

Case Number:	CM15-0066146		
Date Assigned:	04/22/2015	Date of Injury:	05/26/2010
Decision Date:	07/28/2015	UR Denial Date:	03/06/2015
Priority:	Standard	Application Received:	04/07/2015

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: New York

Certification(s)/Specialty: Emergency Medicine

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 45 year old female who has reported the gradual onset of widespread pain and mental illness attributed to her usual work activities, with a listed injury date of 5/26/10. The diagnoses have included cervical radiculopathy, cervical spinal stenosis, cervical disc degeneration, lumbar disc protrusion, lumbar spinal stenosis, meniscal tear, arm overuse syndrome, shoulder strain, lumbar radiculopathy, depression, and anxiety. Treatment has included epidural injections, medications, and physical therapy. The injured worker has been seen by at least 5 physicians concurrently during 2014 and 2015. At least three of them prescribe medications, some of which are overlapping, and urine drug screens. All physician reports reflect high pain levels, poor function, and no significant benefit from any medication. The injured worker has been treated recently by an orthopedic surgeon and a pain management physician. The pain management physician has prescribed a long list of medications, including those referred for this Independent Medical Review, on a chronic basis since at least 2014. There was no discussion of the results of using any single medication. There was no discussion of functional improvement. There was no work status. Pain levels are routinely reported as very high, even though unspecified medications are reported to provide good, partial pain relief. Per the pain management physician report of 1/30/15, there was ongoing 8-10/10 pain. Pain was reportedly reduced to 5/10 with unspecified medications. There was no discussion of the results of using any single medication. There was no discussion of functional improvement. There was no work status. A long list of medications, including those referred for this Independent Medical Review, were prescribed/dispensed. On 3/6/15 and 3/9/15 Utilization Review non-certified capsaicin, Terocin, Theramine, Sentra AM and PM, Gabodone, Zofran, topical compounds, cyclobenzaprine, Somnicin, and Ativan.

IMR ISSUES, DECISIONS AND RATIONALES

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

Pharmacy purchase of Capsaicin 0.025%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113.

Decision rationale: No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. None of the reports describes the individual results of using capsaicin. Per the MTUS, capsaicin has some indications after other treatments have failed. The treating physician did not discuss the failure of other, adequate trials of other treatments. The treating physician reports mention only that there are no significant side effects of medications and that they provide good pain relief. Capsaicin is not medically necessary based on the lack of indications per the MTUS.

Pharmacy purchase of Terocin Pain Patch #20: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: December 5, 2006 FDA Alert, FDA Warns Five Firms To Stop Compounding Topical Anesthetic Creams.

Decision rationale: Per the manufacturer, Terocin is Methyl Salicylate 25%, Menthol 10%, Capsaicin 0.025%, Lidocaine 2.5%, Aloe, Borage Oil, Boswellia Serrata, and other inactive ingredients. Per page 60 of the MTUS, medications should be trialed one at a time. Regardless of any specific medication contraindications for this patient, the MTUS recommends against starting 3-7 medications simultaneously. Per the MTUS, any compounded product that contains at least one drug that is not recommended, is not recommended. Boswellia serrata resin and topical lidocaine other than Lidoderm are not recommended per the MTUS. The MTUS does not recommend topical anesthetics other than Lidoderm for neuropathic pain (a condition not present in this case). No benefit is apparent per the available reports. Note the FDA warning cited above. Topical lidocaine like that in Terocin is not indicated per the FDA, and places patients at an unacceptable risk of seizures, irregular heartbeats and death. Capsaicin has already been prescribed and is not indicated, as per the above discussion. The capsaicin in Terocin is redundant and possibly toxic. Terocin is not medically necessary based on lack of specific medical indications, the MTUS, lack of medical evidence, FDA directives, and inappropriate prescribing.

Pharmacy purchase of 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, Medical food.

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

Decision rationale: Medical foods, per the FDA definition, are for treatment of specific dietary conditions and deficiencies. No medical reports have established any specific dietary deficiencies. The MTUS does not address medical food. The Official Disability Guidelines have several recommendations and indications (such as liver deficiency, achlorhydria), per the citation above. This injured worker does not meet any of the indications in the Official Disability Guidelines, and the treating physician has neither defined the ingredients nor identified any specific indications for the ingredients in this medical food. The Official Disability Guidelines specifically recommend against Theramine. This medical food is not medically necessary based on the lack of any indications in this injured worker and the recommendations of the guidelines and the FDA.

Pharmacy purchase of 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 food.

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

Decision rationale: Medical foods, per the FDA definition, are for treatment of specific dietary conditions and deficiencies. No medical reports have established any specific dietary deficiencies. The MTUS does not address medical food. The Official Disability Guidelines have several recommendations and indications (such as liver deficiency, achlorhydria), per the citation above. This injured worker does not meet any of the indications in the Official Disability Guidelines, and the treating physician has neither defined the ingredients nor identified any specific indications for the ingredients in this medical food. This medical food is not medically necessary based on the lack of any indications in this injured worker and the recommendations of the guidelines and the FDA.

Pharmacy purchase of 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, Medical food.

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

Decision rationale: Medical foods, per the FDA definition, are for treatment of specific dietary conditions and deficiencies. No medical reports have established any specific dietary deficiencies. The MTUS does not address medical food. The Official Disability Guidelines have several recommendations and indications (such as liver deficiency, achlorhydria), per the citation above. This injured worker does not meet any of the indications in the Official Disability Guidelines, and the treating physician has neither defined the ingredients nor identified any specific indications for the ingredients in this medical food. This medical food is not medically necessary based on the lack of any indications in this injured worker and the recommendations of the guidelines and the FDA.

Pharmacy purchase of 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, Medical food.

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

Decision rationale: Medical foods, per the FDA definition, are for treatment of specific dietary conditions and deficiencies. No medical reports have established any specific dietary deficiencies. The MTUS does not address medical food. The Official Disability Guidelines have several recommendations and indications (such as liver deficiency, achlorhydria), per the citation above. This injured worker does not meet any of the indications in the Official Disability Guidelines, and the treating physician has neither defined the ingredients nor identified any specific indications for the ingredients in this medical food. This medical food is not medically necessary based on the lack of any indications in this injured worker and the recommendations of the guidelines and the FDA.

Pharmacy purchase of Zofran ODT 4mg #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), Pain Chapter, Anti-emetics (for opioid nausea).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Antiemetics.

Decision rationale: The MTUS does not provide direction for the use of antiemetics. The Official Disability Guidelines recommends against their use for nausea presumed to be caused by chronic opioid intake. Per the FDA, ondansetron is indicated for nausea caused by chemotherapy, radiation treatment, postoperative use, and acute gastroenteritis. This injured worker does not have an FDA-approved indication, and the only apparent indication is for nausea possibly related to chronic opioid intake. The treating physician has not provided an adequate evaluation of any condition causing nausea. None of the reports described the specific results of using ondansetron. The necessary indications are not present per the available guidelines and evidence and the ondansetron is not medically necessary.

Pharmacy purchase of Flurbi (NAP) cream-LA 180mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

Decision rationale: Flurbi (NAP) Cream-LA is flurbiprofen-lidocaine-amitriptyline. No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state that Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm. The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical lidocaine, only in the form of the Lidoderm patch, is indicated for neuropathic pain (which is not present in this case). The MTUS states that the only form of topical lidocaine that is recommended is Lidoderm. The topical lidocaine prescribed in this case is not Lidoderm. Topical lidocaine has been prescribed in two different topical agents, which is redundant, toxic, and not indicated. Topical anesthetics like the ones dispensed are not indicated per the FDA, are not FDA approved, and place injured workers at an unacceptable risk of seizures, irregular heartbeats and death. Per the MTUS, topical NSAIDs for short-term pain relief may be indicated for pain in the extremities caused by osteoarthritis or tendonitis. There is no good evidence supporting topical NSAIDs for shoulder or axial pain. The treating physician did not provide any indications or body part intended for this NSAID. Note that topical

flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. Topical antidepressants are not addressed in the MTUS. The topical compounded medication prescribed for this injured worker is not medically necessary based on the MTUS, the Official Disability Guidelines, lack of medical evidence, and lack of FDA approval.

Pharmacy purchase of Gabacyciotram 180gms: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

Decision rationale: Gabacyclotram is gabapentin, cyclobenzaprine, and tramadol. No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state that Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm. The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Per the MTUS citation, there is no good evidence in support of topical gabapentin or muscle relaxants; these agents are not recommended. The topical compounded medication prescribed for this injured worker is not medically necessary based on the MTUS, the Official Disability Guidelines, and lack of medical evidence

Pharmacy purchase of Terocin 240ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: December 5, 2006 FDA Alert, FDA Warns Five Firms To Stop Compounding Topical Anesthetic Creams.

Decision rationale: Per the manufacturer, Terocin is Methyl Salicylate 25%, Menthol 10%, Capsaicin 0.025%, Lidocaine 2.5%, Aloe, Borage Oil, Boswellia Serrata, and other inactive ingredients. Per page 60 of the MTUS, medications should be trialed one at a time. Regardless of

any specific medication contraindications for this patient, the MTUS recommends against starting 3-7 medications simultaneously. Per the MTUS, any compounded product that contains at least one drug that is not recommended, is not recommended. Boswellia serrata resin and topical lidocaine other than Lidoderm are not recommended per the MTUS. The MTUS does not recommend topical anesthetics other than Lidoderm for neuropathic pain (a condition not present in this case). No benefit is apparent per the available reports. Note the FDA warning cited above. Topical lidocaine like that in Terocin is not indicated per the FDA, and places patients at an unacceptable risk of seizures, irregular heartbeats and death. Capsaicin has already been prescribed and is not indicated, as per the above discussion. The capsaicin in Terocin is redundant and possibly toxic. Terocin is not medically necessary based on lack of specific medical indications, the MTUS, lack of medical evidence, FDA directives, and inappropriate prescribing.

Pharmacy purchase of Cyclobenzaprine 10mg #45: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 63-66.

Decision rationale: The MTUS for Chronic Pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. This injured worker has chronic pain with no evidence of prescribing for flare-ups. Prescribing has occurred consistently for months at minimum. No reports show any specific and significant improvements in pain or function as a result of prescribing muscle relaxants. Topical and oral cyclobenzaprine were prescribed, which is redundant and possibly toxic. Cyclobenzaprine, per the MTUS, is indicated for short-term use only and is not recommended in combination with other agents. This injured worker has been prescribed multiple medications along with cyclobenzaprine. Per the MTUS, this muscle relaxant is not indicated and is not medically necessary.

Pharmacy purchase of Somnicin #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), Pain Chapter, Medical food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Insomnia treatment, melatonin, vitamin B and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: ACOEM Guidelines, Chronic Pain update, 2008, page 137: Vitamins for Chronic Low Back and Other Chronic Pain.

Decision rationale: Somnicin contains melatonin, 5-HTP, L-tryptophan, vitamin B6, and magnesium. The MTUS does not provide direction for the use of vitamins, minerals, or

hypnotics other than benzodiazepines. The treating physician has not discussed these ingredients and their specific indications for this injured worker. There was no evidence of any specific nutritional deficiencies for which an amino acid, vitamin, or mineral would be indicated. Melatonin alone may have indications for some medical conditions, including certain kinds of sleep disorders, per the Official Disability Guidelines citation above. The treating physician has not described any of these conditions. The treating physician has provided no evidence of a vitamin deficiency or any other specific indication for vitamin replacement. The Official Disability Guidelines citation above recommends against vitamin B for chronic pain. The ACOEM update cited above recommends against vitamin supplementation unless there is a documented deficiency, which there is not in this case. There is no medical necessity for Somnicin based on the guidelines and the available records.

Pharmacy purchase of Ativan 1mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines, Muscle Relaxants Page(s): 24, 66.

Decision rationale: The treating physician has not provided a sufficient account of the indications and functional benefit for this medication. The physician has prescribed this medication chronically and none of the reports address the specific results of use or any specific benefit. The MTUS does not recommend benzodiazepines for long term use for any condition. The prescribing has occurred chronically, not short term as recommended in the MTUS. The MTUS does not recommend benzodiazepines as muscle relaxants. This benzodiazepine is not prescribed according the MTUS and is not medically necessary.

Pharmacy purchase of Lorazepam 1mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines, Muscle Relaxants Page(s): 24, 66.

Decision rationale: The treating physician has not provided a sufficient account of the indications and functional benefit for this medication. The physician has prescribed this medication chronically and none of the reports address the specific results of use or any specific benefit. The MTUS does not recommend benzodiazepines for long term use for any condition. The prescribing has occurred chronically, not short term as recommended in the MTUS. The MTUS does not recommend benzodiazepines as muscle relaxants. This benzodiazepine is not prescribed according the MTUS and is not medically necessary.

Pharmacy purchase of Ondansetron 4mg #30: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Antiemetics.

Decision rationale: The MTUS does not provide direction for the use of antiemetics. The Official Disability Guidelines recommends against their use for nausea presumed to be caused by chronic opioid intake. Per the FDA, ondansetron is indicated for nausea caused by chemotherapy, radiation treatment, postoperative use, and acute gastroenteritis. This injured worker does not have an FDA-approved indication, and the only apparent indication is for nausea possibly related to chronic opioid intake. The treating physician has not provided an adequate evaluation of any condition causing nausea. None of the reports described the specific results of using ondansetron. The necessary indications are not present per the available guidelines and evidence and the ondansetron is not medically necessary.