

<b>Case Number:</b>	CM15-0143485		
<b>Date Assigned:</b>	08/04/2015	<b>Date of Injury:</b>	03/26/2013
<b>Decision Date:</b>	09/22/2015	<b>UR Denial Date:</b>	07/10/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/23/2015

### 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 65-year-old male who sustained an industrial injury on 03-26-2013. Mechanism of injury was not found in documents presented for review. Diagnoses include headaches, cervical radiculopathy, and cervical disc protrusion, left shoulder sprain-strain, status post right shoulder surgery, elevated blood pressure and cerebral stroke. Treatment to date has included diagnostic studies, medications, physical therapy, home exercises, cervical epidural injections, and right shoulder surgery on 11-26-2014. His medications include Norco, Flexeril and Fioricet. He is not working at this time. A physician progress note dated 05-13-2015 documents the injured worker complains of constant headaches, rated 9 out of 10, constant neck pain rated 10 out of 10 and constant bilateral shoulder pain, which he rates as 9 out of 10. He notes he received 90% relief from his neck pain and arm pain for one week after receiving a cervical epidural injection on 03-16-2015. However, his pain returned to baseline. Cervical range of motion is limited and painful. He has tenderness along the subacromial segment and the trapezius muscle on the left. Treatment requested is for Retrospective: Amlodipine 10mg #30 (DOS 06/11/15), Retrospective: Aspirin 81mg #30 (DOS 06/11/15), Retrospective: Citrucel #120 (DOS 06/11/15), Retrospective: Clopidogrel 75mg #30 (DOS 06/11/15), and Retrospective: Simvastatin 40mg #30 (DOS 06/11/15).

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective: Hypertensa #90 (DOS 06/11/15): 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).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter Pain under medical food.

**Decision rationale:** The patient presents on 05/13/15 with headaches rated 9/10 neck pain rated 10/10, bilateral shoulder pain rated 9/10. The patient's date of injury is 03/26/13. Patient is status post cervical ESI on 03/20/15, status post unspecified right shoulder surgery on 11/26/14. The request is for HYPERTENSA #90 (DOS 06/11/15). The RFA was not provided. Physical examination dated 05/13/15 reveals decreased cervical range of motion in all planes, and tenderness to palpation along the subacromial segment and trapezius muscle on the left side. The patient is currently prescribed Norco, Flexeril, and Fioricet. Diagnostic imaging was not included. Patient is currently not working. Regarding medical food, ODG states that it is intended for a specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. To be considered, the product must meet the following criteria: 1. The product must be a food for oral or tube feeding. 2. The product must be labeled for dietary management of a specific medical disorder. 3. The product must be used under medical supervision. In regard to the request for Hypertensa, a medical food for blood pressure management, the requested medication does not meet guideline criteria. The reports provided do indicate that this patient suffers from elevated blood pressure, and a history of CVA. Patient vital signs listed on the 06/16/15 progress report show a systolic blood pressure of 149, meeting the criteria for stage 1 hypertension. The previous progress reports also provide similar blood pressure values. However, there are no discussions of mainstream therapies such as anti-hypertensive medications or dietary interventions (such as salt limitation) directed at this complaint or their failure to control this patient's blood pressure. Furthermore, there is no indication that this medical food will be utilized under medical supervision. Therefore, this request IS NOT medically necessary.

**Retrospective: Clopidogrel 75mg #30 (DOS 06/11/15): Overturned**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby drug consult.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/020839s044lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020839s044lbl.pdf).

**Decision rationale:** The patient presents on 05/13/15 with headaches rated 9/10 neck pain rated 10/10, bilateral shoulder pain rated 9/10. The patient's date of injury is 03/26/13. Patient is status post cervical ESI on 03/20/15, status post unspecified right shoulder surgery on 11/26/14. The request is for CLOPIDOGREL 75MG #30 (DOS 06/11/15). The RFA was not provided. Physical examination dated 05/13/15 reveals decreased cervical range of motion in all planes, and tenderness to palpation along the subacromial segment and trapezius muscle on the left side. The patient is currently prescribed Norco, Flexeril, and Fioricet. Diagnostic imaging was not included. Patient is currently not working. MTUS and ODG are silent on Clopidogrel, FDA Guidelines were consulted. Regarding Clopidogrel (Plavix), FDA Guidelines (<http://www.fda.gov/oc/ohrt/ohrt040107.pdf>).

accessdata.fda.gov/drugsatfda\_docs/label/2009/020839s044lbl.pdf) have the following:  
DOSAGE AND ADMINISTRATION Recent MI, Recent Stroke, or Established Peripheral Arterial Disease The recommended daily dose of Plavix is 75 mg once daily. In regard to the request of Plavix for the prevention of stroke in this patient, the request is appropriate. While MTUS and ODG criteria are silent on this matter, FDA guidelines support the use of this medication in patients who present with a history of CVA. In this case, the patient does present with a history of CVA, though the date of the incident is not provided and there is no discussion in recent progress notes regarding this medication. Given this patient's continuing hypertension, history of stroke, and the appropriate dosing schedule provided, the use of this medication is substantiated. The request IS medically necessary.

**Retrospective: Amlodipine 10mg #30 (DOS 06/11/15): Overturned**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby Drug Consult.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.ghc.org/all-sites/guidelines/hypertension.pdf](http://www.ghc.org/all-sites/guidelines/hypertension.pdf).

**Decision rationale:** The patient presents on 05/13/15 with headaches rated 9/10 neck pain rated 10/10, bilateral shoulder pain rated 9/10. The patient's date of injury is 03/26/13. Patient is status post cervical ESI on 03/20/15, status post unspecified right shoulder surgery on 11/26/14. The request is for AMLODIPINE 10MG #30 (DOS 06/11/15). The RFA was not provided. Physical examination dated 05/13/15 reveals decreased cervical range of motion in all planes, and tenderness to palpation along the subacromial segment and trapezius muscle on the left side. The patient is currently prescribed Norco, Flexeril, and Fioricet. Diagnostic imaging was not included. Patient is currently not working. According to [www.drugs.com](http://www.drugs.com), Amlodipine-Amlodipine is in a group of drugs called calcium channel blockers. Amlodipine relaxes (widens) blood vessels and improves blood flow. Amlodipine is used to treat high blood pressure (hypertension) or chest pain (angina) and other conditions caused by coronary artery disease. This medication is for use in adults and children who are at least 6 years old. Regarding Calcium channel blockers for the management of hypertension, Group Health Hypertension guidelines (<https://www.ghc.org/all-sites/guidelines/hypertension.pdf>) states the following: "There is evidence that calcium channel blockers slightly decrease the risk of all-cause mortality and stroke versus other treatments, but increase the risk of heart failure." In regard to Amlodipine in the management of this patient's hypertension, the request is appropriate. Progress notes indicate that this patient suffers from a history of hypertension and recent CVA. This patient's most recent blood pressure reading was 149, meeting criteria for stage I hypertension, and this value is consistent across several progress notes. Given this patient's current presentation and CVA history, Amlodipine is warranted and could prove useful in preventing future strokes. The request IS medically necessary.

**Retrospective: Citrucel #120 (DOS 06/11/15): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby Drug Consult.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter Diabetes under dietary fiber.

**Decision rationale:** The patient presents on 05/13/15 with headaches rated 9/10 neck pain rated 10/10, bilateral shoulder pain rated 9/10. The patient's date of injury is 03/26/13. Patient is status post cervical ESI on 03/20/15, status post unspecified right shoulder surgery on 11/26/14. The request is for CITRUCEL #120 (DOS 06/11/15). The RFA was not provided. Physical examination dated 05/13/15 reveals decreased cervical range of motion in all planes, and tenderness to palpation along the subacromial segment and trapezius muscle on the left side. The patient is currently prescribed Norco, Flexeril, and Fioricet. Diagnostic imaging was not included. Patient is currently not working. Citrucel is a proprietary dietary fiber supplement; ODG Diabetes chapter has the following under dietary fiber: Recommended for the prevention and treatment of type 2 diabetes. The favorable effect of various fibers and particularly of psyllium on body weight reduction and satiety, on cholesterol and triglycerides levels, on fasting glycaemia and on blood pressure suggests a potential role of these fibers in the treatment of metabolic syndrome, a condition that identifies patients who are at high risk of developing type 2 diabetes. (Giacosa, 2010) According to one article, minimum fiber intake of 25 g/d based on a diet rich in whole grains, fruits and legumes will probably decrease the risk of obesity, metabolic syndrome and type 2 diabetes. In regard to the request for fiber supplementation, the patient does not meet guideline criteria. The RFA and the progress note associated with this request were not included with the supporting documentation in this case. ODG supports fiber supplementation in diabetic patients as they have a beneficial effect on blood glucose levels and overall GI function. However, this patient does not present with a formal diagnosis of diabetes and therefore does not meet guideline criteria for fiber supplementation. Without a clear rationale as to why this medication is being prescribed, or evidence that this patient is in fact diabetic, this supplement cannot be substantiated. The request IS NOT medically necessary.

**Retrospective: Simvastatin 40mg #30 (DOS 06/11/15): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby Drug Consult.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes chapter under Statins.

**Decision rationale:** The patient presents on 05/13/15 with headaches rated 9/10 neck pain rated 10/10, bilateral shoulder pain rated 9/10. The patient's date of injury is 03/26/13. Patient is status post cervical ESI on 03/20/15, status post unspecified right shoulder surgery on 11/26/14. The request is for SIMVASTATIN 40MG #30 (06/11/15). The RFA was not provided. Physical examination dated 05/13/15 reveals decreased cervical range of motion in all planes, and tenderness to palpation along the subacromial segment and trapezius muscle on the left side. The patient is currently prescribed Norco, Flexeril, and Fioricet. Diagnostic imaging was not included. Patient is currently not working. Simvastatin belongs to the Statin class of medications. ODG Diabetes chapter has the following under Statins: Not recommended as a first-line treatment for diabetics. Patients with DM should be screened for dyslipidemia, and therapeutic recommendations should include lifestyle changes and, as needed, consultation with a registered dietitian. Statins may be a treatment in the absence of contraindications, but recent studies have associated increased risk of DM with use of all types of statins. Statin use in postmenopausal women is associated with a significantly increased risk of diabetes mellitus, according to data from the Women's Health Initiative, with a 48% increased risk of diabetes among the women taking these lipid-lowering medications. At baseline, 7% of women were taking statins, with 30% of women taking simvastatin, 27% taking lovastatin, 22% taking pravastatin, 12.5% taking fluvastatin, and 8% taking atorvastatin. In an unadjusted risk model,

statin use at baseline was associated with a 71% increased risk of diabetes. After adjusting for potential confounding variables, the risk of diabetes associated with statin therapy declined to 48%. The association was observed for all types of statins. In regard to the request for Simvastatin, presumably to control this patient's blood cholesterol, this patient does not meet guideline criteria. The documentation provided does not include the RFA or the progress note associated with this request. In those notes, which were provided, no discussion of this medications utilization is included, and no formal diagnosis of diabetes or hyperlipidemia is included. Given the lack of documentation of a condition for which this medication is considered appropriate, and the lack of firm guideline support for this medication, the request cannot be substantiated. The request IS NOT medically necessary.

**Retrospective: Asprin 81mg #30 (DOS 06/11/15): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation U. S. Preventive Services Task Force.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes chapter, under Antiplatelet therapy.

**Decision rationale:** The patient presents on 05/13/15 with headaches rated 9/10 neck pain rated 10/10, bilateral shoulder pain rated 9/10. The patient's date of injury is 03/26/13. Patient is status post cervical ESI on 03/20/15, status post unspecified right shoulder surgery on 11/26/14. The request is for ASPRIN 81MG #30 (06/11/15). The RFA was not provided. Physical examination dated 05/13/15 reveals decreased cervical range of motion in all planes, and tenderness to palpation along the subacromial segment and trapezius muscle on the left side. The patient is currently prescribed Norco, Flexeril, and Fioricet. Diagnostic imaging was not included. Patient is currently not working. ODG Diabetes chapter, under Antiplatelet therapy has the following regarding Aspirin: Under study. The use of aspirin for primary prevention has become controversial due to recent data showing little benefit. Several recent meta-analyses show no statistically significant benefit on either total cardiovascular outcomes or the individual events such as death, myocardial infarction, or stroke. The controversial findings of the different studies may reflect the results of studies showing that patients with DM have an increased resistance to the effects of aspirin, linked in part to an effect of hyperglycemia. Some studies, but not all, support the use of low-dosage aspirin in the secondary prevention of CVD in patients with DM. In regard to the request for 81MG Aspirin as an antiplatelet preventative measure, such treatments are not currently supported by guidelines. Official disability guidelines indicate that antiplatelet therapy with Aspirin is currently being re-examined owing to recent meta-analyses showing no statistically significant benefits for patients at risk of myocardial infarction or stroke. While this patient presents with significant history of CVA and concurrent diabetes, guidelines do not support Aspirin as an effective prophylactic treatment at this time. Therefore, the request IS NOT medically necessary.