

Case Number:	CM13-0053099		
Date Assigned:	04/28/2014	Date of Injury:	07/28/1999
Decision Date:	06/12/2014	UR Denial Date:	11/07/2013
Priority:	Standard	Application Received:	11/18/2013

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:

The patient is a 58 year old female who was injured on 07/28/1999 when she tripped over an open desk drawer sustaining an injury to the lower back and left leg. Around May 23, 2013, the patient fell off the toilet and struck her head on the marble floor. The patient's medications as of 03/19/2013 include Opana IR 10 mg 2 tabs q. 6 hour p.r.n pain; Soma 350 mg q. 4 hour p.r.n spasms, Valium 10 mg 1 tab q. a.m. and 2 tabs q. h.s., Wellbutrin 75 mg 3 tabs p.o. b.i.d., Fentanyl patch 100 mg 1 patch q. 3 days, Tegaderm 4x4.75 to use as directed, Glycopyrrolate (non-industrial), Protonix (non-industrial). A follow-up note dated 09/24/2013 indicates the lumbar and thoracic ranges of motion were restricted by pain in all directions. Discogenic provocative maneuvers were positive. Nerve root tension signs were positive on the left, muscle stretch reflexes are symmetric bilaterally in all limbs, Muscle strength in 5/5 in all limbs, except for 3-/5 strength in the left quadriceps, 2/5 strength in the bilaterally iliopsoas and left EHL, 4/5 strength in the bilateral tibialis anterior, left posterior tibialis, and gastrocsoleus muscles, and 3/5 strength in the left peroneal muscles. The patient has an antalgic gait. The patient has bowel or bladder incontinence. The remainder of the examination is unchanged from the previous visit. Diagnoses are thoracic disc protrusion, left L4, L5, S1 radiculopathy, epidural fibrosis, battered nerve root syndrome, lumbar post-laminectomy syndrome, status post L3-S1 fusion, lumbar degenerative disc disease, Deconditioning, restlessness and constant pacing, depression and anxiety.

IMR ISSUES, DECISIONS AND RATIONALES

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

TEGADERM (10/14/13 REPORT): 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)- Low Back (Updated 10/09/13) Wound Dressings.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation M Website, Nexcare, Tegaderm.

Decision rationale: California MTUS and ODG do not address the issue in dispute and hence other evidence based guidelines have been consulted. According to manufacturer, Nexcare's Tegaderm Waterproof Transparent Dressing is the #1 hospital brand in transparent dressings. Tegaderm Dressing can be worn for up to 7 days, making it ideal for securing IV catheters or other tubing, and for post-surgical dressings. Apparently, this product has been used to keep the Fentanyl patch in place. This is not the intended use of this product. Furthermore, the medical records do not establish the request for Fentanyl patch is medically necessary. Consequently, the medical records do not establish the request for Tegaderm is medically necessary.

SOMA (10/14/13 REPORT): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants For Pain, Carisprodol Page(s): 65.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Carisprodol (Soma®), Page(s): 29.

Decision rationale: According to the California MTUS guidelines, Soma is not recommended. The medical records demonstrate the patient has been utilizing Soma chronically. This medication is not intended for long-term use and continued utilization is not supported by the relevant literature. The guidelines note that abuse has been noted for sedative and relaxant effects. The medical necessity of Soma is not established.

OPANA IR 10MG, #240 (10/30/13 REPORT): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids For Chronic Pain Page(s): 93.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: As per California MTUS guidelines, "Opana ER® is not intended for prn use. Patients are to avoid alcohol while on Opana ER® due to increased (possibly fatal) plasma levels. Side Effects: See opioid adverse effects. Immediate release and extended release tablets should be taken 1 hour before or 2 hours after eating. Analgesic dose: (Immediate release) in opioid-naïve patients the starting dose is 10-20mg PO every 4 to 6 hours as needed. Patients may be started at doses of 5mg if appropriate (e.g., renal impairment)." Opana is a highly potent

opiate indicated for patient's that require around the clock pain management. It is not indicated for prn use. Guidelines indicate "four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids; pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors)." In this case, records review indicates that this patient has chronic lower back pain and has been prescribed opiates chronically. The medical records do not document use of a pain diary by the patient to catalog medication use, which is advised by the guidelines. The guidelines state opiates should continue if patient has improved functioning and pain, which has not been demonstrated in this case. It is not established that Opana has increased function and improved pain level. Therefore this request is not medically necessary.

OPANA IR 10MG, #240 (10/14/13 REPORT): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids-Specific Drug List Page(s): 93.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: As per California MTUS guidelines, "Opana ER[®] is not intended for prn use. Patients are to avoid alcohol while on Opana ER[®] due to increased (possibly fatal) plasma levels. Side Effects: See opioid adverse effects. Immediate release and extended release tablets should be taken 1 hour before or 2 hours after eating. Analgesic dose: (Immediate release) in opioid-naïve patients the starting dose is 10-20mg PO every 4 to 6 hours as needed. Patients may be started at doses of 5mg if appropriate (e.g., renal impairment)." Opana is a highly potent opiate indicated for patient's that require around the clock pain management. It is not indicated for prn use. Guidelines indicate "four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids; pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors)." In this case, records review indicates that this patient has chronic lower back pain and has been prescribed opiates chronically. The medical records do not document use of a pain diary by the patient to catalog medication use, which is advised by the guidelines. The guidelines state opiates should continue if patient has improved functioning and pain, which has not been demonstrated in this case. It is not established that Opana has increased function and improved pain level. Therefore this request is not medically necessary.

FENTANYL PATCHES 100MCG (10/14/13 REPORT): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic[®] (Fentanyl Transdermal System), Page(s): 93.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic® (Fentanyl Transdermal System), Page(s): 44.

Decision rationale: As per California MTUS guidelines, Duragesic® (Fentanyl transdermal system) is not recommended as a first-line therapy. Duragesic is the trade name of a Fentanyl transdermal therapeutic system, which releases Fentanyl, a potent opioid, slowly through the skin. The FDA-approved product labeling states that Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means. The guidelines note that chronic opioid use can lead to hyperalgesia. Fentanyl is an opioid analgesic with potency eighty times that of morphine. This strong opioid medication has the potential of significant side effects. The medical records do not establish continued use of the Fentanyl patches led to clinically significant reduction in pain and improved function. The medical records do not document pain level with and without medication use. The patient has not demonstrated improved function, has not returned to work, and the documented physical examination findings are unchanged. Given the lack of benefit, continued Fentanyl is not recommended under the guidelines.

FENTANYL PATCHES 100MCG (10/30/13 REPORT): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic® (Fentanyl Transdermal System), Page(s): 93.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic® (Fentanyl Transdermal System), Page(s): 44.

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