

<b>Case Number:</b>	CM14-0151776		
<b>Date Assigned:</b>	09/19/2014	<b>Date of Injury:</b>	01/13/2009
<b>Decision Date:</b>	11/24/2014	<b>UR Denial Date:</b>	09/03/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/17/2014

### 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 Occupational 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 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 claimant injured his low back on 01/13/09. Exalgo and Norco are under review. The claimant is status post arthrodesis at L5-S1 and has bulging disks at L4-5, L5-S1 and spondylolisthesis at L5-S1. He also has neck and thoracic pain. He is status post spinal fusion followed by the development of a pseudoarthrosis. He underwent anterior L5-S1 interbody fusion with hardware on 04/09/10. The hardware was removed in 2012. He had an arthrodesis at L5-S1 with pedicle screw fixation and multiple laminectomies and foraminotomies at L3-L5. He has also been evaluated for depression and sleep problems. He has been variably authorized for these medications and they were most recently denied. On 02/11/14, he stated his pain averages 7.5/10 medications and with them his level came down to 6-6.5/10 which was tolerable. Without his medications his pain would be above 10. He stated that the hydrocodone and Exalgo take effect within 1 hour and the Exalgo lasts about 8-10 hours and the Norco lasts for several hours. He usually used hydrocodone later in the day. With the medications he can go about his daily activities and self-care and otherwise would be bedridden. There is a signed opioid agreement in the chart. He had severe gastrointestinal (GI) upset with Morphine Sulfate IR (MSIR) and Opana ER. His examination revealed equal and symmetric reflexes but no ankle clonus and the rest of the exam was unchanged but is not described. On 03/11/14, he reported increased back pain that was excruciating and cold rainy weather. Without his medications he could not function. He had a popping sensation in his right lower back but it was not frequent. He had markedly limited range of motion of the low back with tenderness. The rest of the exam was unchanged. On 04/08/14, acupuncture was ordered. His pain was unchanged. Exalgo was very helpful. There are no significant changes in his physical examination. His previous urine drug screen was consistent. On 05/06/14, his pain was worse due to rain. Without the Exalgo he thought he would die. He had markedly limited lumbar spine range of motion and appeared to

be in mild to moderate discomfort and was transferring very slowly. The rest of the exam was unchanged. On 04/29/14, Exalgo was certified and acupuncture was not certified. On 06/03/14, reported that his pain was at level 7/10 and it would go down to 5/10. With his medications he could cook for about a half an hour and without them he would be lying on the ground crying. His medication takes effect within 1 hour and lasts for about 3 hours. The Exalgo lasts about 6 hours. There was no change in his physical examination. A drug screen dated 03/11/14 revealed the presence of hydrocodone but not hydromorphone although he reportedly was taking Exalgo daily. On 07/02/14, he was seen again and again reported that his pain was tolerable with the medication. He was using a single-point cane. He had good strength at 5/5 throughout the lower extremities. There is another drug screen that is illegible and a third request form for a drug screen that is blank. It appears that no drugs were found on 07/14/14. The provider stated that his most recent urine drug screen was consistent. He was getting significant pain relief from the medications. On 07/21/14, he reported he was not getting Exalgo authorized and was concerned about running out. He was in mild discomfort. He was prescribed Dilaudid instead and was to continue the Norco. On 08/18/14, a walker and lumbar MRI were ordered. The Exalgo was not being covered. He stated the Dilaudid did not help as much as the Exalgo. He had a straight leg raise test that was positive on the right side with a decreased reflex at the left patella. He transferred slowly and had a markedly slowed gait velocity. On 08/18/14, he presented with persistent difficulties in his left foot. He had increased pain and numbness. His medications included Norco, Colace, Exalgo, lactulose,

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

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

**Exalgo 16 mg, #30 1 month supply dispensed on 8/18/14: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Pain Page(s): 110.

**Decision rationale:** The history and documentation do not objectively support the request for the opioid, Exalgo 16 mg #30 1 month supply dispensed on 08/18/14. The MTUS outlines several components of initiating and continuing opioid treatment and states "a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or non-steroidal anti-inflammatory drugs. MTUS further explains, "pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts." There is evidence that the claimant has been asked these questions at one visit, but generally his pattern of use of the medication and the benefit he gets from it are difficult to ascertain. Three drug screen forms were submitted and one only showed the presence of hydrocodone, not hydromorphone, despite reported daily use. This has not been addressed by the providers. Also, there are two

drug screens that appear to be blank and do not reveal the presence of either of these opioids he is taking. There is no evidence that the claimant has been involved in an ongoing rehab program to help maintain any benefits he receives from treatment measures. There is evidence that a signed pain agreement is on file at the provider's office but no evidence that a detailed pain diary has been recommended and is being kept by the claimant and reviewed by the prescriber. As such, the medical necessity of the ongoing use of Exalgo has not been clearly demonstrated.

**Norco 10/325 mg, #120 1 month supply dispensed on 8/18/14:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Pain Page(s): 110.

**Decision rationale:** The history and documentation do not objectively support the request for the opioid, Norco 10/325 mg #120, 1 month supply dispensed on 08/18/14. The MTUS outlines several components of initiating and continuing opioid treatment and states "a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or non-steroidal anti-inflammatory drugs. MTUS further explains, "pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts." There is evidence that the claimant has been asked these questions at one visit, but generally his pattern of use of the medication and the benefit he gets from it are difficult to ascertain. Three drug screen forms were submitted and one only showed the presence of hydrocodone despite reported daily use. This has not been addressed by the providers. Also, there are two drug screens that appear to be blank and do not reveal the presence of either of these opioids he is taking. There is no evidence that the claimant has been involved in an ongoing rehab program to help maintain any benefits he receives from treatment measures. There is evidence that a signed pain agreement is on file at the provider's office but no evidence that a detailed pain diary has been recommended and is being kept by the claimant and reviewed by the prescriber. As such, the medical necessity of the ongoing use of Norco 10/325 mg #120 has not been clearly demonstrated.