

Case Number:	CM15-0075127		
Date Assigned:	04/27/2015	Date of Injury:	12/26/2002
Decision Date:	05/28/2015	UR Denial Date:	04/21/2015
Priority:	Standard	Application Received:	04/20/2015

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: Physical Medicine & Rehabilitation

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 46 year old male, who sustained an industrial/work injury on 12/26/02. He reported initial complaints of back pain. The injured worker was diagnosed as having post laminectomy pain syndrome, asthma, depression, and anxiety. Treatment to date has included medication, lumbar brace, and diagnostics. Currently, the injured worker complains of ongoing back pain. Per the primary physician's progress report (PR-2) on 3/9/15, examination revealed use of a rigid lumbar brace support, antalgic gait, painful range of motion to the lumbar spine, positive straight leg raise bilaterally, and hypoesthesia in the left L5-S1 dermatome. The requested treatments include Senokot-S, Butrans Patch, and topical diclofenac & Lidoderm 5% Creams.

IMR ISSUES, DECISIONS AND RATIONALES

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

Senokot-S #30: 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 Pain chapter, Prophylactic treatment for constipation.

Decision rationale: The patient presents on 03/09/15 with unrated lower back pain. The patient's date of injury is 12/26/02. Patient is status post L5-S1 fusion with subsequent hardware removal at dates unspecified. The request is for SENOKOT-S #30. The RFA was not provided. Physical examination dated 03/09/15 reveals an antalgic gait, painful and limited range of motion in the lumbar spine, positive straight leg raise bilaterally, and hypoesthesia in the L5-S1 dermatome distribution. The patient is currently prescribed Trazodone, Advair, Senocot, topical Dicofenac/Lidocaine cream, and Butrans. Diagnostic imaging was not included. Patient's current work status is not provided. Regarding Opioid-induced constipation treatment, ODG Pain chapter recommends that Prophylactic treatment of constipation should be initiated, stating: "As first-line treatment, patient should be advised to increase physical activity, maintain appropriate hydration by drinking enough water, and follow a proper diet, rich in fiber. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool." In this case, the patient is prescribed Senokot for opiate-induced constipation. This patient has been taking Senokot since at least 12/15/14, though there is no discussion of efficacy in the subsequent reports. Constipation prophylaxis is generally considered an appropriate measure in patients taking opioid medications. However, the associated Butrans patches are not indicated owing to a lack of 4A's documentation, and this patient is not currently taking any other narcotic medications. Therefore, the request IS NOT medically necessary.

Butrans Patch 5mcg #4: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for the use of Opioids Buprenorphine Page(s): 77, 27.

Decision rationale: The patient presents on 03/09/15 with unrated lower back pain. The patient's date of injury is 12/26/02. Patient is status post L5-S1 fusion with subsequent hardware removal at dates unspecified. The request is for BUTRANS PATCH 5MCG #4. The RFA was not provided. Physical examination dated 03/09/15 reveals an antalgic gait, painful and limited range of motion in the lumbar spine, positive straight leg raise bilaterally, and hypoesthesia in the L5-S1 dermatome distribution. The patient is currently prescribed Trazodone, Advair, Senocot, topical Dicofenac/Lidocaine cream, and Butrans. Diagnostic imaging was not included. Patient's current work status is not provided. MTUS Guidelines page 77 under Criteria for the use of Opioids states: "Initiating Therapy: a. Intermittent pain: Start with a short-acting opioid trying one medication at a time. b. Continuous pain: extended-release opioids are recommended. Patients on this modality may require a dose of "rescue" opioids. The need for extra opioid can be a guide to determine the sustained release dose required. c. Only change 1 drug at a time. d. Prophylactic treatment of constipation should be initiated. e. If partial analgesia is not obtained, opioids should be discontinued." Specifically addressing Buprenorphine, MTUS page 27 has the

following: "Recommended. When used for treatment of opiate dependence, clinicians must be in compliance with the Drug Addiction Treatment Act of 2000. Buprenorphine's pharmacological and safety profile makes it an attractive treatment for patients addicted to opioids. Buprenorphine's usefulness stems from its unique pharmacological and safety profile, which encourages treatment adherence and reduces the possibilities for both abuse and overdose. Studies have shown that buprenorphine is more effective than placebo and is equally as effective as moderate doses of methadone in opioid maintenance therapy. Few studies have been reported on the efficacy of buprenorphine for completely withdrawing patients from opioids. In general, the results of studies of medically assisted withdrawal using opioids (-e.g., methadone) have shown poor outcomes. Buprenorphine, however, is known to cause a milder withdrawal syndrome compared to methadone and for this reason may be the better choice if opioid withdrawal therapy is elected." The request for an initial trial of Butrans patches for this patient's chronic pain is not medically appropriate. The documentation provided does not indicate that this patient has trialed Butrans patches to date, and progress note dated 03/09/15 indicates the discontinuation of all other opioid medications and the intent to perform a one month trial of Butrans patches. Addressing prior opioid efficacy, progress note dated 01/26/15 states: "He has discontinued Tramadol and Norco and remains on Nucynta for pain control... It was helpful but he continues to complain of pain in his low back..." The subsequent progress note, dated 03/09/15 states: "He does not feel Nucynta is helpful and makes him nauseous." No other discussion of medication efficacy, specific functional improvements, or a lack of aberrant behavior is provided. Furthermore, supplemental progress report, dated 03/11/15 discusses the results of a urine toxicology screen from 12/09/14, stating: "The urine toxicology screen did not detect the presence of the following analytes: Amphetamines, anticonvulsants, opiates..." At the time of this urine toxicology screening, the patient was prescribed Nucynta, however no discussion is provided regarding its absence from the toxicology report. Given the lack of 4A's documentation as required by MTUS, opioid continuation via the requested Butrans patches cannot be substantiated. The request IS NOT medically necessary.

Topical Diclofenac & Lidoderm 5% Creams: Upheld

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

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

Decision rationale: The patient presents on 03/09/15 with unrated lower back pain. The patient's date of injury is 12/26/02. Patient is status post L5-S1 fusion with subsequent hardware removal at dates unspecified. The request is for TOPICAL DICLOFENAC AND LIDODERM 5% CREAMS. The RFA was not provided. Physical examination dated 03/09/15 reveals an antalgic gait, painful and limited range of motion in the lumbar spine, positive straight leg raise bilaterally, and hypoesthesia in the L5-S1 dermatome distribution. The patient is currently prescribed Trazodone, Advair, Senocot, topical Diclofenac/Lidocaine cream, and Butrans. Diagnostic imaging was not included. Patient's current work status is not provided. MTUS page 111 of the chronic pain section states the following under Topical Analgesics: "Largely experimental in use with few randomized controlled trials to determine efficacy or safety... 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. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required." Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain." MTUS page 112, regarding topical NSAIDs also has the following: "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." In regard to the topical cream containing Diclofenac and Lidoderm; the cream contains ingredients which are not supported by guidelines as topical agents in this form, or for this patient's chief complaint. Lidocaine is not supported by MTUS guidelines in topical formulations and is only approved in patch form. Topical NSAIDs are only approved for peripheral joint pain, as there is little evidence of efficacy for conditions of the spine, hip, or shoulder. Guidelines specify that any cream which contains an unsupported ingredient is not indicated. Therefore, the request IS NOT medically necessary.