

Case Number:	CM14-0142131		
Date Assigned:	09/12/2014	Date of Injury:	09/26/1997
Decision Date:	10/14/2014	UR Denial Date:	08/27/2014
Priority:	Standard	Application Received:	09/03/2014

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 Emergency Medicine and is licensed to practice in New York. 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 patient is a 76-year-old male who was injured on September 26, 1997. The patient continued to experience pain in his low back, which radiates into both legs. Physical examination was not documented in the available medical records. Diagnoses included lumbar degenerative joint disease, lumbar generative disc disease, lumbosacral facet syndrome, right radiculopathy, and plantar fasciitis. Treatment included medications, H-wave unit, and spinal cord stimulator. Requests for authorization for Zanaflex 4 mg # 90, Flurbi (NAP) cream #180, Gabacyclotram cream, Terocin patches # 30, Genecin cream, Gabapentin, pain management referral, lumbar injections, and physical therapy 8 sessions were submitted for consideration.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zanaflex 4mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 63, 65.

Decision rationale: Tizanidine is a muscle relaxant that acts centrally as an alpha2-adrenergic agonist that is FDA approved for management of spasticity. Side effects include somnolence,

dizziness, dry mouth, hypotension, weakness, and hepatotoxicity. Non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment (less than two weeks) of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. In this case the request was for 90 pills, indicating long-term use of the muscle relaxant. The duration of treatment surpasses the term duration of two weeks. The request should not be authorized.

Flurbi (NAP) Cream #180: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 15, 111-112.

Decision rationale: Flurbi (NAP) cream is a compounded topical analgesic containing Flurbiprofen, Lidocaine, and Amitriptyline. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Flurbiprofen is a non-steroidal anti-inflammatory drug (NSAID). Flurbiprofen is recommended as an oral agent for the treatment of osteoarthritis and the treatment of mild to moderate pain. It is not recommended as a topical preparation. Lidocaine is recommended for localized peripheral pain after the evidence of a trial for first-line therapy, such as an antidepressant or antiepileptic drug. It is only FDA approved for the treatment of post-herpetic neuralgia. The guidelines state that further research is needed to recommend this treatment for chronic neuropathic pain. It is not recommended. Amitriptyline is a tricyclic antidepressant. Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. They are contraindicated in patients with cardiac conduction disturbances or epilepsy. They can create anticholinergic side effects of dry mouth, sweating, dizziness, orthostatic hypotension, fatigue, constipation, and urinary retention. Tricyclics are not recommended as a topical preparation. This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request should not be authorized.

Gabacyclotram Cream: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 111-112.

Decision rationale: Gabacyclotram cream is a compounded topical analgesic containing Gabapentin, Cyclobenzaprine, and Tramadol. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "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. Cyclobenzaprine is a muscle relaxant. There is no evidence for use of any muscle relaxant as a topical product. Tramadol is a synthetic opioid affecting the central nervous system. It has several side effects, which include increasing the risk of seizure in patients taking SSRI's, TCA's and other opioids. It is not recommended as a topical medication. This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request should not be authorized.

Terocin Patches #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 28, 105, 111-112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Treatment Guidelines from the Medical Letter, April 1, 2013, Issue 128: Drugs for Pain Interventions and Guidelines

Decision rationale: Terocin is a topical multidrug compound, which contains Methylsalicylate, Lidocaine, Capsaicin, and Menthol. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Methylsalicylate is a topical salicylate and is recommended, being significantly better than placebo in chronic pain. Lidocaine is recommended for localized peripheral pain after the evidence of a trial for first-line therapy. It is only FDA approved for the treatment of post-herpetic neuralgia. The guidelines state that further research is needed to recommend this treatment for chronic neuropathic pain. Capsaicin is recommended only as an option in patients who have not responded or cannot tolerate other treatments. It is recommended for osteoarthritis, fibromyalgia, and chronic non-specific back pain and is considered experimental in high doses. Topical analgesics containing Menthol, Methylsalicylate or Capsaicin are generally well-tolerated, but there have been rare reports of severe skin burns requiring treatment or hospitalization. This medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request should not be authorized.

Genecin #90: 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 Pain Interventions and Guidelines Page(s): 50.

Decision rationale: Genecin is not found on Google search and is presumed to be Genicin, which is Glucosamine. It is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. In this case the patient is not suffering from osteoarthritis. There is no recommendation for the use of Glucosamine in for lumbar spine pain. The request should not be authorized.

Gabapentin (Dosage Unspecified): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 18-19.

Decision rationale: Gabapentin is an anti-epileptic medication. Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain and has FDA approval for treatment of post-herpetic neuralgia. Gabapentin appears to be effective in reducing abnormal hypersensitivity, to have anti-anxiety effects, and may be beneficial as a sleep aid. Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, dry mouth, and weight gain. It has been recommended for the treatment of pain from spinal cord injury, fibromyalgia, lumbar spinal stenosis, and chronic regional pain syndrome. Recommended trial period is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. If inadequate control of pain is found, a switch to another first-line drug is recommended. In this case there is no documentation to support that the patient is experiencing neuropathic pain or that the medication has been effective. Medical necessity is not supported by the documentation in the medical record. The request should not be authorized.

Pain Management Referral: 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 Other Medical Treatment Guideline or Medical Evidence: UpToDate; Evaluation of Chronic Pain in Adults

Decision rationale: Many patients with chronic pain may be managed without specialty referral. Patients may require referral to a pain specialist for the following reasons: - Symptoms that are debilitating- Symptoms located at multiple sites- Symptoms that do not respond to initial therapies- Escalating need for pain medication In this case the referral for pain management was for lumbar injections. There is no medical indication for lumbar injections. The request should not be authorized.

Lumbar Injections (Unspecified): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 46.

Decision rationale: Epidural steroid injections are recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy). Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing. Epidural steroid injection can offer short term pain relief and use should be in conjunction with other rehab efforts, including continuing a home exercise program. There is little information on improved function. The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. In this case the documentation does not support the presence of radicular pain on physical examination and there is no corroboration by imaging and/or electrodiagnostic testing. Medical necessity has not been established. The request should not be authorized.

Physical Therapy x 8: 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 Pain Interventions and Guidelines Page(s): 898-899.

Decision rationale: Chronic Pain Medical Treatment Guidelines state that there is no high-grade scientific evidence to support the effectiveness or ineffectiveness of passive physical modalities such as traction, heat/cold applications, massage, diathermy, TENS units, ultrasound, laser treatment, or biofeedback. They can provide short-term relief during the early phases of treatment. Active treatment is associated with better outcomes and can be managed as a home exercise program with supervision. ODG states that physical therapy is more effective in short-term follow up. Patients should be formally assessed after a "six-visit clinical trial" to see if the patient is moving in a positive direction, no direction, or a negative direction (prior to continuing

with the physical therapy). When treatment duration and/or number of visits exceed the guideline, exceptional factors should be noted. Recommended number of visits for myalgia and myositis is 9-10 visits over 8 weeks; and for neuralgia, neuritis, and radiculitis is 8-10 visits over 4 weeks. In this case the request for 8 physical therapy visits surpasses the recommended number of 6 for clinical trial to determine the effectiveness of treatment. The request should not be authorized.