

MAXIMUS FEDERAL SERVICES, INC.

Independent Medical Review

P.O. Box 138009

Sacramento, CA 95813-8009

(855) 865-8873 Fax: (916) 605-4270

**Independent Medical Review Final Determination Letter**

[REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]

Dated: 12/23/2013

IMR Case Number:	CM13-0023067	Date of Injury:	12/03/2007
Claims Number:	[REDACTED]	UR Denial Date:	07/25/2013
Priority:	Standard	Application Received:	08/09/2013
Employee Name:	[REDACTED]		
Provider Name:	[REDACTED] MD		
Treatment(s) in Dispute Listed on IMR Application:	Hydrocodone/APAP 10/325mg, Pantoprazole 20mg, Cyclobenzaprine 7.5mg, Butrans 10mcg/hr patch, Lidoderm 5% patch.		

DEAR [REDACTED]

MAXIMUS Federal Services has completed the Independent Medical Review (“IMR”) of the above workers’ compensation case. This letter provides you with the IMR Final Determination and explains how the determination was made.

k

Final Determination: PARTIAL OVERTURN. This means we decided that some (but not all) of the disputed items/services are medically necessary and appropriate. A detailed explanation of the decision for each of the disputed items/services is provided later in this letter.

The determination of MAXIMUS Federal Services and its physician reviewer is deemed to be the Final Determination of the Administrative Director of the Division of Workers’ Compensation. This determination is binding on all parties.

In certain limited circumstances, you can appeal the Final Determination. Appeals must be filed with the Workers’ Compensation Appeals Board within 30 days from the date of this letter. For more information on appealing the final determination, please see California Labor Code Section 4610.6(h).

Sincerely,

Paul Manchester, MD, MPH
 Medical Director

cc: Department of Industrial Relations, [REDACTED]

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Internal Medicine, 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 physician 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.

DOCUMENTS REVIEWED

The following relevant documents received from the interested parties and the documents provided with the application were reviewed and considered. These documents included:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

CLINICAL CASE SUMMARY

The physician reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 57 year old male who sustained a work injury on 12/3/2007. Patient developed left extremity and shoulder overuse by driving/steering the trash truck. Diagnosis relevant to this case include: cervical and lumbar disc degeneration, cervical and lumbar radiculopathy, chronic pain syndrome, Patient is on multiple medication due to his chronic pain and the relevant issues in this case is whether Hydrocodone/APAP 10/325mg, Pantoprazole 20mg, Cyclobenzaprine 7.5mg, Butrans 10mcg hr patch and Lidoderm 5% patch is medically necessary.

IMR DECISION(S) AND RATIONALE(S)

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

1. Hydrocodone/APAP 10/325mg is not medically necessary and appropriate.

The Claims Administrator based its decision on: not clear from the UR determination

The Physician Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, pages 80 and 91, which is part of the MTUS.

The Physician Reviewer's decision rationale:

My rationale for the above decision on Hydrocodone/APAP 10/325mg not medically appropriate in this specific case is due to the following guidelines of the MTUS:

"Hydrocodone/Acetaminophen (Anexsia®, Co-Gesic®, Hycet™; Lorcet®, Lortab®; Margesic-H®, Maxidone™; Norco®, Stagesic®, Vicodin®, Xodol®, Zydone®; generics available): Indicated for moderate to moderately severe pain. Note: there are no FDA-approved

hydrocodone products for pain unless formulated as a combination. Side Effects: See opioid adverse effects. Analgesic dose: The usual dose of 5/500mg is 1 or 2 tablets PO every four to six hours as needed for pain (Max 8 tablets/day). For higher doses of hydrocodone (>5mg/tab) and acetaminophen (>500mg/tab) the recommended dose is usually 1 tablet every four to six hours as needed for pain. Hydrocodone has a recommended maximum dose of 60mg/24 hours. The dose is limited by the dosage of acetaminophen, which should not exceed 4g/24 hours".

"Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior."

After careful review of the medical records and documentation provided to me the long term use of opioids is unfavorable. Alternative treatment should be evaluated and considered in this case. Therefore on the above basis the request for Hydrocodone/APAP 10/325mg is not medically necessary.

2. Pantoprazole 20mg is medically necessary and appropriate.

The Claims Administrator based its decision on: not clear from the UR determination

The Physician Reviewer found that no section of the MTUS was applicable. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Expert Reviewer based his/her decision on the Official Disability Guidelines (ODG), proton pump inhibitor section, which is not part of the MTUS.

The Physician Reviewer's decision rationale:

My rationale for the above decision on Pantoprazole 20mg is medically appropriate in this specific case is due to the following guidelines of the ODG:

"Recommended for patients at risk for gastrointestinal events. See NSAIDs, GI symptoms & cardiovascular risk. Prilosec® (omeprazole), Prevacid® (lansoprazole) and Nexium® (esomeprazole magnesium) are PPIs. Omeprazole provides a statistically significantly greater acid control than lansoprazole. (Miner, 2010) Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. For many people, Prilosec is more affordable than Nexium. Nexium is not available in a generic (as is Prilosec). Also, Prilosec is available as an over-the-counter product (Prilosec OTC®), while Nexium is not. (Donnellan, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi,

2008) A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)"

After careful review of the medical records and documentation provided to me there is sufficient evidence that patient is in need of a PPI due to chronic pain medication use. Therefore on the above basis the request for Pantoprazole 20mg is medically necessary.

3. Cyclobenzaprine 7.5mg is not medically necessary and appropriate.

The Claims Administrator based its decision on: not clear from the UR determination

The Physician Reviewer found that no section of the MTUS was applicable. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Expert Reviewer based his/her decision on the Official Disability Guidelines (ODG), muscle relaxants for pain, which is not part of the MTUS.

The Physician Reviewer's decision rationale:

My rationale for the above decision on Cyclobenzaprine 7.5mg is not medically appropriate in this specific case is due to the following guidelines of the ODG:

"Recommended for a short course of therapy. Immediate release (eg, Flexeril, generic) recommended over extended release (Amrix) due to recommended short course of therapy (also note substantial increase in cost for extended release without corresponding benefit for short course of therapy). Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. (Browning, 2001) (Kinkade, 2007) (Toth, 2004) See Cyclobenzaprine. Cyclobenzaprine has been shown to produce a modest benefit in treatment of fibromyalgia. Cyclobenzaprine-treated patients with fibromyalgia were 3 times more likely to report overall improvement and to report moderate reductions in individual symptoms (particularly sleep). A meta-analysis concluded that the number needed to treat for patients with fibromyalgia was 4.8. (ICSI, 2007) (Tofferi, 2004) A recent RCT found that time to relief was better with immediate release compared to extended release cyclobenzaprine. (Landy, 2011)"

After careful review of the medical records and documentation provided to me patient has passed the beneficial duration of the requested medication. Cyclobenzaprine is used for a short course duration and not for chronic use and per records this time frame has been surpassed.

Therefore on the above basis the request for Cyclobenzaprine is not medically necessary.

4. Butrans 10mcg hr/patch is medically necessary and appropriate.

The Claims Administrator based its decision on: not clear from the UR determination

The Physician Reviewer found that no section of the MTUS was applicable. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of

Workers' Compensation, the Expert Reviewer based his/her decision on the Official Disability Guidelines (ODG), Buprenorphine for chronic pain, which is not part of the MTUS.

The Physician Reviewer's decision rationale:

My rationale for the above decision on Butrans 10mcg is medically appropriate in this specific case is due to the following guidelines of the MTUS and ODG:

"Recommended for treatment of opiate addiction. Also recommended as an option for chronic pain, especially after detoxification in patients who have a history of opiate addiction (see below for specific recommendations). A schedule-III controlled substance, buprenorphine is a partial agonist at the mu-receptor (the classic morphine receptor) and an antagonist at the kappa-receptor (the receptor that is thought to produce alterations in the perception of pain, including emotional response). In recent years, buprenorphine has been introduced in most European countries as a transdermal formulation ("patch") for the treatment of chronic pain. Proposed advantages in terms of pain control include the following: (1) No analgesic ceiling; (2) A good safety profile (especially in regard to respiratory depression); (3) Decreased abuse potential; (4) Ability to suppress opioid withdrawal; & (5) An apparent antihyperalgesic effect (partially due to the effect at the kappa-receptor). (Kress, 2008) (Heit, 2008) (Johnson, 2005) (Landau, 2007) Available formulations: Buprenorphine hydrochloride: Buprenex®: Supplied as an injection solution; Subutex®: Supplied as a sublingual tablet in 2 daily dosage strengths (2 mg or 8 mg). Buprenorphine hydrochloride and naloxone hydrochloride: Suboxone®: Also supplied as a sublingual tablet in 2 dosage strengths (2/0.5 mg or 8/2 mg). Developed to have a lower intravenous (IV) misuse potential. When injected IV, naloxone is intended to cause withdrawal effects in individuals who are opiate-dependent, and to prevent the "high-effect" related to opioids such as euphoria. Pharmacokinetics: After sublingual administration the onset of effect occurs in 30 to 60 minutes. Peak blood levels are found at 90 to 100 minutes, followed by a rapid decline until 6 hours, and then a gradual decline over more than 24 hours. (Helm, 2008) (Koppert, 2005)"

"Recommended as an option for treatment of chronic pain (consensus based) in selected patients (not first-line for all patients). Suggested populations: (1) Patients with a hyperalgesic component to pain; (2) Patients with centrally mediated pain; (3) Patients with neuropathic pain; (4) Patients at high-risk of non-adherence with standard opioid maintenance; (5) For analgesia in patients who have previously been detoxified from other high-dose opioids. Use for pain with formulations other than Butrans is off-label. Due to complexity of induction and treatment the drug should be reserved for use by clinicians with experience.

Drug description: Buprenorphine is a schedule-III controlled substance. Its mechanism of action is complex, involving four different opioid receptors at central and peripheral sites. It is primarily classified as a partial mu-agonist and kappa antagonist. It blocks effects of subsequently administered opioid agonists.

Proposed advantages of treatment: (1) An apparent antihyperalgesic effect (partially due to the effect at the kappa-receptor); (2) Ability to suppress opioid withdrawal; (3) Indications of safety for use in patients with renal impairment. There appears to be a ceiling effect for respiratory depression. (Johnson, 2005) (Koppert, 2005) (Pergolizzi, 2008) (Malinoff, 2005) (Landau, 2007) (Kress, 2008) (Heit, 2008) (Helm, 2008) (Silverman, 2009) (Pergolizzi, 2010) (Lee, 2011) (Rosenblum, 2012) (Daitch, 2012) (Colson, 2012)"

After careful review of the medical records and documentation provided to me there is sufficient evidence that patient will benefit from butrans therapy. Patient with chronic pain and has failed the different modalities for pain control. Butrans is a beneficial alternative for pain management in this patient.

Therefore on the above basis the request for Butrans 10mcg is medically necessary.

5. Lidoderm 5% patch is not medically necessary and appropriate.

The Claims Administrator based its decision on: not clear from the UR determination

The Physician Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, pages 56-57, which is part of the MTUS.

The Physician Reviewer's decision rationale:

My rationale for the above decision on Lidoderm 5% patch is not medically appropriate in this specific case is due to the following guidelines of the MTUS:

Lidoderm® is the brand name for a lidocaine patch produced by Endo Pharmaceuticals. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics.

After careful review of the medical records and documentation provided to me patient does not have post-herpetic neuralgia in which this medication is approved for.

Therefore on the above basis the request for Lidoderm 5% patch is not medically necessary.

Disclaimer: MAXIMUS is providing an independent review service under contract with the California Department of Industrial Relations. MAXIMUS is not engaged in the practice of law or medicine. Decisions about the use or nonuse of health care services and treatments are the sole responsibility of the patient and the patient's physician. MAXIMUS is not liable for any consequences arising from these decisions.

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]