

Case Number:	CM13-0013276		
Date Assigned:	11/08/2013	Date of Injury:	02/16/2005
Decision Date:	03/09/2015	UR Denial Date:	07/30/2013
Priority:	Standard	Application Received:	08/16/2013

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: Family Practice

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 female suffered an industrial injury on 3/31/12, with subsequent ongoing low back, right shoulder and neck pain. MRI right shoulder (5/14/12) showed a partial thickness tear of the rotator cuff. MRI cervical spine (5/14/12) showed left C5-6 disc herniation. MRI lumbar spine (8/4/12) showed discogenic changes with disc bulge at L5-S1. Treatment included a lumbar support, wrist splint, medications, epidural steroid injections, right shoulder injections, acupuncture, chiropractic care, pain management consultation, physical therapy, cognitive behavioral therapy and medications. In a PR-2 dated 7/16/13, the injured worker complained of neck, right shoulder and low back pain at a 4/10 on the visual analog scale with radiation down the right arm into the right thumb and index finger. The injured worker reported greater than 50% improvement to symptoms with Savella in the past without side effects. Physical exam was remarkable for right shoulder with decreased and painful range of motion, right shoulder with decreased grip strength 3/5 and neck with diffuse tenderness and decreased range of motion. Current diagnoses included chronic pain syndrome, neck and lumbar sprain/strain, degenerative lumbar disc and frozen shoulder. Work status was modified limiting weight lifting to under 10 pounds. The treatment plan included restarting Savella 12.5 mg, one tab daily, continuing Naprosyn 500mg and Flector Patch 1.3%, continuing home exercises and considering a multidisciplinary evaluation due to chronicity of injury and inadequate response to treatment. On 7/31/13, Utilization Review noncertified a request for a Trial of Savella 12.5 mg #30 and Flector Patch 1.3% daily # 30. Utilization Review certified a request for Naprosyn 500mg at

bedtime #60. Utilization Review cited CA MTUS 2009: 9792.24.2 Chronic Pain Medical Treatment Guidelines, pg. 67-68, 73.

IMR ISSUES, DECISIONS AND RATIONALES

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

TRIAL OF SAVELLA 12.5MG #30 .: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 62.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for Chronic Pain/SNRIs Page(s): 13-16.

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of anti-depressants as a treatment modality. Savella is a serotonin norepinephrine reuptake inhibitor (SNRI). In general, antidepressants are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment.

Neuropathic pain: Recommended (tricyclic antidepressants) as a first-line option, especially if pain is accompanied by insomnia, anxiety, or depression. Other recent reviews recommended both tricyclic antidepressants and SNRIs (i.e., duloxetine and venlafaxine) as first line options. Non-neuropathic pain: Recommended as an option in depressed patients, but effectiveness is limited. Non-neuropathic pain is generally treated with analgesics and anti-inflammatories. In guidelines for painful rheumatic conditions recommended by Perrot, it was suggested that antidepressants may be prescribed as analgesics in non-depressed patients, with the first-line choice being tricyclics initiated at a low dose, increasing to a maximally tolerated dose.

Specific studied disease states

Low Back Pain: Chronic: A systematic review indicated that tricyclic antidepressants have demonstrated a small to moderate effect on chronic low back pain (short-term pain relief), but the effect on function is unclear. This effect appeared to be based on inhibition of norepinephrine reuptake. SSRIs have not been shown to be effective for low back pain (there was not a significant difference between SSRIs and placebo) and SNRIs have not been evaluated for this condition. Reviews that have studied the treatment of low back pain with tricyclic antidepressants found them to be slightly more effective than placebo for the relief of pain. A non-statistically significant improvement was also noted in improvement of functioning. SSRIs do not appear to be beneficial.

Radiculopathy: Antidepressants are an option, but there are no specific medications that have been proven in high quality studies to be efficacious for treatment of lumbosacral radiculopathy. In this case, there is insufficient documentation as to the rationale for the use of Savella. While there is insufficient evidence for neuropathic pain as a contributing factor, there is no evidence that the patient has been given a trial of a tricyclic antidepressant, as recommended in the cited guidelines. If Savella is being used for chronic low back pain, the MTUS guidelines do not support the use of an SNRI. For these reasons, Savella is not considered as medically necessary.

FLECTOR PATCH 1.3 PERCENT DAILY #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

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

Decision rationale: The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of topical analgesics, such as Flector, as a treatment modality. These guidelines state the following: Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adenosine, cannabinoids, cholinergic receptor agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. 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. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended 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. Neuropathic pain: Not recommended as there is no evidence to support use. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). In this case, there is insufficient documentation to support the rationale for the use of this topical NSAID. If the indication was for neuropathic pain, there is no evidence that the patient has had a sufficient trial of an antidepressant or anticonvulsant. If it was intended for the treatment of osteoarthritis or the patient's spine complaints, the above cited guidelines do not support its use. Finally, there is no evidence to support the long-term use of this medication. Given these concerns, a Flector Patch is not considered as a medically necessary treatment.

