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| <b>Case Number:</b>   | CM14-0008868 |                              |            |
| <b>Date Assigned:</b> | 02/14/2014   | <b>Date of Injury:</b>       | 12/30/2003 |
| <b>Decision Date:</b> | 06/24/2014   | <b>UR Denial Date:</b>       | 12/24/2013 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 01/23/2014 |

### 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 & Rehabilitation, has a subspecialty in Interventional Spine 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:

This patient is a 50-year-old male with date of injury of 12/30/2003. Per treating physician's report, 12/02/2013, patient presents with low back pain, routinely takes up to 3 Duexis per day as well as 5 to 6 Norco tablets. Patient has had significant side effects from Opana ER and OxyContin. There is a concern regarding his liver and renal function; the request, which has been repeatedly denied. Patient states that the pain is very severe. He cannot get by without medications. Current medications are Norco 6 a day, Duexis 800 mg/25.5 two to three a day. The impressions are: 1) L5-S1 laminectomy, facetectomy from 2006 with failed back surgery syndrome. 2) Continued low back and left leg pain, weakness. 3) Computed tomography (CT) scan for evidence of severe L5-S1 degenerative disk disease. 4) Electromyography (EMG) for left S1 radiculopathy. The patient is able to continue with present job without restrictions except for no lifting, pushing, or pulling greater than 50 pounds. Request was for liver function studies as well as renal studies, urine drug screen today. Patient's last urine drug screen was back in April and has been over 6 months. Request was for starting long-acting opiates to replace the Norco and try Exalgo 60mg a day; possibly, up to 24mg. Request was also for swim therapy, aqua therapy visits. Patient's Norco was renewed as well as Duexis. If the long-acting opiates are authorized then back sooner than 2 months, he will start this regimen. 10/14/2013 report is reviewed. The patient has been fairly stable using Motrin on regular basis as well as 6 Norco tablets per day. The patient's pain level is at 6/10, 60% in the back, 40% in left leg. He continues to have neck pain, C7-T1 region. Duexis has been helpful with pain and less risk of ulcer or true gastritis. Recommendation was for Duexis to protect patient's stomach from gastritis due to long-term use of Motrin. Two samples of Duexis were given to the patient and Norco was also provided #180. 08/15/2013 report is reviewed. Patient's best response was to lumbar

radiofrequency ablation. Overall, fairly stable, but needs pain medications with patient's pain generally at 5/10 to 6/10. "He is able to handle his work without difficulty." The requests were denied by utilization review letter, 12/24/2013, with the rationale that Duexis was not indicated as there was no documentation of gastrointestinal (GI) event, Norco was certified, and Exalgo was non-certified due to the lack of quantity specified. Urine drug screen was denied with the statement that prior drug tests have not detected illicit substances and that another urine drug screen (UDS) was not consistent with MTUS Guidelines.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **EXALGO 16-24MG DAILY: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 106.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines Medications for chronic pain Page(s): 60,61.

**Decision rationale:** This patient presents with post-laminectomy syndrome and suffers from chronic low back and lower extremity pain. The request is for Exalgo with long-acting opiate 16 to 24 mg daily. Review of the reports shows that this patient is working for functional measure. The patient has had back surgery back in 2006 and continues to experience significant pain. Patient has failed other long-acting opiates. Patient's current pain level is not adequately controlled on just Norco, and the treating physician is asking for the ability to use and try Exalgo 16 and 24 mg. MTUS Guidelines require documentation of analgesia, activities of daily living (ADLs), adverse effects, aberrant drug-seeking behavior when opiates are used for chronic pain. This patient does not suffer from moderately severe pain, and for pain reduction, the patient has been on Norco with significant pain reduction, but still inadequate. The treating physician would like to try Exalgo, which appears quite reasonable, particularly given the fact that this patient is working which is the highest form of functional improvement that one can reach with chronic pain. Recommendation is for medical necessity of Exalgo 16 to 24 mg to be used on a daily basis per treating physician's discretion.

#### **URINE DRUG SCREEN (UDS): Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing Page(s): 58.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines MTUS Chronic Pain Medical Treatment Guidelines, for Steps to avoid opioid misuse Page(s): 43, 94.

**Decision rationale:** This patient presents with post-laminectomy syndrome and suffers from chronic low back and lower extremity pains. The request is for urine drug screen. The treating physician indicates that the last urine drug screen was from April 2013 with consistent results. He has not been able to repeat the urine drug screen due to utilization review denials. Review of

the utilization review letter, 12/24/2013, does show that the repeat urine drug screen was denied with the statement that the last urine drug screen was consistent. MTUS Guidelines support urine drug screens to monitor chronic opiate use, compliance. For frequency, Official Disability Guidelines (ODG) recommends 1 or 2 urine drug screens every 12 months for low-risk patients. In this patient, the last urine drug screen was in April per treating physician's report. There is no reason not to be able to repeat the urine drug screen once or twice a year. Due to the random nature of these urine drug screens, the treating physician should be allowed a certain amount of leeway in performing this at once- or twice-per-year frequency. Recommendation is for medical necessity.

**DUEXIS 800/26.5MG QTY:180.00:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI SYMPTOMS AND CARDIOVASCULAR RISK Page(s): 93.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 69.

**Decision rationale:** This patient suffers from chronic low back pain with post-laminectomy syndrome. The request is for Duexis. The treating physician makes the argument that this patient has been using Motrin more regularly, and he is quite concerned about the patient's gastrointestinal (GI) side effects and kidney/liver problems. He would like to use Duexis so that there is some gastrointestinal (GI) protection. The treating physician, on his report, does indicate that this patient has GI side effects from chronic use of the Motrin. Use of Duexis appeared quite reasonable and consistent with MTUS Guidelines, which states that when patients have gastritis side effects from NSAIDs, either the medication is to be stopped, switched to another medication, or proton pump inhibitors (PPI) medication added. Duexis is a reasonable option as this medication contains ibuprofen with famotidine or proton pump inhibitors (PPI). Recommendation is for medical necessity.