MAXIMUS Federal Services

Case Number:	CM13-0006170		
Date Assigned:	08/26/2013	Date of Injury:	12/08/2007
Decision Date:	01/15/2014	UR Denial Date:	07/10/2013
Priority:	Standard	Application Received:	08/02/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Physical Medicine & Rehabilitation, and is licensed to practice in Oklahoma. 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 physician 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 claimant is a 59-year-old male with a reported date of injury of 01/01/1979. He reports a continuous trauma injury from 01/01/1979 through 12/08/2007 as well as a right shoulder injury 01/01/1979 through 12/08/2007 due to continuous trauma. On 12/12/2012, he was seen and was status post left micro decompression at that time. He reported pain and numbness in his left lower extremity had subsided postoperatively. He returned to clinic with decreased dermatomal sensation with pain over the left SI dermatome. On 02/04/2013, it was noted that he was using medications which reduced his pain and maintained function. On 07/12/2013, he was seen back in clinic and there were no signs of sedation and he had mild spasms and tenderness in the paravertebral muscles of the lumbar spine. Medications were refilled as they were reported to cause no side effect and helped to maintain functional capacity. It was noted that he was taking 1 tablet of Prozac, 20 mg. Diagnoses included lumbar disc disorder with myelopathy, thoracic or lumbosacral neuritis or radiculitis not otherwise specified, shoulder bursae and tendon disorders not otherwise specified and sprains and strains of shoulder and upper arm, not otherwise specified. Treatment plan was to continue medications hydrocodone, norflex, medrox patch, omeprazole, gabapentin, hydrocodone bit & acet., fluoxetine, Tizanadine, C-Keto 10%, lido 10, baclo 10 % 180 gms.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective hydrocodone: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78,91.

Decision rationale: This request is for hydrocodone. The clinical notes indicate that on 04/15/2013, it was noted that he takes occasional hydrocodone. On serial examinations of 05/31/2013, 06/19/2013, and 07/12/2013, his pain scale was not documented to objectively document how much pain he was in. The submitted medical records do not include urine drug screens to objectively document he is not aberrant. MTUS Chronic Pain Guidelines, in addressing opiate medications, state that the 4 A's should be evaluated for patients on opiate medication. This would include analgesia, activities of daily living, adverse side effects, and aberrant drug taking behavior. MTUS Chronic Pain Guidelines state, "Monitoring these outcomes over time should effect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." MTUS Chronic Pain Guidelines goes further stating that hydrocodone is, "Indicated for moderate to moderately severe pain." MTUS Chronic Pain Guidelines state the usual dose is 5/500 mg with 1 or 2 tablets by mouth every 4 to 6 hours as needed for pain for higher doses. The recommended dosage is usually 1 tablet every 4 to 6 hours as needed for pain. Records do not indicate the strength and dosing of this requested medication and do not indicate that he has significant pain for which this medication has been intended for. MTUS Chronic Pain Guidelines also advocate a pain treatment agreement. Patients being treated with opiates for a significant length of time and a psychological evaluation are, "Recommended as an option to improve the effectiveness of opiates for chronic pain." Thus, lacking objective evidence of the degree of pain this claimant is in, the strength and dosing requested, lacking documentation of a psychological evaluation, lacking documentation of a pain agreement, and noting that this patient has been on this medication for a significant length of time, this request is not considered medically necessary at this time and is non-certified.

Retrospective Norflex: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Chronic Pain Treatment Muscle Relaxant Page 63-66

Decision rationale: MTUS Chronic Pain Guidelines, Page 65, indicates that Norflex is a drug similar to diphenhydramine but has greater anticholinergic effects. MTUS Chronic Pain Guidelines indicate, "The mode of action is not clearly understood." This medication as also reported in case studies per MTUS Chronic Pain Guidelines to be used for euphoria and to have mood elevating effects. Dosage is stated to be 100 mg twice a day per MTUS Chronic Pain Guidelines with combination products to be given 3 to 4 times a day. MTUS Chronic Pain Guidelines also indicate that muscle relaxants are recommended with caution as a second line option for short-term treatment of acute exacerbations in patients with chronic low back pain.

The submitted records indicate this request does not indicate the strength and dosing of Norflex requested. The records do not indicate the overall efficacy of the medication that has been prescribed for this patient as recommended by MTUS Chronic Pain Guidelines. The most recent clinical note fails to reveal significant muscle spasms for which this medication would be used for and fails to indicate that a first line treatment has been tried and failed prior to consuming this medication. As such, the rationale for approving this medication has not been demonstrated by the records provided and is non-certified.

Retrospective Medrox patch: 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: This request is for a Medrox patch. MTUS Chronic Pain Guidelines indicate this type of medication is largely experimental in use with few randomized controlled trials to determine efficacy or safety. MTUS Chronic Pain Guidelines indicate that any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. This product contains Capsaicin which is recommended only as an option in patients who have not responded or are intolerant to other treatments. MTUS Chronic Pain Guidelines indicate the medication has had positive randomized studies in cream form in patients with osteoarthritis, fibromyalgia, and chronic nonspecific back pain but it should be considered experimental in very high doses. The requested does not include the strength and dosing of this medication. The submitted medical records do not include pain scores to objectively document how much pain this claimant is in and does not include documentation of efficacy of this medication. Therefore, due to lack of documentation of strength and dosing, lack of documentation of failure of lesser medications, and this drug being considered experimental with few randomized controlled trials to determine overall efficacy, this request is not considered medically necessary and is non-certified.

Retrospective Omeprazole: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 68.

Decision rationale: This request is for Omeprazole. MTUS Chronic Pain Guidelines indicate that for patients who are taking nonsteroidal anti-inflammatories and who are at risk for gastrointestinal events and who have no cardiovascular disease, a nonselective nonsteroidal anti-inflammatory with either a PPI (such as the proton pump inhibitor Omeprazole) daily or misoprostol or a COX-2 selective agent can be considered reasonable. The submitted records do not indicate this patient has significant gastrointestinal events either currently or in the past. The

records do not indicate he has a history of GERD or ulcers currently or in the past. Records do not indicate overall efficacy of this medication. There is no indication of his cardiovascular status. The strength and dosing of the medication request has not been demonstrated. Therefore, this request is not considered medically necessary and is non-certified.

Retrospective Gabapentin: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines AED Page(s): 16-21, 49.

Decision rationale: The medical records demonstrate that on 05/31/2013, this claimant was started on a trial of gabapentin for his neuropathic pain and paresthesias. When he returned to clinic on 06/19/2013, there was no indication of the efficacy of the trial and when the returned on 07/12/2013 there was no specific indication of the efficacy of the medication. It was noted then that he would start on Neurontin with improved control of neuropathic pain. MTUS Chronic Pain Guidelines, Page 49 states gabapentin is an anti-epilepsy drug also known as an AED which has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first line treatment for neuropathic pain. However, MTUS Chronic Pain Guidelines indicate that there are few RCTs directed at central pain and none for painful radiculopathy. The strength and dosage of this medication requested has not been documented for this review and the overall efficacy of the trial of gabapentin has not been documented as previously stated. Therefore, this request is not considered medically necessary at this time and is non-certified.

Retrospective Hydrocodone Bit & Acet: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 11,78,91.

Decision rationale: This is a request for hydrocodone Bit & Acet. MTUS Chronic Pain Guidelines indicate that for hydrocodone, the usual dose is 5/500 mg 1 to 2 tablets by mouth every 4 to 6 hours as needed for pain for a maximum of 8 tablets per day; as for a combination of hydrocodone and acetaminophen. MTUS Chronic Pain Guidelines also state for acetaminophen, new information questions the use of nonsteroidal anti-inflammatories and acetaminophen should be recommended on a case by case basis. The strength and dosage of this medication requested has not been documented for the records. The overall efficacy, as evidenced by objective pain scale has not been demonstrated. The records indicate this patient has been on hydrocodone for a significant length of time. MTUS Chronic Pain Guidelines go further, stating that opiates are not recommended as a first line treatment for neuropathic pain and appear to be efficacious but limited for short-term pain relief for chronic back pain and long-term efficacy is

unclear greater than 16 weeks. Thus, with lack of documentation of the specific strength and dosage of this medication, lack of documentation of efficacy of the medication with guidelines recommending low doses for the shortest period of time for this medication, and lacking documentation of a urine drug screen to demonstrate that is claimant is not aberrant as recommended by the 4 A's of MTUS Chronic Pain Guidelines, this request is not considered medically necessary and is non-certified.

Retrospective Fluoxetine HCL 20mg #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines antidepressants. Page(s): 13-16.

Decision rationale: This request is for Fluoxetine. This is an antidepressant. MTUS Chronic Pain Guidelines recommend antidepressants as a first line option for neuropathic pain and as a possibility for nonneuropathic pain. MTUS Chronic Pain Guidelines further indicate that Tricyclics are generally considered a first line agent unless they are ineffective, poorly tolerated, or contraindicated. It is in a class called SSRIs. MTUS Chronic Pain Guidelines indicate this type of medication has been suggested for addressing psychological symptoms associated with chronic pain, but more information is needed regarding the role of SSRIs in pain per MTUS Chronic Pain Guidelines. The overall efficacy of this medication has not been demonstrated objectively by the records provided. The records do not indicate he has tried and failed tricyclic antidepressants as recommended by guidelines. With the need for more information regarding the role of this type of medication and pain, with lack of documentation of the overall efficacy of this medication, lack of documentation of failure of a first line medication such as a tricyclic antidepressant, this request is not considered medically necessary and is non-certified.

Tizanidine HCL 4mg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxant.

Decision rationale: This request is for tizanidine HCl 4 mg. MTUS Chronic Pain Guidelines, Page 63, indicates that muscle relaxants are recommended with caution as a second line option for short-term treatment of acute exacerbations in patients with chronic low back pain. Specifically, guidelines indicate that Tizanadine has side effects of dizziness, dry mouth, hypotension, weakness, hepatotoxicity, and indicate that liver function tests should be monitored at baseline, 1, 3, and 6 months. Dosing per guidelines is 4 mg initial dose to be titrated up gradually by 2 to 4 mg every 6-8 hours until therapeutic dose with tolerable side effects has been demonstrated. The records provided for this review do not document a liver function test to demonstrate that this medication is not causing harm to this claimant. The overall efficacy of this

medication has not been demonstrated by the records provided. There is no indication of significant muscle spasms as noted on the clinical notes, he only has mild spasms. There is lack of documentation that this medication is being used only for short-term treatment of an acute exacerbation for this claimant with chronic low back pain. As such, this request is not considered medically necessary and is clinical note dated.

Retrospective C-Keto 10% Baclo 10% 180 gms DOS 2/6/2013: Upheld

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

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

Decision rationale: This is a compounded medication. MTUS Chronic Pain Guidelines, Pages 111 to 113, state that this type of medication is largely experimental in use with few randomized controlled trials to determine efficacy or safety and also state that any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. This is a combination of baclofen, Lidocaine, and keto. MTUS Chronic Pain Guidelines indicate that Lidocaine is recommended for localized peripheral pain after there has been evidence of a trial of a first line therapy such as tricyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica. MTUS Chronic Pain Guidelines, Page 113, states that baclofen is not recommended as there is currently only one phase III study of baclofen/amitriptyline/Ketamine gel in cancer patients for treatment of chemotherapy induced peripheral neuropathy and there is no peer reviewed literature to support the use of topical baclofen. Ketamine also is under study and only recommended for treatment of neuropathic pain refractory to other treatments after all primary and secondary treatment has been exhausted. The submitted records fail to indicate objective evidence that the claimant is in pain as his Visual Analog Scale has not been demonstrated on serial examinations. The records do not indicate that he has failed tricyclic antidepressants and does not indicate that he has failed primary and secondary treatment for which Ketamine would be possibly supported. The records do not indicate that he has failed or been intolerant to other treatments for which Capsaicin might be considered reasonable, as such, this request is not considered medically necessary at this time and is non-certified.

Retrospective C-Keto 10% Baclo 10% 180 gms DOS 3/20/2013: Upheld

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

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

Decision rationale: This is a compounded medication. MTUS Chronic Pain Guidelines, Pages 111 to 113, state that this type of medication is largely experimental in use with few randomized controlled trials to determine efficacy or safety and also state that any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. This is a

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