

**MAXIMUS FEDERAL SERVICES, INC.**

Independent Medical Review

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**Independent Medical Review Final Determination Letter**

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Dated: 12/26/2013

<b>IMR Case Number:</b>	CM13-0007921	<b>Date of Injury:</b>	11/01/1993
<b>Claims Number:</b>	██████████	<b>UR Denial Date:</b>	07/25/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/07/2013
<b>Employee Name:</b>	████████████████████		
<b>Provider Name:</b>	████████████████████		
<b>Treatment(s) in Dispute Listed on IMR Application:</b>	Aciphex 20mg, with 1 year fill, Advair Diskus 500/50mcg, with 1 year fill, Allopurinol 300mg, with 1 year refill, Celebrex 200mg, with 1 year refill, Crestor 5mg, with 1 year refill, Glipizide ER 2.5mg, with 1 year refill, Morphine ER 60mg, with 1 year refill, Onglyza 5mg, with 1 year refill, Propafenone ER 325mg, with 1 year refill, Valsartan-hydrochlorothiazine 80/12.5mg, with 1 year refill, vitamin B12-folic acid 0.5mg, with 1 year refill, vitamin D3 2000mg, with 1 year refill		

DEAR Mr. ██████████,

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.

Final Determination: UPHOLD. This means we decided that none 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, ██████████

## 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 Anesthesiology and Pain Management, has a subspecialty in Acupuncture 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:

- Application of Independent Medical Review
- Utilization Review Determination
- Medical Records from (Claims Administrator, employee/employee representative, Provider)
- Medical Treatment Utilization Schedule (MTUS)

### CLINICAL CASE SUMMARY

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

73 y/o male injured worker who suffers from lower back pain for which he has failed PT in the past and currently treats with medications, including opiates and NSAIDs. Issues at Dispute include numerous medications associated with other medical conditions from which the claimant suffers, including cardiovascular concerns. Many of these requests were partially certified in recent UR decision, in that the indication and medical necessity seems to be affirmed however the request for the dispensation of one year's medications was not certified by the UR physician.

The issues at dispute are whether the Aciphex 20mg with 1 year fill is/are medically necessary and appropriate, whether the Advair Diskus 500/50mcg with 1 year fill is/are medically necessary and appropriate, whether the Allopurinol 300mg with 1 year refill is/are medically necessary and appropriate, whether the Celebrex 200mg with 1 year refill is/are medically necessary and appropriate, whether the Crestor 5mg with 1 year refill is/are medically necessary and appropriate, whether the Glipizide ER 2.5mg with 1 year refill is/are medically necessary and appropriate, whether the Morphine ER 60mg with 1 year refill is/are medically necessary and appropriate, whether the Onglyza 5mg with 1 year refill is/are medically necessary and appropriate, whether the Propafenone ER 325mg with 1 year refill is/are medically necessary and appropriate, whether the Vaisartan-hydrochlorothiazine 80/12.5mg with 1 year refill is/are medically necessary and appropriate, whether the Vitamin B 12-folic acid 0.5/1 mg with 1 year refill is/are medically necessary and appropriate and whether the Vitamin D3 2000mg with 1 year refill is/are medically necessary and appropriate.

### IMR DECISION(S) AND RATIONALE(S)

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

**1. Aciphex 20mg, with 1 year fill is not medically necessary and appropriate.**

The Claims Administrator based its decision on the Chronic Pain Medical Treatment Guidelines, which is part of the MTUS.

The Physician Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, pg. 68, which is part of the MTUS.

The Physician Reviewer's decision rationale:

Use is consistent with cited guidelines for PPIs as the patient is at risk for GI events given that he is over 65, is prescribed an NSAID, and utilizes fluticasone. MTUS citation above notes that intermediate-high risk of GI events, with or without cardiovascular disease, is an indication for a PPI.

This issue of whether the indication is appropriate is not at dispute as this request was partially certified in the UR. However the number of refills is not medically necessary (one year's worth of refills) as I believe proper medical care for this concern requires periodic monitoring for efficacy and side effects and possible change in use of this particular medication.

**2. Advair Diskus 500/50mcg, with 1 year fill is not medically necessary and appropriate.**

The Claims Administrator based its decision on the Official Disability Guidelines (ODG), which is not part of the MTUS.

The Physician Reviewer based his/her decision on the Official Disability Guidelines (ODG) Asthma, which is not part of the MTUS.

The Physician Reviewer's decision rationale:

Advair contains a long acting beta agonist and fluticasone, an inhaled corticosteroid (ICS); ODG states "Inhaled corticosteroids (ICSs) are the most effective long-term control therapy." It is the first-line treatment, as seen under "Step 2" after use of prn inhaler.

This issue of whether the indication is appropriate is not at dispute as this request was partially certified in the UR. However the number of refills is not medically necessary (one year's worth of refills) as I believe proper medical care for this concern requires periodic monitoring for efficacy and side effects and possible change in use of this particular medication.

**3. Allopurinol 300mg, with 1 year refill is not medically necessary and appropriate.**

The Claims Administrator based its decision on: Not clear from UR Determination.

The Physician Reviewer based his/her decision on the Reinders et al 2009 RCT, [www.accessdata.fda.gov/.../drugsatfda/index.cfm?...ALLOPURINOL](http://www.accessdata.fda.gov/.../drugsatfda/index.cfm?...ALLOPURINOL), which is not part of the MTUS.

The Physician Reviewer's decision rationale:

Allopurinol is used to treat gout, tumor lysis syndrome, and for cardiovascular and renal reasons. Other possible indications for allopurinol therapy include ischemic reperfusion injury, kidney stones with a uric acid component (uric acid nephrolithiasis), and protozoal infections (Leishmaniasis).

In my review of available records, I cannot find a diagnosis of gout documented. Patient also has chronic renal insufficiency and hypertension exacerbated by NSAIDs according to his

cardiologist. This medication may be indicated for those reasons. However, I cannot find documentation from the cardiologist that these medications are used for this reason. Affirmation of medical necessity would require clear documentation regarding the use of allopurinol in this context if being prescribed for this reason.

Also the number of refills is not medically necessary (one year's worth of refills) as I believe proper medical care for this concern requires periodic monitoring for efficacy and side effects and possible change in use of this particular medication.

#### **4. Celebrex 200mg, with 1 year refill is not medically necessary and appropriate.**

The Claims Administrator based its decision on the Chronic Pain Medical Treatment Guidelines, which is part of the MTUS.

The Physician Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Anti-inflammatory medications, pg. 22 and pg. 68, which is part of the MTUS.

The Physician Reviewer's decision rationale:

Per MTUS citation above, "A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective nonsteroidal anti-inflammatory drugs (NSAIDs) in chronic LBP and of antidepressants in chronic LBP. (Schnitzer, 2004)

MTUS p68 Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another.

Patient also has chronic renal insufficiency and hypertension exacerbated by NSAIDs according to his cardiologist.

The number of refills requested makes the overall requested treatment not medically necessary (one year's worth of refills) as I believe proper medical care for this concern requires periodic monitoring for efficacy and side effects and possible change in use of this particular medication.

#### **5. Crestor 5mg, with 1 year refill is not medically necessary and appropriate.**

The Claims Administrator based its decision on: Not clear from UR Determination.

The Physician Reviewer based his/her decision on the NGC <http://www.guideline.gov/content.aspx?id=14421> University of Michigan Health System. Screening and management of lipids. Ann Arbor (MI): University of Michigan Health System; 2009 Feb. 15, which is part of the MTUS.

The Physician Reviewer's decision rationale:

Crestor is rosuvastatin. Patient has chronic renal insufficiency. Cardiologist noted that patient benefits from statin therapy. Above cited evidence states "For patients with known risk factors for rhabdomyolysis, including those with hypothyroidism, chronic renal insufficiency, and those

over age 65, who require LDL-C lowering greater than can be achieved with simvastatin 40 mg, atorvastatin or rosuvastatin may be considered as alternatives”

The number of refills requested makes the overall requested treatment not medically necessary (one year’s worth of refills) as I believe proper medical care for this concern requires periodic monitoring for efficacy and side effects and possible change in use of this particular medication.

**6. Glipizide ER 2.5mg, with 1 year refill is not medically necessary and appropriate.**

The Claims Administrator based its decision on the Official Disability Guidelines (ODG).

The Physician Reviewer based his/her decision on the American Diabetes Association (ADA). Standards of medical care in diabetes. VI. Prevention and management of diabetes complications. Diabetes Care 2013 Jan;36 (Suppl 1):S28-39, which is part of the MTUS.

The Physician Reviewer’s decision rationale:

Glipizide may be indicated for the patient as he does have a diagnosis of diabetes and this medication is FDA approved for this purpose. However, the number of refills requested makes the overall requested treatment not medically necessary (one year’s worth of refills) as I believe proper medical care for this concern requires periodic monitoring for efficacy and side effects and possible change in use of this particular medication.

**7. Morphine ER 60mg, with 1 year refill 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, pgs. 78-80, which is part of the MTUS.

The Physician Reviewer’s decision rationale:

The MTUS has a detailed list of recommendations for initiation and continuation of opioids, and these recommendations do not appear to have been addressed by the treating physician in the documentation available for review. It is noted that the UR determination was of an administrative non-certification pending receipt of information. To reach the MTUS definition of medical necessity for ongoing treatment, efforts to rule out aberrant behavior (i.e. CURES report, UDS, opiate agreement) and assure safe usage are needed.

The number of refills requested makes the overall requested treatment not medically necessary (one year’s worth of refills) as I believe proper medical care for this concern requires periodic monitoring for efficacy and side effects and possible change in use of this particular medication.

**8. Onglyza 5mg, with 1 year refill is not medically necessary and appropriate.**

The Claims Administrator based its decision on the Official Disability Guidelines (ODG), which is not part of the MTUS.

The Physician Reviewer based his/her decision on the American Diabetes Association (ADA). Standards of medical care in diabetes. VI. Prevention and management of diabetes complications. Diabetes Care 2013 Jan; 36(Suppl 1):S28-39, which is not part of the MTUS.

The Physician Reviewer’s decision rationale:

Onglyza may be indicated for the patient as he does have a diagnosis of diabetes and this medication is FDA approved for this purpose. However, the number of refills requested makes the overall requested treatment not medically necessary (one year's worth of refills) as I believe proper medical care for this concern requires periodic monitoring for efficacy and side effects and possible change in use of this particular medication.

**9. Propafenone ER 325mg, with 1 year refill is not medically necessary and appropriate.**

The Claims Administrator based its decision on the National Guideline Clearinghouse, which is not part of the MTUS.

The Physician Reviewer based his/her decision on the National Guidelines Clearinghouse, <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=578d747f-c023-4d5a-9e9a-d4a970d8f69f>, which is not part of the MTUS.

The Physician Reviewer's decision rationale:

Propafenone is indicated to prolong the time to recurrence of PAF and PSVT. In the UR determination, the physician states "Based on the history of hyperlipidemia and the patient's advanced age of 73, the presence of coronary artery disease is almost certain", and cites that since it is not recommended in patients with CAD, it should be non-certified. I will note that the evidence above confirms that CAD is not a contraindication to the medication. Also, the patient's provider who has provided the majority of his records for review is also his cardiologist, who has not diagnosed him with coronary artery disease. I do not feel the UR physician's rationale is adequate to determine a lack of medical necessity.

However, the number of refills requested makes the overall requested treatment not medically necessary (one year's worth of refills) as I believe proper medical care for this concern requires periodic monitoring for efficacy and side effects and possible change in use of this particular medication.

**10. Valsartan-hydrochlorothiazine 80/12.5mg, with 1 year refill 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 NGC Clinical practice guidelines on arterial hypertension. 2007 update.

The Physician Reviewer's decision rationale:

This medication may be indicated for the patient as he does have a diagnosis of hypertension and this medication is FDA approved for this purpose. However, the number of refills requested makes the overall requested treatment not medically necessary (one year's worth of refills) as I believe proper medical care for this concern requires periodic monitoring for efficacy and side effects and possible change in use of this particular medication.

**11. Vitamin B12-folic acid 0.5mg, with 1 year refill 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 National Guideline Clearinghouse <http://www.guideline.gov/content.aspx?id=12988>, which is part of the MTUS.

The Physician Reviewer's decision rationale:

The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the use of B12 or folic acid to treat any condition other than their documented deficiencies. Affirmative documentation would be required to meet conditions for medical necessity. NGC in citation above notes there may be a benefit for folate and B12 supplementation in heart failure patients, however patient's cardiologist has not diagnosed him with heart failure.

The number of refills requested makes the overall requested treatment not medically necessary (one year's worth of refills) as I believe proper medical care for this concern requires periodic monitoring for efficacy and side effects and possible change in use of this particular medication.

**12. Vitamin D3 2000mg, with 1 year refill 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 National Guideline Clearinghouse, University of Texas at Austin, School of Nursing, Family Nurse Practitioner Program. Recommendations for the diagnosis and management of vitamin D deficiency in adults. Austin (TX): University of Texas at Austin, School of Nursing; 2009 May. 16, which is part of the MTUS.

The Physician Reviewer's decision rationale: The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the use of Vitamin D to treat any condition other than their documented deficiencies.

No documentation of Vitamin D deficiency. Affirmative documentation would be required to meet conditions for medical necessity.

The number of refills requested makes the overall requested treatment not medically necessary (one year's worth of refills) as I believe proper medical care for this concern requires periodic monitoring for efficacy and side effects and possible change in use of this particular medication.

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.

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