

Case Number:	CM13-0018068		
Date Assigned:	11/08/2013	Date of Injury:	05/11/2005
Decision Date:	07/16/2015	UR Denial Date:	08/08/2013
Priority:	Standard	Application Received:	08/29/2013

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: Pennsylvania

Certification(s)/Specialty: Internal 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 55-year-old female who has reported widespread pain after an injury on 05/11/2005. The diagnoses have included chronic upper extremity pain, anxiety, depression, chronic mixed headaches, sleep disorder, bilateral temporal mandibular joint dysfunction, irritable bowel syndrome, gastroesophageal reflux disease (GERD), chronic bilateral feet pain, carpal tunnel syndrome, cubital tunnel syndrome, and medication-induced xerostomia. Treatments to date have included psychotherapy, several upper extremity surgeries, and medications. Reports from the pain management physician during 2013 state that Lyrica provides pain relief. Modafinil caused constipation. Modafinil was changed to Ritalin due to cheek biting. Muscles feel very weak. There were "herpes breakouts from the increase stress." Gastrointestinal (GI) symptoms were better controlled. The mouth was dry. Bloating was present. Biotene was prescribed for a dry mouth but the reports state that the mouth was still dry even with using Biotene. Librax was apparently for GI symptoms. Short term memory deficits were present. The treatment plans have included home care assistance, Lyrica, modafinil, docusate, Lidoderm, Voltaren gel, Effexor, tramadol, Biotene for dry mouth, levothyroxine, famcyclovir, sertraline, ranitidine, Librax, pantoprazole, Benefiber. The work status was "unable to work" or it was not addressed. A mattress and sheets were prescribed for migraine headache treatment. None of the available reports discuss the specific indications and results for Lidoderm, Voltaren gel, levothyroxine, ranitidine, zolpidem, Relpax, pilocarpine, Centrum, or tramadol. Per the report of 07/08/2013, cheek biting would get worse in parallel with increased pain and anxiety. Some bloating continued. Ritalin helped energy and focus. There was no mention of any skin conditions. The thyroid stimulating hormone (TSH) was 2.8. There was no discussion of

any other medications. The treatment plan included those items referred for this Independent Medical Review. On 8/8/13 Utilization Review certified docusate, sertraline, pantoprazole, simethicone, and Lyrica. Tramadol was partially certified. Ritalin, Lidoderm, Voltaren gel, Biotene, levothyroxine, ranitidine, Librax, zolpidem, Relpax 40mg, pilocarpine 5mg, Centrum Silver, and acyclovir were non-certified.

IMR ISSUES, DECISIONS AND RATIONALES

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

RANITIDINE 300MG QHS: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation UpToDate, ranitidine drug information.

Decision rationale: There are no medical reports which adequately describe the relevant signs and symptoms of possible gastrointestinal disease. There are no reports which adequately discuss the specific indications for ranitidine or the specific results of using it over time. The MTUS addresses the use of H2 blockers in the context of prescribing non-steroidal anti-inflammatory agents (NSAIDs). None of the indications in the MTUS are present. The UpToDate reference above notes that ranitidine is for "duodenal ulcer, gastric ulcer, gastroesophageal reflux disease (GERD), active benign ulcer, erosive esophagitis, and pathological hypersecretory conditions." None of these conditions are described in any detail, and the specific impact of using this drug is not discussed. Although there may be an indication for ranitidine for this injured worker, the available reports are not sufficient to demonstrate medical necessity for ongoing use. The injured worker is already taking a proton pump inhibitor (PPI). Ranitidine is therefore not medically necessary.

LIBRAX 1 CAP Q 8 HRS AS NEEDED: 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 UpToDate, Librax drug information.

Decision rationale: The treating physician has not provided a sufficient account of the indications and functional benefit for this medication. None of the reports adequately address the specific results of using Librax. 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 UpToDate reference above notes the side effects of dry mouth, constipation, and memory deficits. These symptoms are present in this patient and were not discussed by the physician. The available reports do not contain a sufficient evaluation of any gastrointestinal conditions for which there might an indication, the results of use are not adequately described, and there are possible toxicity issues. Librax is therefore not medically necessary.

ZOLPIDEM 5MG 1 TAB QHS AS NEEDED FOR SLEEP: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Insomnia Treatment.

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.

Decision rationale: The MTUS does not address the use of hypnotics other than benzodiazepines. The Official Disability Guidelines were used instead. The Official Disability Guidelines recommend the short term use of hypnotics like zolpidem (less than two months), discuss the significant side effects, and note the need for a careful evaluation of the sleep difficulties. No physician reports describe the specific criteria for a sleep disorder. The treating physician has not addressed major issues affecting sleep in this patient, including the use of other psychoactive agents like opioids, which significantly impair sleep architecture. Zolpidem, a benzodiazepine agonist, is habituating and recommended for short term use only. This injured worker has been given a hypnotic for a duration in excess of what is recommended in the guidelines cited above. This patient has also been given a benzodiazepine, which is additive with the hypnotic, and which increases the risk of side effects and dependency. Note the ODG citation which recommends short term use of zolpidem, a careful analysis of the sleep disorder, and caution against using zolpidem in the elderly. Prescribing in this case meets none of the guideline recommendations. There are no reports which adequately address the specific results of using zolpidem. Zolpidem is not medically necessary based on prolonged use contrary to guideline recommendations, lack of specific benefit, and lack of sufficient evaluation of the sleep disorder.

RITALIN 10MG FOUR TIMES A DAY #120: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medline Plus Drug Information.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate, Methylphenidate: Drug information.

Decision rationale: The MTUS does not address the use of methylphenidate. The UpToDate reference cited above states that methylphenidate is for attention-deficit/hyperactivity disorder (ADHD), and symptomatic management of narcolepsy. Neither of these conditions is present in this injured worker. This same reference also states that methylphenidate has been used off label for terminal illnesses as part of palliative care. This injured worker does not meet these indications. The apparent indication in the reports is "fatigue", which is not a diagnosis or a sufficient indication for methylphenidate. There is not a sufficient evaluation of fatigue in the available reports. Any evaluation of fatigue should incorporate a detailed medical evaluation including the many medications which might cause this. Ongoing use of methylphenidate is not medically necessary due to the lack of sufficient indications.

LIDODERM PATCH 1-3/24HR: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm Page(s): 57.

Decision rationale: Topical lidocaine (Lidoderm patch) is indicated for post-herpetic neuralgia, according to the manufacturer. This condition is not present per the available reports. The MTUS recommends Lidoderm only for localized peripheral neuropathic pain after trials of "tri-cyclic or serotonin norepinephrine reuptake inhibitor (SNRI) anti-depressants or an antiepileptic drug (AED) such as gabapentin or Lyrica." The MTUS recommends against Lidoderm for low back pain or osteoarthritis. There is no evidence in any of the medical records that this injured worker has peripheral neuropathic pain (which is not radiculopathy), or that she has failed the recommended oral medications. There is no evidence of any benefit from the Lidoderm used to date. Lidoderm is not medically necessary based on the MTUS.

VOLTAREN GEL 4MG- APP QID: 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): s 60, 111-113. Decision based on Non-MTUS Citation FDA MedWatch, 12/5/09: Voltaren Gel (diclofenac sodium topical gel) 1% - Hepatic Effects Labeling Changes.

Decision rationale: No physician reports discuss the specific indications and results of use in support of the ongoing prescribing of Voltaren gel prescribed in this case. Note the FDA warning above. There is no evidence in this case that the prescribing physician is carefully monitoring for liver toxicity. None of the reports describe any specific benefit. Per the MTUS, topical non-steroidal anti-inflammatory agents (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. It is not clear that the Voltaren gel has been prescribed for extremity pain caused by arthritis or tendonitis. Prescribing has been long term. Voltaren gel is not medically necessary based on long term prescribing contrary to guidelines, lack of sufficient indications, lack of apparent benefit, and lack of the necessary toxicity monitoring.

BIOTENE PRODUCTS FOR DRY MOUTH: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.biotene.com/>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate, Artificial saliva: Drug information.

Decision rationale: None of the available reports provide an adequate evaluation of xerostomia. A variety of causes are possible and the treating physician should investigate causes, particularly when the condition is chronic. This injured worker has been given medications, which can cause xerostomia, and this is not adequately discussed. The treating physician has provided only

minimal information about any xerostomia in this patient, and Biotene was stated to be ineffective. The MTUS does not provide direction for treating xerostomia. The cited guidelines provide direction for evaluation and treatment of xerostomia. The available reports do not show that the necessary evaluation has occurred, and Biotene was stated to be ineffective. Continued use of Biotene is therefore not medically necessary.

LEVOTHYROXINE 88MCG DAILY: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Physician's Desk Reference.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate: Levothyroxine: drug information.

Decision rationale: This injured worker was noted to have a diagnosis of hypothyroidism. There is a slightly elevated thyroid stimulating hormone (TSH) in the reports from July 2013. Medications were noted to include levothyroxine. Levothyroxine is a thyroid product indicated for replacement or supplemental therapy in congenital or acquired hypothyroidism. This injured worker was noted to have thyroid dysfunction. Monitoring during use of levothyroxine should include measurement of the thyroid stimulating hormone (TSH) every 6-8 weeks until normalized, every 8-12 weeks after dosage changes, and every 6 to 12 months throughout therapy. The requested prescription is for an unstated quantity; an unspecified quantity and duration can imply a potentially unlimited duration and quantity, which is not medically necessary or indicated, as dosing requirements may change with time. As such, the request for levothyroxine is not medically necessary.

ACYCLOVIR 400MG 1 TAB TWICE A DAY: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. CharFormat Decision based on Non-MTUS Citation Medline Plus Drug Information.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate, Acyclovir: An overview.

Decision rationale: The available reports provide only minimal information about possible indications for acyclovir. One report states that "there were herpes breakouts from the increase stress." No other information was provided and there was no description of any skin lesions. This is not an adequate basis for long term prescribing of acyclovir or equivalents. The MTUS does not address the use of acyclovir. The UpToDate reference cited above discusses the indications for this drug, including herpes simplex and varicella-zoster. There is not an adequate evaluation in the records and sufficient indications have not been presented. The requested prescription is for an unstated quantity; an unspecified quantity and duration can imply a potentially unlimited duration and quantity, which is not medically necessary or indicated. Acyclovir is not medically necessary based on the lack of sufficient indications in the available records.

RELPAK 40MG UP TO 2 TABLS/24 HOURS AS NEEDED: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Durg Manufacturer, Relpax (Eletriptan).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Head chapter, Triptans and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence:UpToDate, Acute treatment of migraine in adults.

Decision rationale: None of the available reports provide any information regarding the nature of any headaches in this injured worker beyond a report which recommended a mattress and sheets for treating migraine headache. There are no reports which address the pattern of headaches, specific symptoms, indications for specific medications, or results of using any medications. The MTUS does not address migraine treatment. Relpax is a triptan used to treat migraine headaches. The Official Disability Guidelines and UpToDate references discuss the use of triptans for migraines. Although a triptan may be indicated in this case, the available reports do not provide a sufficient evaluation or account of treatment results to demonstrate medical necessity for Relpax. The requested prescription is for an unstated quantity; an unspecified quantity and duration can imply a potentially unlimited duration and quantity, which is not medically necessary or indicated. As such, the request for relpax is not medically necessary.

CENTRUM SILVER 1 TAB/DAY: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation State of California Workers' Compensation Office Medical Fee Schedule (page 7) April 1999 and Cigna, Vitamins.

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, B vitamins and vitamin B complex and Other Medical Treatment Guidelines.

Decision rationale: Centrum Silver is a multivitamin. None of the physician reports address the medical necessity for vitamins. The MTUS does not provide direction for the use of vitamins. 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 some vitamins 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. The multivitamin is therefore not medically necessary.

PILOCARPINE 5MG 1 TABL 3 TIMES A DAY: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drug Manufacturer, Pilocarpine.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate, Artificial saliva: Drug information.

Decision rationale: None of the available reports provide an adequate evaluation of xerostomia, the apparent intended indication for pilocarpine. None of the reports discuss the specific indications for pilocarpine. A variety of causes for xerostomia are possible and the treating physician should investigate causes, particularly when the condition is chronic. This injured worker has been given medications, which can cause xerostomia, and this is not adequately discussed. The treating physician has provided only minimal information about any xerostomia in this patient, and none about any results of using pilocarpine. The MTUS does not provide direction for treating xerostomia. The cited guidelines provide direction for evaluation and treatment of xerostomia. The available reports do not show that the necessary evaluation has occurred. Ongoing or initial use of pilocarpine is therefore not medically necessary.

TRAMADOL 50MG 1 TAB 2-3 TIMES/DAY AS NEEDED: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tamadol (Ultram).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioid management, Opioids, steps to avoid misuse/addiction, indications, Chronic back pain, Mechanical and compressive etiologies, Medication Page(s): 77-81, 94, 80, 81, and 60.

Decision rationale: There is insufficient evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, opioid contract, and there should be a prior failure of non-opioid therapy. None of these aspects of prescribing are in evidence. The prescribing physician does not specifically address function with respect to prescribing opioids. There is no evidence of significant pain relief or increased function from the opioids used to date. The prescribing physician describes this patient as "unable to work," which fails the "return-to-work" criterion for opioids in the MTUS, and represents an inadequate focus on functional improvement. The MTUS recommends random urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. Tramadol has been prescribed simultaneously with sertraline. There are significant risks due to toxicity and this has not been addressed by the treating physician. As currently prescribed, this opioid does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary. This is not meant to imply that some form of analgesia is contraindicated; only that the opioids as prescribed have not been prescribed according to the MTUS and that the results of use do not meet the requirements of the MTUS.