

<b>Case Number:</b>	CM14-0214577		
<b>Date Assigned:</b>	01/07/2015	<b>Date of Injury:</b>	02/15/1996
<b>Decision Date:</b>	02/28/2015	<b>UR Denial Date:</b>	12/02/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/22/2014

### 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. 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: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

### 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 is a 51 year old with a date of injury of 2/16/96. The patient is being treated for cervical spondylosis without myelopathy, degenerative cervical intervertebral disc, post laminectomy syndrome, cervicgia, neck pain and myalgias/myositis. Subjective findings on 12/10/14 include chronic left sided neck pain, history of arm with current numbness and tingling in bilateral upper extremities R>L, headaches and left sided shoulder pain. Objective findings include tenderness over left trapezius and mid-scapular region, tenderness over cervical paraspinal region, normal sensation in bilateral upper extremities, increase pain on cervical extension and lateral bending. MRI of the C-spine on 04/18/11 showed C5-6 mild to moderate right sided foraminal narrowing due to mild disc height reduction and 2-3 mm right posterolateral disc protrusion and s/p prior anterior cervical discectomy with vertical plate fusion of C6-7. Treatment thus far has consisted of facet blocks, radiofrequency ablations, surgery and medications (Zanaflex, Nuvigil, Lyrica, AndroGel, Dilaudid, Duexis, Exalgo, Norco, Vicodin, Percocet, Anaprox, Ultracet, Ambien, Methadone-SOB, Trazadone, Celebrex, Nucynta ER, and Lunesta). The Utilization Review on 12/2/14 found the request for Lyrica 150mg #60 non-certify due to lack of documented improvement on this medication. The request for AndroGel 1.62%/1.25mg #2 pumps per day to be noncertified due to lack of documented hypogonadism. The request for Duexis 800mg/26.6mg #90 to be noncertified due to lack of GI symptoms documented in the record. The request for Dilaudid 4mg #90 to be modified to #45 due to lack of documentation necessitating its use (no pain contract, urine drug screen) and modified for

weaning purposes. The request for Exalgo 16mg #30 to be modified for weaning due to unclear usage, no pain contract and lack of urine drug screening.

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

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

#### **Lyrica 150mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-17 & 99.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pregabalin Page(s): 99. Decision based on Non-MTUS Citation Official Disability Guidelines, Anti-epilepsy drugs (AEDs) for pain

**Decision rationale:** MTUS and Official Disability Guidelines state that "Pregabalin (Lyrica ) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia. See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Pregabalin listing for more information and references." The medical records fail to document that this patient is being treated for postherpetic neuralgia or diabetic neuropathy. There are no electrodiagnostic studies to confirming neuropathy. The medical records also fail to document improvement in the patient's pain while on this medication. As such, the request for Lyrica 150mg #60 is not medically necessary.

#### **Androgel 1.62%/1.25gm #2 pumps/day: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Testosterone Replacement for Hypogonadism

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone replacement for hyogonadism (secondary to opioids) Page(s): 110-111.

**Decision rationale:** Per the MTUS guidelines, testosterone replacement is "Recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. Hypogonadism has been noted in patients receiving intrathecal opioids and long-term high dose opioids. Routine testing of testosterone levels in men taking opioids is not recommended; however, an endocrine evaluation and/or testosterone levels should be considered in men who are taking long term, high dose oral opioids or intrathecal opioids and who exhibit symptoms or signs of hypogonadism, such as gynecomastia. If needed, testosterone replacement should be done by a physician with special knowledge in this field given the potential side effects such as hepatomas." In this case, there is no evidence of intrathecal use of opioid, no documentation of hypogonadism on physical exam (gynecomastia) and the prescribing provider is not an expert at replacing testosterone. As such, the request for AndroGel 1.62%/1.25gm #2 pumps/day is not medically necessary.

**Duexis 800mg/26.6mg #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Duexis (Ibuprofen & Famotidine)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk

**Decision rationale:** MTUS and Official Disability Guidelines states, "Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease:(1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or(2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." The medication, Duexis, is the combination Ibuprofen and Famotidine. The medical documents provided do not establish the patient as having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. As such, the request for Duexis 800mg/26.6mg #90 is not medically necessary.

**Dilaudid 4mg #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 77-78.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 51, 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, Opioids

**Decision rationale:** Per MTUS, Dilaudid is the brand name version of Hydromorphone, which is a pure agonist/short acting opioid and "they are often used for intermittent or breakthrough pain." Official Disability Guidelines does not recommend the use of opioids for low back pain "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. 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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not document any of the following: the least reported pain over the period since last assessment, intensity of pain after

taking opioid, pain relief. The UR recommended weaning which was appropriate. As such, the question for Dilaudid 4mg, #90 is not medically necessary.

**Exalgo 16mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Hydrocodone, Opioids Page(s): 51, 74-95.

**Decision rationale:** Official Disability Guidelines does not recommend the use of opioids for neck and low back pain "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. 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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. Additionally, medical documents indicate that the patient has been in excess of the recommended 2-week limit. The treating physician does not detail sufficient information to substantiate the need for continued opioid medication. As such, the question for Hydrocodone 16mg #30 is not medically necessary.