

Case Number:	CM15-0143258		
Date Assigned:	08/17/2015	Date of Injury:	05/04/2000
Decision Date:	10/07/2015	UR Denial Date:	06/30/2015
Priority:	Standard	Application Received:	07/23/2015

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 60 year old male who sustained an industrial injury on 5-4-00. Progress report dated 6-1-15 reports continued complaints of constant low back pain associated with left leg pain and arm numbness. The pain is described as a pinch feeling. Diagnoses include: lumbago, thoracic or lumbar radiculitis and left foot degenerative joint disease. Plan of care includes: update urine analysis today, continue to wear lumbar support brace, use topical analgesic compound cream; flurbiprofen 20%, lidocaine 5% 4 gm topical 2-3 times per day alternating with cyclobenzaprine 10%, lidocaine 2%, 4 gm topical 2-3 times per day, gas-x extra strength 1 three times per day, ambien 5 mg at night, # 30, norco 7.5-325 mg 1 every 4-6 hours as needed, #120, lyrica 75 mg 1 four times per day, #120, celebrex 200 mg one per day, #30, protonix 40 mg twice per day, #60, flexeril 10 mg one at night as needed, #30. Follow up in 1 month.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gas-X extra strength gel #120 with 3 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.pdr.net/drug-summary/gas-x?druglabelid=2675>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.com: Simethicone.

Decision rationale: Based on the 06/01/15 progress report provided by treating physician, the patient presents with low back pain associated with left leg pain and arm numbness. The patient is status post left knee surgery around 2002. The request is for gas-x extra strength gel #120 with 3 refills. Patient's diagnosis per Request for Authorization form dated 06/01/15 includes chronic back pain, right knee pain and gait derangement. Patient's diagnosis has also included lumbago, thoracic or lumbar radiculitis and left foot degenerative joint disease, sleep apnea, DM, HTN, CHO, vascular insufficiency. Physical examination revealed trace DTR, diminished pin-prick in low leg, ankle and feet, and poor tolerance to SLR. Patient's medications include Flexeril, Hydrocodone, Ambien, Lyrica, Celebrex, Protonix and topical creams. Patient's work status not provided. Simethicone is an anti-flatulent. It works by breaking up gas bubbles, which makes gas easier to eliminate. Drugs.com states indication for use is "Relief of painful symptoms and pressure of excess gas in digestive tract; adjunct in treatment of many conditions in which gas retention may be problem, such as postoperative gaseous distention and pain, endoscopic examination, air swallowing, functional dyspepsia, peptic ulcer, spastic or irritable colon, diverticulosis." Gas-X has been included in patient's medications, per progress reports dated 02/03/15, 04/30/15, and 06/25/15. It is not known when this medication was initiated. Treater has not provided reason for the request. Drugs.com supports Simethicone/Gas-X for "conditions in which gas retention may be problem, such as postoperative gaseous distention and pain, endoscopic examination, air swallowing, functional dyspepsia, peptic ulcer, spastic or irritable colon, diverticulosis." There are no discussions that patient presents with any of the aforementioned problems to warrant continuation of this medication. Furthermore, MTUS page 60 requires documentation of medication efficacy when medications are prescribed for chronic pain. Given lack of documentation, this request is not medically necessary.

Ambien 5mg, #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain (updated 06/15/15); FDA (Ambien) Zolpidem.

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 Zolpidem (Ambien).

Decision rationale: Based on the 06/01/15 progress report provided by treating physician, the patient presents with low back pain associated with left leg pain and arm numbness. The patient is status post left knee surgery around 2002. The request is for Ambien 5MG, #30. Patient's diagnosis per Request for Authorization form dated 06/25/15 includes chronic back pain, right knee pain and gait derangement. Patient's diagnosis has also included lumbago, thoracic or

lumbar radiculitis and left foot degenerative joint disease, sleep apnea, DM, HTN, CHO, vascular insufficiency. Physical examination revealed trace DTR, diminished pin-prick in low leg, ankle and feet, and poor tolerance to SLR. Patient's medications include Flexeril, Hydrocodone, Ambien, Lyrica, Celebrex, Protonix and topical creams. Patient's work status not provided. ODG-TWC, Pain (Chronic) Chapter, Zolpidem (Ambien) Section states: "Zolpidem is a prescription short-acting nonbenzodiazepine hypnotic, which is recommended for short-term (7-10 days) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. (Feinberg, 2008)" Ambien has been included in patient's medications, per progress reports dated 02/03/15, 04/30/15, and 06/25/15. It is not known when this medication was initiated. The patient has a diagnosis of sleep apnea. ODG recommends Ambien for only short-term use (7-10 days), due to negative side effect profile. In this case, the patient has been prescribe Ambien for at least 4 months from UR date of 06/30/15. Furthermore, the request for quantity 30 exceeds ODG indications. Therefore, the request is not medically necessary.

Lyrica 75mg, #120 with 3 refills: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

Decision rationale: Based on the 06/01/15 progress report provided by treating physician, the patient presents with low back pain associated with left leg pain and arm numbness. The patient is status post left knee surgery around 2002. The request is for Lyrica 75mg, #120 with 3 refills. Patient's diagnosis per Request for Authorization form dated 06/25/15 includes chronic back pain, right knee pain and gait derangement. Patient's diagnosis has also included lumbago, thoracic or lumbar radiculitis and left foot degenerative joint disease, sleep apnea, DM, HTN, CHO, vascular insufficiency. Physical examination revealed trace DTR, diminished pin-prick in low leg, ankle and feet, and poor tolerance to SLR. Patient's medications include Flexeril, Hydrocodone, Ambien, Lyrica, Celebrex, Protonix and topical creams. Patient's work status not provided. MTUS, Chronic Pain Treatment Guidelines, Anti-epileptic drugs Section, pages 19-20, have the following regarding Lyrica: Pregabalin Lyrica, no generic available 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. It further states, "Weaning: Do not discontinue pregabalin abruptly and weaning should occur over 1-week period. Withdrawal effects have been reported after abrupt discontinuation." Lyrica has been included in patient's medications, per progress reports dated 02/03/15, 04/30/15, and 06/25/15. It is not known when this medication was initiated. Per 06/01/15 report, treater states "Lyrica helps for sensory problem, improve sleep duration." This patient has a diagnosis of DM, and

radiculitis. Treater has documented benefit from this medication. The request appears reasonable and in accordance with guidelines. Therefore, the request is medically necessary.

Protonix 40mg, #60 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation ODG (Pain Chapter) Proton pump inhibitors (PPIs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: Based on the 06/01/15 progress report provided by treating physician, the patient presents with low back pain associated with left leg pain and arm numbness. The patient is status post left knee surgery around 2002. The request is for Protonix 40MG, #60 with 3 refills. Patient's diagnosis per Request for Authorization form dated 06/25/15 includes chronic back pain, right knee pain and gait derangement. Patient's diagnosis has also included lumbago, thoracic or lumbar radiculitis and left foot degenerative joint disease, sleep apnea, DM, HTN, CHO, vascular insufficiency. Physical examination revealed trace DTR, diminished pin-prick in low leg, ankle and feet, and poor tolerance to SLR. Patient's medications include Flexeril, Hydrocodone, Ambien, Lyrica, Celebrex, Protonix and topical creams. Patient's work status not provided. MTUS pg 69, NSAIDs, GI symptoms & cardiovascular risk Section states, clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. 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)." "Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI." Protonix and Celebrex have been included in patient's medications, per progress reports dated 02/03/15, 04/30/15, and 06/25/15. It is not known when Protonix was initiated. Prophylactic use of PPI is indicated by MTUS, and the patient is on NSAID therapy. However, treater has not provided GI risk assessment for prophylactic use of PPI, as required by MTUS. Provided progress reports do not show evidence of gastric problems, and there is no mention of GI issues. Furthermore, MTUS requires a record of pain and function when medications are used for chronic pain and physician monitoring. This request is not in accordance with guideline indications. Therefore, the request is not medically necessary.

Flexeril 5mg, #45: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: Based on the 06/01/15 progress report provided by treating physician, the patient presents with low back pain associated with left leg pain and arm numbness. The patient is status post left knee surgery around 2002. The request is for Flexeril 5MG, #45. Patient's diagnosis per Request for Authorization form dated 06/25/15 includes chronic back pain, right knee pain and gait derangement. Patient's diagnosis has also included lumbago, thoracic or lumbar radiculitis and left foot degenerative joint disease, sleep apnea, DM, HTN, CHO, vascular insufficiency. Physical examination revealed trace DTR, diminished pin-prick in low leg, ankle and feet, and poor tolerance to SLR. Patient's medications include Flexeril, Hydrocodone, Ambien, Lyrica, Celebrex, Protonix and topical creams. Patient's work status not provided. MTUS pg 64, Muscle relaxants for pain Section states that Cyclobenzaprine (Flexeril, Amrix, Fexmid, generic available): "Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). This medication is not recommended to be used for longer than 2-3 weeks." Flexeril has been included in patient's medications, per progress reports dated 02/03/15, 04/30/15, and 06/25/15. It is not known when this medication was initiated. MTUS recommends Flexeril, only for a short period (no more than 2-3 weeks). The patient has been prescribed Flexeril for at least 4 months from UR date of 06/30/15. The request for additional prescription of Flexeril would exceed guideline recommendations. Furthermore, the requested quantity 45 does not indicate intended short-term use of this medication. Therefore, the request is not medically necessary.

Compound-Flurbiprofen 20%, Lidocaine 5%, 4gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: Based on the 06/01/15 progress report provided by treating physician, the patient presents with low back pain associated with left leg pain and arm numbness. The patient is status post left knee surgery around 2002. The request is for Compound- Flurbiprofen 20%, Lidocaine 5%, 4GM. Patient's diagnosis per Request for Authorization form dated 06/25/15 includes chronic back pain, right knee pain and gait derangement. Patient's diagnosis has also included lumbago, thoracic or lumbar radiculitis and left foot degenerative joint disease, sleep apnea, DM, HTN, CHO, vascular insufficiency. Physical examination revealed trace DTR, diminished pin-prick in low leg, ankle and feet, and poor tolerance to SLR. Patient's medications include Flexeril, Hydrocodone, Ambien, Lyrica, Celebrex, Protonix and topical creams. Patient's work status not provided. MTUS, Topical Analgesics section, page 111 has the following: Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine whether creams, lotions or gels- are indicated for neuropathic pain. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Analgesics: Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this

treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. MTUS further states, "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Treater has not provided reason for the request. There are no discussions regarding location that will be treated, nor medication efficacy. MTUS page 111 states that if one of the compounded topical product is not recommended, then the entire product is not. In this case, the requested topical compound contains Lidocaine, which is not supported for topical use in lotion form, per MTUS. This request is not in accordance with guideline indications. Therefore, the request is not medically necessary.

Compound- Cyclobenzaprine 10%, Lidocaine 4%, 4gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: Based on the 06/01/15 progress report provided by treating physician, the patient presents with low back pain associated with left leg pain and arm numbness. The patient is status post left knee surgery around 2002. The request is for Compound- Cyclobenzaprine 10%, Lidocaine 4%, 4GM. Patient's diagnosis per Request for Authorization form dated 06/25/15 includes chronic back pain, right knee pain and gait derangement. Patient's diagnosis has also included lumbago, thoracic or lumbar radiculitis and left foot degenerative joint disease, sleep apnea, DM, HTN, CHO, vascular insufficiency. Physical examination revealed trace DTR, diminished pin-prick in low leg, ankle and feet, and poor tolerance to SLR. Patient's medications include Flexeril, Hydrocodone, Ambien, Lyrica, Celebrex, Protonix and topical creams. Patient's work status not provided. MTUS, Topical Analgesics section, page 111 has the following: Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine whether creams, lotions or gels- are indicated for neuropathic pain. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Analgesics: Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. MTUS further states, "Non FDA-approved agents: Ketoprofen: This

agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Treater has not provided reason for the request. There are no discussions regarding location that will be treated, nor medication efficacy. MTUS page 111 states that if one of the compounded topical product is not recommended, then the entire product is not. In this case, the requested topical compound contains Lidocaine and Cyclobenzaprine which are not supported for topical use in lotion form, per MTUS. This request is not in accordance with guideline indications. Therefore, the request is not medically necessary.

Celebrex 200mg, #30 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications, NSAIDs, specific drug list & adverse effects.

Decision rationale: Based on the 06/01/15 progress report provided by treating physician, the patient presents with low back pain associated with left leg pain and arm numbness. The patient is status post left knee surgery around 2002. The request is for Celebrex 200MG, #30 with 3 refills. Patient's diagnosis per Request for Authorization form dated 06/25/15 includes chronic back pain, right knee pain and gait derangement. Patient's diagnosis has also included lumbago, thoracic or lumbar radiculitis and left foot degenerative joint disease, sleep apnea, DM, HTN, CHO, vascular insufficiency. Physical examination revealed trace DTR, diminished pin-prick in low leg, ankle and feet, and poor tolerance to SLR. Patient's medications include Flexeril, Hydrocodone, Ambien, Lyrica, Celebrex, Protonix and topical creams. Patient's work status not provided. MTUS, Chronic Pain Medical Treatment Guidelines, Anti-inflammatory medications Section page 22 supports NSAIDs for chronic LBP but for Celebrex, it states, "COX-2 inhibitors (e.g., Celebrex) may be considered if the patient has a risk of GI complications, but not for the majority of patients. Generic NSAIDs and COX-2 inhibitors have similar efficacy and risks when used for less than 3 months, but a 10-to-1 difference in cost." MTUS Chronic Pain Medical Treatment Guidelines, NSAIDs, specific drug list & adverse effects Section, pg. 70-73 states "Selective COX-2 NSAIDs, for Celecoxib (Celebrex), states this is the only available COX-2 in the United States and that the Recommended Dose is 200 mg a day (single dose or 100 mg twice a day)." Celebrex has been included in patient's medications, per progress reports dated 02/03/15, 04/30/15, and 06/25/15. It is not known when this medication was initiated. Given the patient's continued pain and diagnosis, this request would appear to be indicated. However, treater has not documented how this medication has impacted the patient in terms of decrease in pain and functional improvement. MTUS p60 states "a record of pain and function with the medication should be recorded," when medications are used for chronic pain. In this case, treater has not provided reason for the request nor documented medication efficacy. Furthermore,

MTUS Recommended Dose is 200 mg a day, and treater has not discussed why the patient requires such a high dosage of this medication. Therefore, the request is not medically necessary.