

Case Number:	CM14-0009808		
Date Assigned:	02/21/2014	Date of Injury:	01/12/2012
Decision Date:	09/24/2014	UR Denial Date:	01/08/2014
Priority:	Standard	Application Received:	01/23/2014

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 Family Medicine 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:

This 63-year old marketer reported neck and back pain as well as headaches, shoulder and leg pain after she was involved in a motor vehicle accident on 1/11/12. She has been treated with medications, chiropractic manipulation, and epidural steroid injections. Her current primary physician is a chiropractor, but she is also followed by an occupational medicine physician, a pain specialist and an internist. There are references in the notes regarding plans to perform more epidural steroid injections, and to request authorization for extracorporeal shock wave therapy. In a 7/26/13 note, the occupational medicine physician makes reference to a 7/11/13 orthopedic QME evaluation, in which the orthopedist recommended a sleep study due to the patient's high Epworth sleepiness scale points. The occupational medicine physician prescribes the patient's medications and dispenses them from his office. A form signed by the patient on 12/6/13 indicates that she received Gabapentin 600 mg #60, Norco 10/325 #60, Vicodin 5/500 #60, Lortab Plus 7.5/750 (500 lined out, 750 written in by hand), Menthoderm 120 ml, Ultram ER #30, Zofran 8 mg #10, Soma 350 mg #60, Fexmid 7.5 mg #50, Protonix 20 mg (quantity obscured by a label for Hydrocodone/APAP 7.5/750, Sonata 10 mg #60, quazepam 15 mg #60, sumatriptan 50 mg # 9, topiramate 50 mg #60, cephalexin 500 mg #30, and lovastatin #60. A 12/13/13 progress note by the occupational physician states that the patient is symptomatic and frustrated. Exam findings include tenderness of the neck and back, with normal range of motion of both. Positive Spurling's and straight leg test are noted. A sensory deficit in the R C5-6 and R L5 distributions are noted. Diagnoses included cervical and lumbar discopathy, and R upper and lower extremity radiculopathy. The occupational physician stated that he encouraged the patient to lose weight, and continue her exercises. He stated that he provide her with medications "that I believe will enhance pain relief, help restore function, improve overall to better perform activities of daily living". Exactly what medications were provided, and exactly how they were

to restore the patient's function or improve her ability to perform activities of daily living was not specified. The patient is totally disabled, and has been since at least 3/28/13. Apparently a request for authorization of medications was made on 1/3/14 which was non-certified in UR on 1/8/14. The request itself is not available in the records. A request for IMR of the not medically necessary medications was generated on 1/20/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Hydrocodone/APAP 7.5/750mg (?5/500mg) #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for Use of Opioids, Steps to Take Before a Therapeutic Trial of Opioids; Ongoing Management; When to Discontinue Opioids; Indications; Long Term Use Page(s): 60, 76-77; 78; 79-80; 83; 88. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: UptoDate, an online evidence-based review service for clinicians (www.uptodate.com), Acetaminophen: Drug Information.

Decision rationale: Per the MTUS recommendations cited above, medications should be trialed one at a time while other treatments are held constant, with careful assessment of function, and there should be functional improvement with each medication in order to continue it. If opioids are used, it is recommended that goals for pain and function be set and monitored. Opioids should be discontinued if there is no improvement in function. There is no good evidence that opioids are effective for radicular pain. If long-term use of opioids occurs, there is a need for ongoing pain and function assessments, as well as assessments for side effects, of concurrent other treatments, and of concurrent psychological issues. Given the number of medications dispensed at one time to this patient, it appears highly unlikely that they were started one at a time with careful assessment of the improvement in function provided by each. The guidelines regarding opioid use are clearly not being followed. This patient has been taking hydrocodone for many months, and perhaps years. No goals regarding pain and function were set or are being monitored. Her pain level actually appears to be increasing, which may be a function of opioid-induced hyperalgesia. She remains totally disabled. An additional major concern is the number of opioids that are being prescribed to her. She is apparently taking up to two forms of hydrocodone/APAP 7.5/750, as well as tramadol. If she takes all of these in combination with the six other medications dispensed on 12/6/13 that are likely to cause drowsiness, it is certainly clear why she scores high on a sleepiness scale. It is remarkable that she is upright. Finally, the combination of medications prescribed puts her at risk for acetaminophen toxicity. In January 2014 the FDA released a MedWatch Safety Alert stating that combination drug products containing more than 325 mg of acetaminophen are no longer considered safe. This would include products that contain either 500 or 750 mg of acetaminophen. If this patient took both of the requested medications, assuming one contained 750 and one 500 mg, three times per day (as they are prescribed) and also the two other forms of hydrocodone/APAP dispensed to her on 12/6/14 (10/325 and 5/500) as directed, she would be taking 6,225 mgs of acetaminophen per

day, which is more than twice the recommended long-term dose, and is potentially hepatotoxic. Based on the evidence-based guidelines above and the clinical findings in this case, hydrocodone/APAP 7.5/750 or 7.5/500 is not medically indicated. Hydrocodone/APAP is not medically necessary due to the lack of documentation regarding appropriate assessment of the patient and monitoring of her progress, and due to the risk that the drug may cause, or is causing serious side effects.

Vicodin 7.5/750mg (?5/500mg) #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for Use of Opioids, Steps to Take Before a Therapeutic Trial of Opioids; Ongoing Management; When to Discontinue Opioids; Indications; Long Term Use Page(s): 60, 76-77; 78; 79-80; 83; 88. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: UptoDate, an online evidence-based review service for clinicians (www.uptodate.com), Acetaminophen: Drug Information.

Decision rationale: Per the MTUS recommendations cited above, medications should be trialed one at a time while other treatments are held constant, with careful assessment of function, and there should be functional improvement with each medication in order to continue it. If opioids are used, it is recommended that goals for pain and function be set and monitored. Opioids should be discontinued if there is no improvement in function. There is no good evidence that opioids are effective for radicular pain. If long-term use of opioids occurs, there is a need for ongoing pain and function assessments, as well as assessments for side effects, of concurrent other treatments, and of concurrent psychological issues. Given the number of medications dispensed at one time to this patient, it appears highly unlikely that they were started one at a time with careful assessment of the improvement in function provided by each. The guidelines regarding opioid use are clearly not being followed. This patient has been taking hydrocodone for many months, and perhaps years. No goals regarding pain and function were set or are being monitored. Her pain level actually appears to be increasing, which may be a function of opioid-induced hyperalgesia. She remains totally disabled. An additional major concern is the number of opioids that are being prescribed to her. She is apparently taking up to two forms of hydrocodone/APAP 7.5/750, as well as tramadol. If she takes all of these in combination with the six other medications dispensed on 12/6/13 that are likely to cause drowsiness, it is certainly clear why she scores high on a sleepiness scale. It is remarkable that she is upright. Finally, the combination of medications prescribed puts her at risk for acetaminophen toxicity. In January 2014 the FDA released a MedWatch Safety Alert stating that combination drug products containing more than 325 mg of acetaminophen are no longer considered safe. This would include products that contain either 500 or 750 mg of acetaminophen. If this patient took both of the requested medications, assuming one contained 750 and one 500 mg, three times per day (as they are prescribed) and also the two other forms of hydrocodone/APAP dispensed to her on 12/6/14 (10/325 and 5/500) as directed, she would be taking 6,225 mgs of acetaminophen per day, which is more than twice the recommended long-term dose, and is potentially hepatotoxic. Based on the evidence-based guidelines above and the clinical findings in this case,

hydrocodone/APAP 7.5/750 or 7.5/500 is not medically indicated. Hydrocodone/APAP is not medically necessary due the lack of documentation regarding appropriate assessment of the patient and monitoring of her progress, and due to the risk that the drug may cause, or is causing serious side effects.

Ultram ER 150mg #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for Use of Opioids, Steps to Take Before a Therapeutic Trial of Opioids; Ongoing Management; When to Discontinue Opioids; Indications; Long Term Use Page(s): 60, 76-77; 78; 79-80; 83; 88. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: UptoDate, an online evidence-based review service for clinicians (www.uptodate.com), Tramadol: Drug Information.

Decision rationale: Per the MTUS recommendations cited above, medications should be trialed one at a time while other treatments are held constant, with careful assessment of function, and there should be functional improvement with each medication in order to continue it. If opioids are used, it is recommended that goals for pain and function be set and monitored. Opioids should be discontinued if there is no improvement in function. There is no good evidence that opioids are effective for radicular pain. If long-term use of opioids occurs, there is a need for ongoing pain and function assessments, as well as assessments for side effects, of concurrent other treatments, and of concurrent psychological issues. Per the UptoDate reference cited above, tramadol increases the risk of seizures even at recommended doses. This risk is increased in patients on other opioids or cyclobenzaprine. The records are not clear as to when exactly tramadol was started and whether it was started in conjunction with other medications. There is no evidence that any pain or functional goals were set or are being monitored. There is no rationale given for starting this medication in a patient who is already taking multiple opioids and other medications that may cause drowsiness, and who is documented as being unacceptably sleepy. In addition, the combination of tramadol, multiple other opioids and cyclobenzaprine (Fexmid) puts this patient at increased risk for seizure. Based on the evidence-based guidelines above and the clinical findings in this case, Ultram ER is not medically indicated. Ultram ER is not medically necessary due the lack of documentation regarding appropriate assessment of the patient and monitoring of her progress, and due to the risk that the drug may cause serious side effects.

Dendracin 120ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Topical Analgesics; Capsaicin Page(s): 60; 111-113; 28.

Decision rationale: The first MTUS guideline cited above states that medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. The second guideline states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The capsaicin guideline cited above states that topical capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. It is indicated for neuropathic pain, osteoarthritis, fibromyalgia, and chronic non-specific back pain, for patients whose pain has not been controlled successfully with conventional therapy. Dendracin is a combination of methyl salicylate, menthol and capsaicin. Starting it means that three medications are being started at once, and cannot be monitored individually. No assessment of the patient was documented before starting it, and no pain or functional goals were set. It is not clear what is being prescribed for. The patient does not have clear documentation of any of the diagnoses for which topical capsaicin might be indicated. Clearly other treatments have not yet been exhausted; epidural steroid injections are still planned. Topical capsaicin is not medically necessary in this patient, and therefore neither is Dendracin. Based on the evidence-based guidelines above and the clinical findings in this case, Dendracin is not medically indicated. Dendracin is not medically necessary due the lack of documentation regarding appropriate assessment of the patient and monitoring of her progress, and because one of its components does not meet criteria for use.

Sumatriptan 50mg #9: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: UptoDate, an online evidence-based review service for clinicians (www.uptodate.com), Sumatriptan: Drug Information.

Decision rationale: Per the UptoDate reference above, sumatriptan is indicated for migraine or cluster headache. Sumatriptan is contraindicated in patients with Wolff-Parkinson-White syndrome or with other arrhythmias associated with aberrant conduction pathways. It is contraindicated in patients with severe hepatic impairment, and should be used with caution in patients with mild to moderate impairment. Sumatriptan can cause cardiac ischemia. A cardiovascular evaluation should be performed prior to beginning sumatriptan in patients who have risk factors for coronary artery disease such as hypertension and obesity. Sumatriptan can lower the seizure threshold. It is not clear from any of the available records why sumatriptan is being prescribed for this patient. It is not clear when and how she is to take it. The medication sheet that documents that sumatriptan 50 mg #9 was dispensed does not document any instructions for taking it. There is no documented diagnosis of migraine or cluster headache. There is no documentation of any evaluation of the patient's risk for arrhythmia or coronary artery disease. The records reveal that she is likely to have at least two risk factors: obesity and

hypertension, since she is taking an antihypertensive and is being counseled to lose weight. The records do not document any assessment of hepatic function. As discussed previously, if she is taking the large amounts of acetaminophen prescribed, she is at risk for liver damage and impaired hepatic function. Also as previously discussed, this patient is taking several medications that may increase her risk of seizures. Adding another medication that does so would be foolhardy, especially without clear indications for adding it. Based on the evidence-based guidelines above and the clinical findings in this case, sumatriptan is not medically indicated. Sumatriptan is not medically necessary due the lack of documentation if its necessity and because of the risk that it may cause serious side effects.