

Case Number:	CM13-0034647		
Date Assigned:	12/11/2013	Date of Injury:	09/12/2003
Decision Date:	04/10/2014	UR Denial Date:	09/06/2013
Priority:	Standard	Application Received:	10/15/2013

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. The expert reviewer is Board Certified in Physical Medicine and 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:

This is a male patient with the date of injury of September 12, 2003. A utilization review determination dated September 6, 2013 recommends non-certification of Medrox patch 1 top ever HS #30, Benadryl 25mg 1-2 PO every HS #60, Calis 10mg 2 PO 30 prior to SA #10, and Ambien CR 12.5mg 1 PO every HS #30. The previous reviewing physician recommended non-certification of Medrox patch 1 top ever HS #30 due to multiple other analgesic medications and antiseizure medication being used with no evidence of intolerance to substantiate the need for this transdermal product; non-certification of Benadryl 25mg 1-2 PO every HS #60 due to lack of documentation evidence based guidelines support for its use in this clinical setting of chronic pain; non-certification of Calis 10mg 2 PO 30 prior to SA #10 due to lack of documentation of the cause of sexual dysfunction; and non-certification of Ambien CR 12.5mg 1 PO every HS #30 due to lack of documentation of evidence based guidelines support. A PR-2 Report dated August 13, 2013 identifies Subjective Complaints of low back pain and left leg pain and numbness and headaches. He had spine surgery July 16, 2013 for hardware removal. Objective Findings identifies swelling above incision. Diagnoses identify severe lumbar radiculopathy, chronic pain syndrome, prescription narcotic dependence, post-laminectomy syndrome, myofascial syndrome, neuropathic pain, chronic pain related insomnia, chronic pain related anxiety, chronic pain related depression, and chronic pain related sexual dysfunction. Treatment Plan identifies refill medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

MEDROX PATCH 1 TOP EVER HS #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation NON-MTUS

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

Decision rationale: Regarding the request for Medrox patch 1 top ever HS #30, Medrox is a combination of methyl salicylate, menthol, and capsaicin. Chronic Pain Medical Treatment Guidelines state that any compounded product that contains at least one drug or drug class that is not recommended, is not recommended. Regarding the use of topical nonsteroidal anti-inflammatory, guidelines state that 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 1st 2 weeks of treatment for osteoarthritis arthritis, but either not afterwards, or with the diminishing effect over another two-week period. Guidelines go on to state that there is little evidence to utilize topical NSAIDs for the treatment of osteoarthritis of the spine, hip, or shoulder. Regarding the use of capsaicin, guidelines state that it is recommended only as an option for patients who have not responded to, or are intolerant to other treatments. Within the documentation available for review, there is no indication that the patient is unable to tolerate oral NSAIDs. Oral NSAIDs have significantly more guideline support compared with topical NSAIDs. Additionally, there is no indication that the topical NSAID is going to be used only for short duration, as recommended by guidelines. Furthermore, guidelines do not support the use of topical NSAIDs for treatment of the spine. Finally, there is no indication that the patient has been intolerant to, or not responded to other treatments prior to the initiation of capsaicin therapy. In the absence of clarity regarding those issues, the currently requested Medrox patch 1 top ever HS #30 is not medically necessary.

BENADRYL 25MG 1-2 PO EVERY HS #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation NON-MTUS

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 treatment

Decision rationale: Regarding the request for Benadryl 25mg 1-2 PO every HS #60, California MTUS guidelines are silent regarding the use of sedative over-the-counter medications. ODG states sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. They go on to state the failure of sleep disturbances to resolve in 7 to 10 days, may indicate a psychiatric or medical illness. Within the documentation available for review, there are no subjective complaints of insomnia, no discussion regarding how frequently the insomnia complaints occur or how long they have been occurring, no statement indicating what behavioral treatments have been attempted for the

condition of insomnia, and no statement indicating how the patient has responded to treatment with Benadryl. Finally, there is no indication that Benadryl is being used for short term use as recommended by guidelines. In the absence of such documentation, the currently requested Benadryl 25mg 1-2 PO every HS #60 is not medically necessary.

CIALIS 10MG 2 PO 30 MIN PRIOR TO SA #10: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation NON-MTUS

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 110-111. Decision based on Non-MTUS Citation J Adv Pharm Technol Res. 2010 Jul-Sep; 1(3): 297-301, <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a604008.html>

Decision rationale: Regarding the request for Calis 10mg 2 PO 30 prior to SA #10, California MTUS guidelines are silent regarding the use of Cialis. Tadalafil (Cialis) is used to treat erectile dysfunction (ED, impotence; inability to get or keep an erection), and the symptoms of benign prostatic hyperplasia (BPH; an enlarged prostate) which include difficulty urinating (hesitation, dribbling, weak stream, and incomplete bladder emptying), painful urination, and urinary frequency and urgency in adult men. Guidelines also state that the etiology of male sexual dysfunction is muliti-factorial and requires adequate diagnostic work-up to determine an appropriate treatment course. Within the medical information made available for review, there is no documentation indicating that an adequate work-up for erectile dysfunction has been performed in an attempt to identify the etiology of the patient's sexual dysfunction. Additionally, there is no documentation regarding the efficacy of the medication, side effects, or evaluation of contraindications. As such, the currently requested Calis 10mg 2 PO 30 prior to SA #10 is not medically necessary.

AMBIEN CR 12.5MG 1 PO EVERY HS #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation NON-MTUS

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG) Chronic Pain, Sleep Medication

Decision rationale: Regarding the request for Ambien CR 12.5mg 1 PO every HS #30, California MTUS guidelines are silent regarding the use of sedative hypnotic agents. ODG recommends the short-term use (usually two to six weeks) of pharmacological agents only after careful evaluation of potential causes of sleep disturbance. They go on to state the failure of sleep disturbances to resolve in 7 to 10 days, may indicate a psychiatric or medical illness. Within the documentation available for review, there are no subjective complaints of insomnia, no discussion regarding how frequently the insomnia complaints occur or how long they have been occurring, no statement indicating what behavioral treatments have been attempted for the condition of insomnia, and no statement indicating how the patient has responded to Ambien

treatment. Finally, there is no indication that Ambien is being used for short term use as recommended by guidelines. In the absence of such documentation, the currently requested Ambien CR 12.5mg 1 PO every HS #30 is not medically necessary.