

Case Number:	CM14-0040217		
Date Assigned:	08/01/2014	Date of Injury:	02/09/2011
Decision Date:	09/16/2014	UR Denial Date:	03/07/2014
Priority:	Standard	Application Received:	04/04/2014

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 Physical Medicine and Rehabilitation 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 injured worker is a 61-year-old female who reported an injury on 02/09/2011. The mechanism of injury was not documented in the submitted report. The injured worker has diagnoses of headache, neck sprain/strain, lumbar radiculopathy, status post lumbar surgery, status post left shoulder surgery, bilateral tenosynovitis, bilateral carpal tunnel syndrome, bilateral knee sprain/strain, bilateral knee medial meniscus tear, anxiety and depression. The injured worker's past treatment revealed medication therapy. Medications include Cyclobenzaprine, Xolido, Theramine, Sentra AM, Sentra PM, Gabadone, Somnicin capsules, Terocin cream, Flurbi cream, Gabacyclotram cream, Ambien and Norco 10/325. The duration, frequency and dosage were not submitted in the documentation on these medications. It was noted in the submitted report that the efficacy of these medications would be review upon the injured worker's return visit. A urinalysis drug screen that was collected on 02/17/2014 revealed that the injured worker was not in compliance with their prescription drug medications. The submitted report revealed that the results were inconsistent. The injured worker is post-op lumbar surgery 2010 and post-op left shoulder surgery in 2009. The injured worker complained of frequent headaches, which she rated a 3/10, constant neck pain that radiated to upper extremities rated at a 7/10, constant low back pain rated at a 7/10, constant left shoulder pain rated at a 6/10, constant bilateral wrist/hand pain rated at a 7/10 and constant bilateral knee pain rated 7/10. The injured worker stated that pain without medication was 8/10, and with medication was 5/10. Physical examination dated 10/07/2013 revealed that the cervical spine had a range of motion with a flexion of 45 degrees, extension of 50 degrees, right rotation of 65 degrees, internal rotation of 65 degrees, right lateral flexion 35 degrees, and left lateral flexion 35 degrees. Shoulder depression and cervical distraction were positive bilaterally. Left shoulder range of motion revealed a flexion of 50 degrees, extension of 50 degrees, right hand deviation

of 20 degrees, and ulnar deviation of 30 degrees. Phalen's, Tinel's median/ulnar and Finkelstein's tests were positive bilaterally. Examination of the lumbar spine revealed a range of motion of a flexion of 30 degrees, extension 0 degrees, right lateral flexion 10 degrees, and left lateral flexion of 10 degrees. Straight leg raise was positive bilaterally. Bilateral knee range of motion revealed a flexion of 120 degrees to the right and 130 in the left, extension 0 bilaterally. Right upper extremity sensation was decreased at the C6 dermatome. Left upper extremity sensation was decreased at the C5-6 dermatome. Bilateral lower extremities' sensation was also decreased at the L5-S1 dermatome. The treatment plan for the injured worker is to continue medication therapy, review drug screen that was completed, and await approval for surgery. The rationale and Request for Authorization form were not submitted for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Drug Screen: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids (Screening for Risk of Addiction).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug testing Page(s): 43.

Decision rationale: The request for Drug Screen is non-certified. A drug screen was submitted on 02/17/2014 showing that the injured worker was not compliant with her prescribed medications. The Medical Treatment Utilization Schedule (MTUS) guidelines state using a urine drug screen to assess for the use or the presence of illegal drugs is recommended as an option. Drug screens are one of the steps used to take before a therapeutic trial of Opioids and on-going management of opioids. They are also used to differentiate dependence and addiction. The injured worker was being prescribed opioids and periodic quantitative drug screens to monitor prescription medication compliance and/or potential substance abuse, which is guideline supported. However, the submitted report documentation stated that the injured worker was no longer on any type of narcotic medications. Furthermore, the injured worker underwent a drug screen on 02/17/2014. Based on the current available information submitted for review, the medical necessity for an additional drug screen has not been established. As such, the request for an additional drug screen is non-certified.

Cyclobenzaprine Hydrochloride 7.5mg, #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41-42.

Decision rationale: The request for Cyclobenzaprine Hydrochloride 7.5mg, #60 is non-certified. The injured worker complained of frequent headaches, which she rated a 3/10, constant neck

pain that radiated to upper extremities rated at a 7/10, constant low back pain rated at a 7/10, constant left shoulder pain rated at a 6/10, constant bilateral wrist/hand pain rated at a 7/10 and constant bilateral knee pain rated 7/10. The injured worker stated that pain without medication was 8/10, and with medication was 5/10. The California Medical Treatment Utilization Schedule (MTUS) guidelines only recommend Flexeril as an option, using a short course of therapy. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief. The addition of Cyclobenzaprine to other agents is not recommended. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. Evidence in progress note dated 09/09/2013 showed the usage of Flexeril for almost a year, exceeding the recommendations of the MTUS. The efficacy of the medication was also not submitted in the report for review. As such, the request for Cyclobenzaprine HCL (Flexeril 7.5 mg) is non-certified.

Xolindo 2%: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: The request for Xolindo 2% is non-certified. The California Medical Treatment Utilization Schedule (MTUS) Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as Gabapentin or Lyrica). No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. According to the MTUS Guidelines, Xolindo is recommended to patients with a diagnosis of radiculopathy. The submitted report lacked quantified evidence of the injured worker's diagnosis of radiculopathy. Guidelines stipulate that for a diagnosis of radiculopathy there should be objective physical findings with corroboration of imaging to verify diagnosis. Furthermore, there was no quantified evidence showing that the injured worker had trialed and failed any first line therapy (tricyclic or SNRI antidepressants) such as Gabapentin or Lyrica. In addition, the dosage, quantity and frequency for the proposed medication were not provided. As such, the request for Xolindo 2% is non-certified.

Theramine #90: 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), Pain Chapter, Theramine.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Pain, Medical food (Theramine).

Decision rationale: The request for Theramine #90 is non-certified. The Official Disability Guidelines state that Theramine is made up of a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. To be considered for the use of this product the person must, at a minimum, meet the following criteria to include (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Given the above, the injured worker does not meet the Official Disability Guideline requirements for Theramine. The submitted report lacked any quantified evidence showing that the injured worker had any nutritional deficits, diseases or conditions for which the injured worker would need Theramine. The guidelines also stipulate that a person taking Theramine is usually a tube feeder or has problems with oral foods. There was no evidence noted in the reports that this would apply to the injured worker. As such, the request for Theramine is non-certified.

Sentra AM, #60: 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), Pain Chapter, Medical Foods.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Pain, Medical food (Sentra AM).

Decision rationale: The request for Sentra AM, #60 is non-certified. The Official Disability Guidelines state that Sentra AM is made up of a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. To be considered for the use of this product the person must, at a minimum, meet the following criteria to include (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Given the above, the injured worker does not meet the Official Disability Guideline requirements for Sentra AM. The submitted report lacked any quantified evidence showing that the injured worker had any nutritional deficits, diseases or conditions for which the injured worker would need Sentra AM. The guidelines also stipulate that a person taking Sentra AM is usually a tube feeder or has problems with oral foods. There was no evidence noted in the reports that this would apply to the injured worker. As such, the request for Sentra AM, #60 is non-certified.

Sentra PM, #60: 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), Pain Chapter, Sentra PM.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Pain, Medical food (Sentra Pm).

Decision rationale: The request for Sentra PM, #60 is non-certified. The Official Disability Guidelines state that Sentra PM is made up of a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. To be considered for the use of this product the person must, at a minimum, meet the following criteria to include (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Given the above, the injured worker does not meet the Official Disability Guideline requirements for Sentra PM. The submitted report lacked any quantified evidence showing that the injured worker had any nutritional deficits, diseases or conditions for which the injured worker would need the Sentra PM. The guidelines also stipulate that a person taking Sentra PM is usually a tube feeder or has problems with oral foods. There was no such evidence noted in the report that would apply this to the injured worker. As such, the request for Sentra PM, #60 is non-certified.

GABAdone #60: 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), Pain Chapter, Gabadone.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Pain, Medical food (Gabadone).

Decision rationale: The request for GABAdone #60 is non-certified. The Official Disability Guidelines state that Gabadone is made up of a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. To be considered for the use of this product the person must, at a minimum, meet the following criteria to include (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. Given the above, the injured worker did not meet the ODG Guideline requirements for Gabadone. The submitted report lacked any quantified evidence showing that the injured worker had any functional deficits, diseases or conditions for which the injured worker would need Gabadone. The guidelines also stipulate that a person taking Gabadone is usually a tube feeder

or has problems with oral foods. There was no such evidence noted in the submitted report that would apply to the injured worker. As such, the request for Gabadone #60 is non-certified.

Somnicin #30 capsules (Melatonin 2mg/ 5 HTP 50mg/ L-Tryptophan 100mg/ Pyridoxine 10mg/ Magnesium 50mg): 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), Pain Chapter, Medical Food.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, treatment for insomnia. Other Medical Treatment Guideline or Medical Evidence: WebMD (Tryptophan).

Decision rationale: The request for Somnicin #30 capsules (Melatonin 2mg/ 5 HTP 50mg/ L-Tryptophan 100mg/ Pyridoxine 10mg/ Magnesium 50mg) is non-certified. The medication Somnicin is a combination of Magnesium Oxide, Melatonin, Oxitriptan and Tryptophan. Magnesium Oxide is an element your body needs to function normally. Magnesium Oxide can be used as an antacid to relieve heartburn, sour stomach, or acid indigestion, a dietary supplement when the amount of magnesium in the diet is not enough, a laxative for short-term, rapid emptying of the bowel. It should not be used repeatedly. Melatonin, according to the ODG is a melatonin agonist (MT1 and MT2) indicated for difficulty with sleep onset; is nonscheduled (has been shown to have no abuse potential). One systematic review concluded that there is evidence to support the short-term and long-term use of Ramelteon to decrease sleep latency; however, total sleep time has not been improved. Oxitriptan, a type of antidepressant that is recommended as a first line option for neuropathic pain and as a possibility for non-neuropathic pain. Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated, according to the MTUS. It has been suggested that the main role of antidepressants such as Oxitriptan, may be in addressing psychological symptoms associated with chronic pain. Tryptophan is an amino acid, a protein building block that can be found in many plant and animal proteins. Tryptophan is called an "essential" amino acid because the body can't make it. It must be acquired from food. Tryptophan is used for insomnia, sleep apnea, depression, anxiety, and facial pain. The submitted report lacked any quantified evidence as to whether the injured worker had tried and failed any conservative care. Furthermore, there was a lack of subjective complaints of neuropathic pain. Given the above guidelines, the request for the above medication is not medically necessary. Furthermore, the request submitted did not include a dosage, frequency or duration of the medication. As such, the request for Somnicin 30 capsules is non-certified.

Terocin 240ml (Capsaicin 0.025% Methyl Salicylate 25% Menthol 10% Lidocaine 2.5%) apply a thin layer to affected area 3-4 times a day: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-112.

Decision rationale: The request for Terocin 240ml (Capsaicin 0.025% Methyl Salicylate 25% Menthol 10% Lidocaine 2.5%) apply a thin layer to affected area 3-4 times a day is non-certified. The California Medical Treatment Utilization Schedule (MTUS) guidelines state that topical analgesics are largely experimental in use with few randomized controlled trails to determine efficacy or safety. The guidelines also state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Terocin cream contains Lidocaine 4 % and Menthol 4%. The guidelines state that there are no other commercially approved topical formulation of Lidocaine (whether creams, lotions or gels) that are indicated for neuropathic pain other than Lidoderm. The proposed cream contains Lidocaine. There was a lack of subjective complaints of neuropathic pain. There was also no rationale as to why the injured worker would require a topical cream instead of oral medications. The duration for the proposed medication was not provided. As Terocin cream contains Lidocaine, which is not recommended, the proposed compound product is not medically necessary. As such, the request for Terocin 240 ml cream is non-certified.

Flurbi (NAP) cream-LA 180gms (Flurbiprofen 20% Lidocaine 5% Amitriptyline 4%, apply a thin layer to affected area 2-3 times a day as needed: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

Decision rationale: The request for Flurbi (NAP) cream-LA 180gms (Flurbiprofen 20% Lidocaine 5% Amitriptyline 4%, apply a thin layer to affected area 2-3 times a day as needed is non-certified. The California Medical Treatment Utilization Schedule (MTUS) guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. Given the above, the proposed medication is not recommended by the Medical Treatment Utilization Schedule Guidelines. Furthermore, in the submitted report there was no documentation as to where the cream would be applied. There was also a lack of evidence of effectiveness of the current medications the injured worker was taking. There was no rationale submitted as to how the injured worker would benefit from a topical cream instead of oral medications. As such, the request for Flurbi cream is non-certified.

Gabacyclotram 180gms (Gabapentin 10% Cyclobenzaprine 6% Tramadol 10%) apply a thin layer to the affected area 2-3 times a day as needed: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: The request Gabacyclotram 180gms (Gabapentin 10% Cyclobenzaprine 6% Tramadol 10%) apply a thin layer to the affected area 2-3 times a day as needed grams is non-certified. The California Medical Treatment Utilization Schedule (MTUS) Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In the submitted report, there was no documentation as to where the cream would be applied. The report also lacked quantified evidence of the effectiveness of the current medications the injured worker was taking. There was also no rationale submitted in the request as to how the injured worker would benefit from a topical cream instead of oral medications. Furthermore, the request was for a compound that, per California MTUS Guidelines, is not recommended. The request is for Gabapentin, Cyclobenzaprine and Tramadol, which are not supported for topical application. The submitted request also lacked duration of the medication. As such, the request for Gabacyclotram 180 g is non-certified.

Follow-up every 4-6 weeks: 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), Neck and Upper Back Chapter, Office Visits.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Low Back Chapter, Office Visits.

Decision rationale: The request for Follow-up every 4-6 weeks is non-certified. ODG guidelines recommend office visits as they are to be determined medically necessary. Evaluation and management (E&M) outpatient visits to the offices of medical doctor(s) play a critical role in the proper diagnosis and return to function of an injured worker, and they should be encouraged. The need for a clinical office visit with a health care provider is individualized based upon a review of the patient concerns, signs and symptoms, clinical stability, and reasonable physician judgment. The determination is also based on what medications the patient is taking, since some medicines such as opiates, or medicines such as certain antibiotics, require close monitoring. As patient conditions are extremely varied, a set number of office visits per condition cannot be reasonably established. The determination of necessity for an office visit requires individualized case review and assessment, being ever mindful that the best patient outcomes are achieved with

eventual patient independence from the health care system through self-care as soon as clinically feasible. The request submitted did not specify a time frame as to how many follow-up visits the injured worker would be attending, this could essentially be an unlimited number of office visits every 4 to 6 weeks. There was also no submitted documentation regarding the current clinical situation with the injured worker to determine when they would need to be seen again, and without that information, the necessity of office visits every 4 to 6 weeks cannot be determined. Furthermore, findings at an office visit will also determine the frequency of the next visit. As such, the request for follow-up visits every 4 to 6 weeks is non-certified.