicate the frequency at which the medication is prescribed in order to determine the necessity of the medication. Therefore, the request is not medically necessary.

LAXACIN (DOCUSATE SODIUM, SENNA), QTY: 100: 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 Opioids Page(s): 77.

Decision rationale: The California MTUS Guidelines recommend prophylactic treatment of constipation should be initiated when opioid therapy is initiated. There is a lack of documentation indicating the injured worker is experiencing constipation. The efficacy of the medication being used is not indicated within the provided medical records. There is a lack of documentation regarding the injured worker's use of opioids for which prophylactic treatment of constipation is initiated. Additionally, the request does not indicate the frequency at which the medication is prescribed in order to determine the necessity of the medication. Therefore, the request is not medically necessary.