

<b>Case Number:</b>	CM15-0109284		
<b>Date Assigned:</b>	06/15/2015	<b>Date of Injury:</b>	07/16/2010
<b>Decision Date:</b>	09/03/2015	<b>UR Denial Date:</b>	05/29/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/05/2015

### 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 54 year old male who sustained an industrial injury on 07/16/2010. The injured worker was diagnosed with cervical cord myelopathy with central cord syndrome and upper extremity radicular symptoms, cervicogenic headaches, lumbar radiculopathy, medication induced gastritis and depression. The injured worker is status post L5-S1 fusion in 1996, right knee arthroscopy in January 2011, left knee arthroscopy in June 2011, anterior cervical fusion at C2-3, C3-4, C4-5, C5-6 and C6-7 in August 2011 and a posterior fusion from C3-C7 on February 10, 2014. Treatment to date has included diagnostic testing, surgery, physical therapy, home exercise program, lumbar epidural steroid injections (latest in March 2015), lumbar trigger point injections times 4 on May 21, 2015, psychological evaluation and treatment, Synvisc-One injections for the right knee, ambulatory assistive devices and medications. According to the primary treating physician's progress report on May 21, 2015, the injured worker continues to experience debilitating pain in his neck radiating to both upper extremities and low back pain with radicular symptoms. The injured worker rates his pain level at 9/10. The injured worker also reports numerous in-home falls with increased reliance on his wheelchair for mobility and frequent headaches. Examination demonstrated a slow, wide based ataxic gait. There was tenderness to palpation over the posterior cervical musculature with increased muscle rigidity and decreased range of motion with guarding. Upper muscle strength was decreased. Sensory examination documented global decrease in both upper extremities with poor motor control and dysmetria. The lumbar spine demonstrated tenderness to palpation with numerous trigger points throughout the lumbar paraspinal muscles. There was decreased range of motion with guarding,

positive ankle clonus bilaterally and impaired motor control with dysmetria. Current medications are listed as OxyContin, Lyrica, Norco, Ultracet, Naproxen, Prozac, Cialis and Prilosec. Treatment plan consists of Gastrointestinal (GI) and Urology consultation, home health aide 24 hour/day for 7 days a week and the current request for OxyContin 20mg, Xanax, Provigil and Cialis.

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

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

**Oxycontin 20mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use, Therapeutic Trial of Opioids; Opioids for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain Criteria for use of Opioids Page(s): 60, 61, 76-78, 88, 89.

**Decision rationale:** The patient presents with neck pain radiating to bilateral upper extremities and low back pain radiating to bilateral lower extremities. Patient is status post anterior cervical fusion at C2-3, C3-4, C4-5 C5-6 and C6-7 on 08/27/11, posterior fusion from C3 through C7 on 02/10/14, right knee arthroscopic surgery 06/10/11, and L5-S1 fusion, 1996. The request is for OXYCONTIN 20 MG # 60. Patient's diagnosis on 05/21/15 includes cervical myoligamentous injury with bilateral upper extremity radicular symptoms, cervical cord myelopathy with central cord syndrome, bilateral knee internal derangement, lumbar spine post laminectomy syndrome with bilateral lower extremity radiculopathy-industrial related, GI distress with nausea and vomiting, medicine induced gastritis, atopic dermatitis/pruritis secondary to chronic opiate use, and continuous cervicogenic headaches with migrainous component. Physical examination to the cervical spine on 11/03/14 revealed tenderness to palpation bilaterally with increased muscle rigidity. Examination of the lumbar spine revealed tenderness to palpation bilaterally throughout the paraspinal muscles with numerous trigger points. Patient's treatments have included medication, acupuncture, image studies, and ESI injections with benefits. Patient's medications, per 06/19/14 progress report, patient's medications include Norco, Ultram ER, Anaprox, Prozac, Prilosec, Imitrex, Xanax, Flomax, Lyrica, Nuvigil, Cialis, Colace, Dendracin, Dilaudid, Oxycontin, and Fexmid. Patient's work status was not specified. MTUS Guidelines pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS p77 states, "Function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." Pages 80, 81 of MTUS also states "There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant radiculopathy," and for chronic back pain, it "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." Oxycontin has been included in patient's medications per progress reports dated 09/11/13 and 05/21/15. It is not known when Oxycontin was initiated. In

this case, treater has not stated how Oxycontin reduces pain and significantly improves patient's activities of daily living. There are no pain scales or validated instruments addressing analgesia. MTUS states that function should include social, physical, psychological, daily and work activities. There are no specific discussions regarding aberrant behavior, adverse reactions, ADL's, etc. No UDS's, opioid pain agreement or CURES reports. MTUS requires appropriate discussion of the 4A's. Given the lack of documentation as required by guidelines, the request is not medically necessary.

**Provigil #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult, Mosby, Inc, Provigil/Modafinil.

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

**Decision rationale:** The patient presents with neck pain radiating to bilateral upper extremities and low back pain radiating to bilateral lower extremities. Patient is status post anterior cervical fusion at C2-3, C3-4, C4-5 C5-6 and C6-7 on 08/27/11, posterior fusion from C3 through C7 on 02/10/14, right knee arthroscopic surgery 06/10/11, and L5-S1 fusion, 1996. The request is for PROVIGIL # 30. Patient's diagnosis on 05/21/15 includes cervical myoligamentous injury with bilateral upper extremity radicular symptoms, cervical cord myelopathy with central cord syndrome, bilateral knee internal derangement, lumbar spine post laminectomy syndrome with bilateral lower extremity radiculopathy-industrial related, GI distress with nausea and vomiting, medicine induced gastritis, atopic dermatitis/pruritis secondary to chronic opiate use, and continuous cervicogenic headaches with migrainous component. Physical examination to the cervical spine on 11/03/14 revealed tenderness to palpation bilaterally with increased muscle rigidity. Examination of the lumbar spine revealed tenderness to palpation bilaterally throughout the paraspinal muscles with numerous trigger points. Patient's treatments have included medication, acupuncture, image studies, and ESI injections with benefits. Patient's medications, per 06/19/14 progress report, patient's medications include Norco, Ultram ER, Anaprox, Prozac, Prilosec, Imitrex, Xanax, Flomax, Lyrica, Nuvigil, Cialis, Colace, Dendracin, Dilaudid, Oxycontin, and Fexmid. Patient's work status was not specified. ODG Guidelines, Pain (chronic) Chapter under Armodafinil (Nuvigil) states: "Provigil (Modafinil): Not recommended solely to counteract sedation effects of narcotics." Modafinil is used to treat excessive sleepiness caused by narcolepsy, obstructive sleep apnea or shift work sleep disorder. It is very similar to Amodafinil. Studies have not demonstrated any difference in efficacy and safety between armodafinil and modafinil. Provigil (Nuvigil) was included in patient's medications per progress reports dated 09/11/13 and 05/21/15. It is not known when Provigil (Nuvigil) was initiated. Treater has not provided a reason for the request and provided reports do not discuss the purpose of this medication. ODG indicates this medication for excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and shift work sleep disorder. None of these conditions are discussed by requesting physician. This request is not in accordance with guidelines. Therefore, the request is not medically necessary.

**Cialis 5mg #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult. Tadalafil (Cialis).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation AETNA Guidelines Clinical Polity Bulletin No. 0007.

**Decision rationale:** The patient presents with neck pain radiating to bilateral upper extremities and low back pain radiating to bilateral lower extremities. Patient is status post anterior cervical fusion at C2-3, C3-4, C4-5 C5-6 and C6-7 08/27/11, posterior fusion from C3 through C7 on 02/10/14, right knee arthroscopic surgery 06/10/11, and L5-S1 fusion, 1996. The request is for CIALIS 5 MG # 30. Patient's diagnosis on 05/21/15 includes cervical myoligamentous injury with bilateral upper extremity radicular symptoms, cervical cord myelopathy with central cord syndrome, bilateral knee internal derangement, lumbar spine post laminectomy syndrome with bilateral lower extremity radiculopathy-industrial related, GI distress with nausea and vomiting, medicine induced gastritis, atopic dermatitis/pruritis secondary to chronic opiate use, and continuous cervicogenic headaches with migrainous component. Physical examination to the cervical spine on 11/03/14 revealed tenderness to palpation bilaterally with increased muscle rigidity. Examination of the lumbar spine revealed tenderness to palpation bilaterally throughout the paraspinal muscles with numerous trigger points. Patient's treatments have included medication, acupuncture, image studies, and ESI injections with benefits. Patient's medications, per 06/19/14 progress report, patient's medications include Norco, Ultram ER, Anaprox, Prozac, Prilosec, Imitrex, Xanax, Flomax, Lyrica, Nuvigil, Cialis, Colace, Dendracin, Dilaudid, Oxycontin, and Fexmid. Patient's work status was not specified. MTUS, ODG and ACOEM are silent on Cialis. FDA indications/boxed label state that CIALIS is approved to treat erectile dysfunction. AETNA Guidelines Clinical Polity Bulletin No. 0007 regarding erectile dysfunction states that a comprehensive physical/examination and lab workup for the diagnosis of erectile dysfunction (ED) including medical, sexual, and psychosocial evaluation is required. AETNA also does not support performance enhancing drugs such as Viagra or Cialis. Cialis was included in patient's medications in progress reports dated 09/11/13 and 05/21/15. In this case, there are no laboratory tests with patient's testosterone levels showing hypogonadism and no evaluation regarding potential ED, in terms of etiology, severity, etc. Furthermore, life enhancing drugs such as Cialis are not typically supported by the guidelines. Therefore, this retrospective request is not medically necessary.

**Xanax 0.05mg #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Chapter, under Xanax (Alprazolam).

**Decision rationale:** The patient presents with neck pain radiating to bilateral upper extremities and low back pain radiating to bilateral lower extremities. Patient is status post anterior cervical fusion at C2-3, C3-4, C4-5 C5-6 and C6-7 08/27/11, posterior fusion from C3 through C7 on 02/10/14, right knee arthroscopic surgery 06/10/11, and L5-S1 fusion, 1996. The request is for XANAX 0.05 MG # 30. Patient's diagnosis on 05/21/15 includes cervical myoligamentous injury with bilateral upper extremity radicular symptoms, cervical cord myelopathy with central cord syndrome, bilateral knee internal derangement, lumbar spine post laminectomy syndrome with bilateral lower extremity radiculopathy-industrial related, GI distress with nausea and vomiting, medicine induced gastritis, atopic dermatitis/pruritis secondary to chronic opiate use, and continuous cervicogenic headaches with migrainous component. Physical examination to the cervical spine on 11/03/14 revealed tenderness to palpation bilaterally with increased muscle rigidity. Examination of the lumbar spine revealed tenderness to palpation bilaterally throughout the paraspinal muscles with numerous trigger points. Patient's treatments have included medication, acupuncture, image studies, and ESI injections with benefits. Patient's medications, per 06/19/14 progress report, patient's medications include Norco, Ultram ER, Anaprox, Prozac, Prilosec, Imitrex, Xanax, Flomax, Lyrica, Nuvigil, Cialis, Colace, Dendracin, Dilaudid, Oxycontin, and Fexmid. Patient's work status was not specified. The MTUS Guidelines page 24 states, "benzodiazepines are not recommended for long-term use because long-term efficacies are unproven and there is a risk of dependence." ODG-TWC, Pain (Chronic) Chapter, under Xanax (Alprazolam) states: "Not recommended for long-term use. See Alprazolam; & Benzodiazepines. Alprazolam, also known under the trade name Xanax and available generically, is a short-acting drug of the benzodiazepine class used to treat moderate to severe anxiety disorders, panic attacks, and as an adjunctive treatment for anxiety associated with major depression." Xanax (Alprazolam) has been included in patient's medications per progress reports dated 09/11/13 and 05/21/15. It is not known when this medication was initiated. However, guidelines do not recommend long-term use of benzodiazepines due to risk of dependence. The patient has been prescribed this medication at least since 09/11/13. This request is not in accordance with guidelines. Therefore, the request is not medically necessary.