

<b>Case Number:</b>	CM14-0208148		
<b>Date Assigned:</b>	12/22/2014	<b>Date of Injury:</b>	12/18/1989
<b>Decision Date:</b>	02/18/2015	<b>UR Denial Date:</b>	12/11/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/12/2014

### 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: California

Certification(s)/Specialty: Physical Medicine & Rehabn

### 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 patient is a 62 year old female with an injury date of 12/18/89. Based on 12/09/14 progress report, the patient complains of pain in the right shoulder, right hip, right ankle as well as increased low back pain with numbness down her right leg. The patient also has pain and numbness in the right hand. She had spasms in her low back, her right knee gave in, and she fell down a few days before this visit. Physical examination reveals tenderness in the anterior aspect of the right shoulder. The range of motion is limited along with positive Phalen's and Tinel's tests in the right wrist for median nerve compression. There is tenderness over the midline lower lumbar spine, right buttocks, and sciatic notch. The range of motion is very limited. Tenderness is also noted in right knee with +1 effusion and +2 crepitus. The range of motion of the right knee is restricted to 90 degrees. In progress report dated 12/02/14, the patient complains of swollen right knee. The patient also has depression. She rates her pain as 9/10, functional level at 8/10, and mood as 9/10. The patient also has sleep disturbances, as per the same progress report. Medications, as per progress report dated 12/02/14, include Cymbalta, Dilaudid, Exalgo, Lexapro, Lidoderm patch, Lunesta, Nuvigil, Prilosec, Subsys, and Xanax. The patient has received 30 to 40% pain relief from injections to her right knees, as per progress report dated 06/24/14. The patient is currently off work, as per progress report dated 12/09/14. MRI of the Lumbar Spine, 06/27/13, as per progress report dated 12/02/14:- Small fluid collection at surgical site L4-5 possibly representing postoperative seroma- Mild central canal stenosis at L3-4 secondary to 4 mm broad-based disc protrusion, short pedicles, and mild ligamentum flavum redundancy- Minimal to mild central canal stenosis and neural foraminal stenosis at L4-5

secondary to 4 mm broad-based disc protrusion, short pedicles, and mild ligamentum flavum redundancy- Minimal bilateral neural foraminal stenosis at L5-S1 secondary to 2 mm disc bulging- Minimal central canal stenosis at L2-3 secondary to 4 mm broad-based disc protrusion- Degenerative changes to lower lumbar spineMRI of the Right Knee, 03/29/13, as per progress report dated 12/02/14:- Moderate osteoarthritic changes in the medial compartment and mild osteoarthritic changes in the patellofemoral compartment- Mild joint effusion and synovitisDiagnoses, 12/09/14:- Status post lumbar laminectomy and fusion at L4-5 with cage and posterior instrumentation on 03/20/10. - Sprain/strain of the cervical spine, superimposed upon multiple disc bulges- Status post right shoulder arthroscopy and subacromial decompression- Severe bilateral carpal tunnel syndrome, as per EMG studies of 02/27/03- Status post carpal tunnel release- Secondary left wrist sprain/strain and avascular fracture of the left thumb, interphalangeal joint- Fracture, right radial head- Left trigger thumb by history- Strain/sprain of the right knee, rule out meniscus tear- Status post left knee arthroscopy, meniscectomy and chondroplasty- Contusion of the right knee secondary to recent falls- Status post left knee arthroscopy and chondroplasty of the medial femoral condyle and femoral groove, and patella- Status post right carpal tunnel releaseThe treater is requesting for (a) NUVIGIL 250 mg (b) LUNESTA 3 mg QTY 30 (c) ZORVOLEX 18 mg (SAMPLES) (d) SUBSYS 600 ugm (e) RE-TRIAL TN1: COMPOUND CREAM KETO 10% LIDO 5% 120 ml. The utilization review determination being challenged is dated 12/11/14. Treatment reports were provided from 06/11/14 - 12/09/14.

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

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

**Nuvigil 250mg:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.com/Nuvigil

**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 (chronic), Armodafinil (Nuvigil).

**Decision rationale:** The patient presents with pain in the right shoulder, right hip, and right ankle as well as increased low back pain with numbness down her right leg, as per progress report dated 12/09/14. The request is for Nuvigil 250 mg. The patient rates her pain as 9/10, functional level at 8/10, and mood as 9/10, as per progress report dated 12/02/14. The ACOEM and MTUS guidelines do not discuss Armodafinil. The ODG Guidelines, chapter 'Pain (chronic)' and topic 'Armodafinil (Nuvigil)', have the following regarding 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 Armodafinil. Studies have not demonstrated any difference in efficacy and safety between armodafinil and modafinil. A prescription for Nuvigil is first noted in progress report dated 08/21/14. Another prescription for the medication is seen in progress report dated 10/09/14. However, in progress report dated 12/02/14, the treater states that the medication was denied but continues to request for it. The progress reports do not discuss the purpose of this

medication. In progress report dated 12/02/14, the treater states that the patient is experiencing "poor sleep quality due to pain," but does not provide any other details. ODG indicates this medication for excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and shift work sleep disorder, and none of these conditions are documented in the progress reports. Hence, the request is not medically necessary.

**Lunesta 3mg QTY: 30:** 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) and on the Non-MTUS WebMD.com

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Mental & Stress Chapter states: Eszopicolone (Lunesta).

**Decision rationale:** The patient presents with pain in the right shoulder, right hip, and right ankle as well as increased low back pain with numbness down her right leg, as per progress report dated 12/09/14. The request is for Lunesta 3 mg QTY: 30. The patient rates her pain as 9/10, functional level at 8/10, and mood as 9/10, as per progress report dated 12/02/14. ODG-TWC, Mental & Stress Chapter states: "Eszopicolone (Lunesta): Not recommended for long-term use, but recommended for short-term use. See Insomnia treatment. See also the Pain Chapter. Recommend limiting use of hypnotics to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase... The FDA has lowered the recommended starting dose of eszopiclone (Lunesta) from 2 mg to 1 mg for both men and women." A prescription for Lunesta is first noted in progress report dated 06/19/14. In the progress report, the treater states that the patient sleeps for about 3 hours on a good night. The poor quality of her sleep is attributed to her pain. However, in the same report, the treater states that "Lunesta is not working well." The treater repeats the same detail in progress report dated 08/21/14. It is not clear why the treater is requesting the medication if it is not working for the patient. Additionally, ODG guidelines recommend the medication only for short-term use. The request is not medically necessary.

**Zorvolex 18mg (samples):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAID's Page(s): 22. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, under Zorvolex.

**Decision rationale:** The patient presents with pain in the right shoulder, right hip, and right ankle as well as increased low back pain with numbness down her right leg, as per progress report dated 12/09/14. The request is for Zorvolex 18 mg (samples). The patient rates her pain as 9/10, functional level at 8/10, and mood as 9/10, as per progress report dated 12/02/14. Regarding NSAID's, MTUS page 22 supports it for chronic low back pain, at least for short-term relief.

MTUS p60 also states, "A record of pain and function with the medication should be recorded," when medications are used for chronic pain. Regarding Zorvolex (Diclofenac), ODG Pain Chapter, under Zorvolex states, "Not recommended except as a second-line option, because diclofenac products are not recommended as first-line choices due to potential increased adverse effects." A sample of Zorvolex was first recommended for a trial in progress report dated 08/21/14. However, in the next available progress report dated 10/09/14, the treater states that medication was not received by the patient. The treater places a request for retrial of Zorvolex in the same progress report. In a progress report dated 12/02/14, the treater states that the medication was denied and places another request for "few doses." The UR has denied the medication as the request did not include the quantity. While the use of NSAIDs to treat chronic pain is reasonable, Diclofenac is typically not recommended due to risk profile that is similar to Vioxx. There is no evidence that the patient has failed other NSAIDs and why this medication needs to be tried over numerous other NSAIDs. The request is not medically necessary.

**Subsys 600ugm:** Upheld

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

**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 (chronic), Subsys<sup>®</sup> (fentanyl sublingual spray).

**Decision rationale:** The patient presents with pain in the right shoulder, right hip, and right ankle as well as increased low back pain with numbness down her right leg, as per progress report dated 12/09/14. The request is for Subsys 600ugm. The patient rates her pain as 9/10, functional level at 8/10, and mood as 9/10, as per progress report dated 12/02/14. ODG guidelines, chapter 'Pain (chronic)' and topic 'Subsys (fentanyl sublingual spray)' states that the spray is "Not recommended for musculoskeletal pain. FDA has approved Subsys fentanyl sublingual spray, from Insys Therapeutics, only for breakthrough cancer pain." In this case, a prescription for Subsys is first noted in progress report dated 06/19/14. The treater states that "Subsys really helped a lot with her severe pain but she doesn't have it now and her functioning is decreased." The prescription for the medication is seen in subsequent progress reports as well. In progress report dated 12/02/14, the treater reiterates that "Subsys is really the most helpful now for severe breakthrough pain. It helps with severe pain." ODG guidelines, however, do not support the use of this spray for musculoskeletal pain. Hence, the request is not medically necessary.

**Re-Trial TN1: Compound Cream Keto 10% Lido 5% 120ml:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs; Capsaicin, topical Page(s): 111-112; 28-29.

**Decision rationale:** The patient presents with pain in the right shoulder, right hip, and right ankle as well as increased low back pain with numbness down her right leg, as per progress report dated 12/09/14. The request is for re-trial TN1: compound cream keto 10% lido 5% 120 ml. The patient rates her pain as 9/10, functional level at 8/10, and mood as 9/10, as per progress report dated 12/02/14. The MTUS guidelines, page 111-112, do not support the use of topical NSAIDs such as Ketoprofen for axial, spinal pain, but supports its use for peripheral joint arthritis and tendinitis. Regarding Capsaicin, MTUS guidelines, page 29, state that they are "Recommended only as an option in patients who have not responded or are intolerant to other treatments." The prescription for TN1 topical formulation is first seen in progress report dated 08/21/14 where a sample of the medication is requested for a trial. In progress report dated 10/09/14, the treater states that the patient was never given the sample hence; another request for a trial is made. In progress report dated 12/02/14, the treater states that lotion was denied. TN1 contains Ketoprofen and Lidocaine. While Ketoprofen is approved for peripheral joint arthritis, MTUS does not recommend the use of Lidocaine. Additionally, the guidelines also state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." MTUS Guidelines also provide clear discussion regarding topical compounded creams on pg. 111. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Hence, this request is not medically necessary.