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| Case Number: | CM14-0015567 | | |
| Date Assigned: | 02/21/2014 | Date of Injury: | 03/01/2011 |
| Decision Date: | 11/20/2014 | UR Denial Date: | 01/31/2014 |
| Priority: | Standard | Application Received: | 02/07/2014 |

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, has a subspecialty in Pain Management 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 is a female patient with a date of injury of March 1, 2011. A utilization review determination dated January 31, 2014 recommends denial of Cyclobenzaprine 7.5 mg #60, Dyotin SR 250 mg #60, Flurbitac 100/100mg #60, Theraflex cream 180 g #1, Keratek gel 4 ounce bottle #1, Vicosectron 10/300/2mg #40, and Midazolam/Melatonin 10/3mg #30. A progress note dated January 16, 2014 identifies subjective complaints of continued right knee pain and numbness, and she reports that she has completed seven sessions of physical therapy that has helped. Physical examination identifies committed tenderness and pain to the right knee, and a pain level of seven on a scale from 1-10. The diagnoses include tear of medial meniscus of knee and joint pain of lower leg. The treatment plan recommends completion previously certified physical therapy program. The treatment plan also recommends prescriptions for the following cyclobenzaprine 7.5 mg #60, Dyotin SR 250mg #60, Flurbitac 100/100mg #60, Theraflex cream 180 mg #1, Keratek gel 4 ounce #1, Vicosectron 10/300/2mg #40, and Midazolam/Melatonin 10/3mg #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

PRESCRIPTION OF CYCLOBENZAPRINE 7.5MG, #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CYCLOBENZAPRINE Page(s): 41-42.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page(s): 63-66.

Decision rationale: Regarding the request for Cyclobenzaprine 7.5mg #60, Chronic Pain Medical Treatment Guidelines support the use of nonsedating muscle relaxants to be used with caution as a 2nd line option for the short-term treatment of acute exacerbations of pain. Guidelines go on to state that Cyclobenzaprine specifically is recommended for a short course of therapy. Within the documentation available for review, there is no identification of a specific analgesic benefit or objective functional improvement as a result of the Cyclobenzaprine. Additionally, it does not appear that this medication is being prescribed for the short-term treatment of an acute exacerbation, as recommended by guidelines. In the absence of such documentation, the currently requested cyclobenzaprine 7.5mg #60 is not medically necessary.

PRESCRIPTION OF DYOTIN SR 250MG, #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page(s): 16-21 of 127.

Decision rationale: Regarding request for Dyotin (Gabapentin/Pyridoxine) SR 250mg #60, Chronic Pain Medical Treatment Guidelines state that antiepilepsy drugs are recommended for neuropathic pain. They go on to state that a good outcome is defined as 50% reduction in pain and a moderate response is defined as 30% reduction in pain. Guidelines go on to state that after initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. Within the documentation available for review, there is no identification of any specific analgesic benefit (in terms of percent reduction in pain or reduction of NRS), and no documentation of specific objective functional improvement. Additionally, there is no discussion regarding side effects from this medication. In the absence of such documentation, the currently requested Dyotin (Gabapentin/Pyridoxine) SR 250mg #60 is not medically necessary.

PRESCRIPTION OF FLURBITAC 100/100MG, #60: 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 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page(s): 68-69 of 127; 67-72 of 12.

Decision rationale: Regarding the request for Flurbitac (Flurbiprofen/Ranitidine)100/100mg #60, Chronic Pain Medical Treatment Guidelines state that NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Regarding the request for ranitidine, the guidelines state that H2 receptor antagonists are appropriate for the

treatment of dyspepsia secondary to NSAID therapy. Within the documentation available for review, there is no indication that the patient has complaints of dyspepsia secondary to NSAID use or another indication for this medication. Additionally, there is no indication that the Flurbiprofen is providing any specific analgesic benefits (in terms of percent pain reduction, or reduction in numeric rating scale), or any objective functional improvement. In the absence of such documentation, the currently requested Flurbitac (Flubiprofen/Ranitidine) 100/100mg #60 is not medically necessary.

PRESCRIPTION OF THERAFLEX CREAM 180MG, #1: 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 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page(s): 111-113.

Decision rationale: Regarding request for Theraflex cream (Flurbiprofen/Cyclobenzaprine/Menthol) cream 180gm #1. Chronic Pain Medical Treatment Guidelines state that any compounded product that contains at least one drug or drug class that is not recommended, is not recommended. Regarding the use of topical nonsteroidal anti-inflammatory, guidelines state that 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 1st 2 weeks of treatment osteoarthritis, but either not afterwards or with the diminishing effect over another two-week period. Regarding the request for Cyclobenzaprine cream, guidelines state that topical muscle relaxants are not recommended as there is no peer-reviewed literature to support the use of topical baclofen or any other muscle relaxant as a topical product. Within the documentation available for review, there is no indication that the patient is unable to tolerate oral NSAIDs. Oral NSAIDs have significantly more guideline support compared with topical NSAIDs. Additionally, there is no indication that the topical NSAID is going to be used for short duration. In the absence of clarity regarding those issues, the currently requested Theraflex cream (Flurbiprofen/Cyclobenzaprine/Menthol) cream 180gm #1 is not medically necessary.

PRESCRIPTION OF KERATEK GEL 4 OZ BOTTLE, #1: 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 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page(s): 111-112 of 127.

Decision rationale: Regarding the request for Keratek (Methyl Salicylate/Menthol) gel 4oz bottle #1, guidelines state that topical NSAIDs are recommended for short-term use. Oral NSAIDs contain significantly more guideline support, provided there are no contraindications to the use of oral NSAIDs. Within the documentation available for review, there is no indication that the patient has obtained any specific analgesic effect (in terms of percent reduction in pain,

or reduced NRS) or specific objective functional improvement from the use of topical Keratek. Additionally, there is no documentation that the patient would be unable to tolerate oral NSAIDs, which would be preferred, or that the topical Keratek is for short term use, as recommended by guidelines. In the absence of clarity regarding those issues, the currently requested Keratek (Methyl Salicylate/Menthol) gel 4oz bottle #1 is not medically necessary.

PRESCRIPTION OF VICOSETRON 10/300/2 MG, #40: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 80.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page(s): 44, 47, 75-79, 120 of 127.

Decision rationale: Regarding the request for Vicosetron (Hydrocodone/Acetaminophen) 10/300/2mg #40, California Pain Medical Treatment Guidelines state that Vicosetron is an opiate pain medication. Due to high abuse potential, close follow-up is recommended with documentation of analgesic effect, objective functional improvement, side effects, and discussion regarding any aberrant use. Guidelines go on to recommend discontinuing opioids if there is no documentation of improved function and pain. Within the documentation available for review, there is no indication that the medication is improving the patient's function or pain (in terms of specific examples of functional improvement and percent reduction in pain or reduced NRS), no documentation regarding side effects, and no discussion regarding aberrant use. As such, there is no clear indication for ongoing use of the medication. In light of the above issues, the currently requested Vicosetron (Hydrocodone/Acetaminophen) 10/300/2mg #40 is not medically necessary.

PRESCRIPTION OF MIDAZOLAM/MELATONIN 10MG/3MG, #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 FOODS

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page(s): 24. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain Chapter, Benzodiazepine; Pain Medication, Melatonin, Insomnia treatment

Decision rationale: Regarding the request for Midazolam/Melatonin 10mg/3mg #30, Chronic Pain Medical Treatment Guidelines state the benzodiazepines are "Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks... Tolerance to Anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant." Regarding melatonin, California MTUS guidelines do not contain criteria for the use of melatonin. ODG states that melatonin is recommended. They go on to state of the pharmacological agent should only be used after careful evaluation of potential causes of sleep

disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: A) sleep onset; B) sleep maintenance; C) sleep quality; D) next day functioning. Within the documentation available for review, there is no documentation identifying any objective functional improvement as a result of the use of the medication and no rationale provided for long-term use of the medication despite the CA MTUS recommendation against long-term use. Additionally, there is no indication that the patient has had a careful evaluation of potential causes of the sleep disturbance. In the absence of such documentation, the currently requested Midazolam/Melatonin 10mg/3mg #30 is not medically necessary.