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| Case Number: | CM14-0004879 | | |
| Date Assigned: | 04/04/2014 | Date of Injury: | 11/03/2010 |
| Decision Date: | 07/08/2014 | UR Denial Date: | 12/30/2013 |
| Priority: | Standard | Application Received: | 01/10/2014 |

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 & Rehabilitation/Pain Management and is licensed to practice in Texas and Ohio. 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:

The injured worker is a 46-year-old female who reported an injury on 11/03/2010. The mechanism of injury was a fall. The injured worker was initially prescribed pain medications and muscle relaxants, as well as a course of physical therapy. The injured worker is noted to have received electrodiagnostic studies; however, the results of these were not included for review. The injured worker has continued to participate in a home exercise program, including pool exercises, and has returned to work at full duty. She controls her chronic pain with use of multiple topical and oral medications. There was no other information submitted for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

PROSPECTIVE USAGE OF TRAMADOL/DEXTROMETHORPHAN/CAPSAICIN:

Upheld

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

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

Decision rationale: California MTUS/ACOEM Guidelines recommend topical analgesics to treat primarily osteoarthritic and neuropathic pain. Guidelines state any compounded product

that containing at least one drug (or drug class) not recommended by guidelines, deems the entire product not recommended. The current request for Tramadol/Dextromethorphan/Capsaicin topical cream has percentage formulations of 15%/10%/0.025%, respectively. Current medical literature indicates that Tramadol is not currently approved for treatment of any conditions except postherpetic neuralgia and open skin lesions. In addition, current medical literature does not support the use of topical Dextromethorphan in treating neuralgia, as it has either proven ineffective or continued study is recommended. Furthermore, guidelines state that topical products are recommended after there has been failure of a first-line therapy such as antidepressants or antiepileptic medications. The clinical information submitted for review did not provide any evidence that these first-line therapies have been tried, nor did it provide evidence that the topical medications have been effective in decreasing the injured worker's pain levels, as scored on the VAS. As such, the current request for Tramadol/Dextromethorphan/Capsaicin is not medically necessary.

PROSPECTIVE USAGE OF FLURBIPROFEN/LIDOCAIN/MENTHOL/CAMPHOR:

Upheld

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

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

Decision rationale: California MTUS/ACOEM Guidelines recommend topical analgesics to treat primarily osteoarthritic and neuropathic pain. Guidelines state any compounded product containing at least one drug (or drug class) not recommended by guidelines, deems the entire product not recommended. The current request includes a 20% formulation of topical Flurbiprofen, 5% formulation of topical Lidocaine, 5% topical menthol, and 1% topical camphor. Currently, guidelines do not recommend any topical NSAIDs for use, other than Diclofenac 1%. As Flurbiprofen is an NSAID and does not fall under the FDA-approved in guideline recommended topical NSAIDs for use, the entire compounded cream is not recommended. Additionally, topical Lidocaine is not approved for use in any other formulation than a dermal patch, including lotions, creams, or gels. Furthermore, there should be evidence of the failure of a first line therapy, prior to the use of topical agents. As such, the request for Flurbiprofen/Lidocaine/Menthol/Camphor is not medically necessary.

PROSPECTIVE USAGE OF IBUPROFEN: Upheld

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

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

Decision rationale: California MTUS/ACOEM Guidelines recommend NSAID use for the short-term treatment of symptomatic, chronic low back pain. Although the injured worker

suffers from chronic pain and may benefit from the use of ibuprofen periodically, there was no indication within the medical records submitted for review, detailing the frequency and dosage of the ibuprofen used. Additionally, there was no indication that the ibuprofen provides objective pain relief, as scored on the VAS; nor was there discussion as to how this medication increases the injured worker's functional abilities. Furthermore, there was no desired quantity submitted with the request. Until the frequency of use, the dosage, the amount desired, and the efficacy of this medication can be provided, treatment is not indicated. As such, the request for ibuprofen is not medically necessary.

PROSPECTIVE USAGE OF ALPRAZOLAM: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions Page(s): 398-404.

Decision rationale: California MTUS/ACOEM Guidelines do not recommend anxiolytics as a first-line therapy for anxiety as they can lead to dependence and do not alter the stressors or individual coping mechanisms. While they may be appropriate for short periods allowing return to daily functioning, if long term use is warranted, it is recommended the patient be referred for psychiatric care, evaluation, and treatment if needed. The clinical information submitted for review did not provide any evidence the injured worker had been referred for psychiatric treatment; however, there was evidence the injured worker has been utilizing Xanax 0.5 mg since at least 10/2013. Despite this length of use, there was no discussion in the clinical notes regarding the injured worker's response to this medication use, no discussion regarding the injured worker's frequency of use of this medication, and no documentation of the presence of symptoms of anxiety. Additionally, no desired quantity was submitted with the request. Until the injured worker's frequency of use, desired quantity, response to previous treatment, and discussion why she has not been sent for psychiatric treatment can be obtained, this treatment is not recommended. However, it is not recommended for abrupt discontinuation of benzodiazepines, and therefore, it is expected that the physician will allow for safe weaning. As such, the request for Alprazolam is not medically necessary.

PROSPECTIVE USAGE OF TRAMADOL: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CRITERIA FOR USE OF OPIOIDS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 74-95.

Decision rationale: California MTUS/ACOEM Guidelines recommend opioids to treat moderate to severe chronic pain. The clinical information submitted for review provided evidence that the injured worker has been utilizing Tramadol since at least 10/2013. However, there is no discussion regarding the injured worker's response to this medication, to include an

objective decrease in pain levels and increase in functional abilities. Furthermore, there was no inclusion of a urine drug screen and no documented pain levels as scored on the VAS, included in any of the clinical notes submitted for review. Without this information, medication efficacy and guideline compliance cannot be determined. Furthermore, there was no quantity desired submitted with the request. However, it is not recommended to abruptly discontinue opioid medications, and therefore, it is expected that the physician will allow for safe weaning. As such, the request for Tramadol is not medically necessary.

RETROSPECTIVE USAGE OF ALPRAZOLAM: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions Page(s): 389-404.

Decision rationale: California MTUS/ACOEM Guidelines do not recommend anxiolytics as a first-line therapy for anxiety as they can lead to dependence and do not alter the stressors or individual coping mechanisms. While they may be appropriate for short periods allowing return to daily functioning, if long term use is warranted, it is recommended the patient be referred for psychiatric care, evaluation, and treatment if needed. The clinical information submitted for review did not provide any evidence the injured worker had been referred for psychiatric treatment; however, there was evidence the injured worker has been utilizing Xanax 0.5 mg since at least 10/2013. Despite this length of use, there was no discussion in the clinical notes regarding the injured worker's response to this medication use, no discussion regarding the injured worker's frequency of use of this medication, and no documentation of the presence of symptoms of anxiety. Additionally, no desired quantity was submitted with the request. Until the injured worker's frequency of use, desired quantity, response to previous treatment, and discussion why she has not been sent for psychiatric treatment can be obtained, this treatment is not recommended. However, it is not recommended for abrupt discontinuation of benzodiazepines, and therefore, it is expected that the physician will allow for safe weaning. As such, the request for Alprazolam is not medically necessary.

RETROSPECTIVE USAGE OF TRAMADOL: Upheld

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

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

Decision rationale: California MTUS/ACOEM Guidelines recommend opioids to treat moderate to severe chronic pain. The clinical information submitted for review provided evidence that the injured worker has been utilizing Tramadol since at least 10/2013. However, there is no discussion regarding the injured worker's response to this medication, to include an objective decrease in pain levels and increase in functional abilities. Furthermore, there was no inclusion of a urine drug screen and no documented pain levels as scored on the VAS, included

in any of the clinical notes submitted for review. Without this information, medication efficacy and guideline compliance cannot be determined. Furthermore, there was no quantity desired submitted with the request. However, it is not recommended to abruptly discontinue opioid medications, and therefore, it is expected that the physician will allow for safe weaning. As such, the request for Tramadol is not medically necessary.

RETROSPECTIVE USAGE OF TRAMADOL/DEXTROMETHORPHAN/CAPSAICIN:

Upheld

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

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

Decision rationale: California MTUS/ACOEM Guidelines recommend topical analgesics to treat primarily osteoarthritic and neuropathic pain. Guidelines state any compounded product that containing at least one drug (or drug class) not recommended by guidelines, deems the entire product not recommended. The current request for Tramadol/Dextromethorphan/Capsaicin topical cream has percentage formulations of 15%/10%/0.025%, respectively. Current medical literature indicates that Tramadol is not currently approved for treatment of any conditions except postherpetic neuralgia and open skin lesions. In addition, current medical literature does not support the use of topical Dextromethorphan in treating neuralgia, as it has either proven ineffective or continued study is recommended. Furthermore, guidelines state that topical products are recommended after there has been failure of a first-line therapy such as antidepressants or antiepileptic medications. The clinical information submitted for review did not provide any evidence that these first-line therapies have been tried, nor did it provide evidence that the topical medications have been effective in decreasing the injured worker's pain levels, as scored on the VAS. As such, the current request for Tramadol/Dextromethorphan/Capsaicin is not medically necessary.

RETROSPECTIVE USAGE OF IBUPROFEN: Upheld

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

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

Decision rationale: California MTUS/ACOEM Guidelines recommend NSAID use for the short-term treatment of symptomatic, chronic low back pain. Although the injured worker suffers from chronic pain and may benefit from the use of ibuprofen periodically, there was no indication within the medical records submitted for review, detailing the frequency and dosage of the ibuprofen used. Additionally, there was no indication that the ibuprofen provides objective pain relief, as scored on the VAS; nor was there discussion as to how this medication increases the injured worker's functional abilities. Furthermore, there was no desired quantity submitted

with the request. Until the frequency of use, the dosage, the amount desired, and the efficacy of this medication can be provided, treatment is not indicated. As such, the request for ibuprofen is not medically necessary.

RETROSPECTIVE USAGE OF FLURBIPROFEN/LIDOCAINE /MENTHOL /CAMPHOR: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not cite any medical evidence for its decision.

Decision rationale: California MTUS/ACOEM Guidelines recommend topical analgesics to treat primarily osteoarthritic and neuropathic pain. Guidelines state any compounded product containing at least one drug (or drug class) not recommended by guidelines, deems the entire product not recommended. The current request includes a 20% formulation of topical Flurbiprofen, 5% formulation of topical Lidocaine, 5% topical menthol, and 1% topical camphor. Currently, guidelines do not recommend any topical NSAIDs for use, other than Diclofenac 1%. As Flurbiprofen is an NSAID and does not fall under the FDA-approved in guideline recommended topical NSAIDs for use, the entire compounded cream is not recommended. Additionally, topical Lidocaine is not approved for use in any other formulation than a dermal patch, including lotions, creams, or gels. Furthermore, there should be evidence of the failure of a first line therapy, prior to the use of topical agents. As such, the request for Flurbiprofen/Lidocaine/Menthol/Camphor is not medically necessary.