

Case Number:	CM15-0069052		
Date Assigned:	04/16/2015	Date of Injury:	08/10/2011
Decision Date:	05/26/2015	UR Denial Date:	03/19/2015
Priority:	Standard	Application Received:	04/10/2015

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 47-year-old male, who sustained an industrial injury on 08/10/2011. The initial complaints or symptoms included right knee and right ankle pain/injury as well as hernia issues due to cumulative trauma. The initial diagnoses were not mentioned in the clinical notes. Treatment to date has included conservative care, medications, x-rays, MRIs, CT scans, conservative therapies, electrodiagnostic testing, psychiatric evaluation/therapy, shock wave therapy, right knee surgery (03/25/2014), and bilateral hernia repair surgery. Currently, the injured worker complains of constant and moderate residual pain and discomfort to the groin areas (status post bilateral hernia repairs), constant moderate-to-severe residual right knee pain, and burning pain in the left knee, with numbness and tingling in the feet. The injured worker reported that medications offer him temporary relief from pain and increased ability to sleep. The diagnoses include status-post surgery to the right knee with residual pain, bilateral knee pain-rule out internal derangement, left ankle fracture, status post bilateral inguinal hernia repair surgery, and bilateral groin discomfort. The request for authorization consisted of Ketoprofen 20%, cyclobenzaprine 5% and Synapryn.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20% #167gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

Decision rationale: Based on the 03/06/15 progress report provided by treating physician, the patient presents with bilateral knee pain rated 6-7/10, and bilateral groin pain rated 5/10. The patient is status post bilateral inguinal hernia repair, and right knee surgery, unspecified dates. Patient's left ankle is placed in a plaster cast. The request is for KETOPROFEN 20% #167GM. RFA not provided. Patient's diagnosis on 03/06/15 included bilateral knee pain, rule out internal derangement; left ankle fracture; and bilateral groin discomfort. Treatment to date has included conservative care, imaging studies, electrodiagnostic testing, psychiatric evaluation/therapy, shock wave therapy, and medications. Patient's medications include Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex. Per 03/06/15 report, treater states medications offer the patient "temporary relief of pain and improve his ability to have restful sleep. He denies any problems with medications." The patient is off-work, per 03/06/15 treater report. MTUS Topical Analgesics guidelines pages 111 and 112 has the following regarding topical creams, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." MTUS further states, "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Per 02/06/15 progress report, treater states "apply thin layer to affected area(s) 3 times a day for inflammation." In this case, the requested topical compound contains Ketoprofen, which is not currently FDA approved for topical application, per MTUS. MTUS page 111 states that if one of the compounded topical products is not recommended, then the entire product is not. The request does not meet guideline criteria. Therefore, the request IS NOT medically necessary.

Cyclobenzaprine 5% #110gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

Decision rationale: Based on the 03/06/15 progress report provided by treating physician, the patient presents with bilateral knee pain rated 6-7/10, and bilateral groin pain rated 5/10. The patient is status post bilateral inguinal hernia repair, and right knee surgery, unspecified dates. Patient's left ankle is placed in a plaster cast. The request is for CYCLOBENZAPRINE 5% #110GM. RFA not provided. Patient's diagnosis on 03/06/15 included bilateral knee pain, rule out internal derangement; left ankle fracture; and bilateral groin discomfort. Treatment to date has included conservative care, imaging studies, electrodiagnostic testing, psychiatric

evaluation/therapy, shock wave therapy, and medications. Patient's medications include Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex. Per 03/06/15 report, treater states medications offer the patient "temporary relief of pain and improve his ability to have restful sleep. He denies any problems with medications." The patient is off-work, per 03/06/15 treater report. MTUS has the following regarding topical creams (p111, chronic pain section): "Topical Analgesics: Non-steroidal antiinflammatory agents (NSAIDs): 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 first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Per 02/06/15 progress report, treater states "apply thin layer to affected area(s) 3 times a day for inflammation." In this case, the requested topical compound contains Cyclobenzaprine, which is not supported for topical use in lotion form, according to guidelines. MTUS page 111 states that if one of the compounded topical products is not recommended, then the entire product is not. This request does not meet guideline criteria. Therefore, the request IS NOT medically necessary.

Synapryn 10mg/ml 500ml: 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 criteria for use of opioids, Tramadol (Ultram) Page(s): 88-89, 76-78,113.

Decision rationale: Based on the 03/06/15 progress report provided by treating physician, the patient presents with bilateral knee pain rated 6-7/10, and bilateral groin pain rated 5/10. The patient is status post bilateral inguinal hernia repair, and right knee surgery, unspecified dates. Patient's left ankle is placed in a plaster cast. The request is for SYNAPRYN 10MG/ML 500ML. RFA not provided. Patient's diagnosis on 03/06/15 included bilateral knee pain, rule out internal derangement; left ankle fracture; and bilateral groin discomfort. Treatment to date has included conservative care, imaging studies, electrodiagnostic testing, psychiatric evaluation/therapy, shock wave therapy, and medications. Patient's medications include Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex. Per 03/06/15 report, treater states medications offer the patient "temporary relief of pain and improve his ability to have restful sleep. He denies any problems with medications." The patient is off-work, per 03/06/15 treater report. Per Daily med, "SYNAPRYN" is tramadol hydrochloride 10 mg/mL, in oral suspension with glucosamine - compounding kit."

www.dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22416 MTUS Guidelines pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects,

and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS p77 states, "Function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." MTUS page 113 for Tramadol (Ultram) states: Tramadol (Ultram) is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. For more information and references, see Opioids. See also Opioids for neuropathic pain. Synapryn is included in patient medications, per treater reports dated 02/06/15 and 03/06/15. It is not known when Synapryn was initiated. In this case, treater has not stated how Synapryn reduces pain and significantly improves patient's activities of daily living. There are no pain scales or validated instruments addressing analgesia. MTUS states that "function should include social, physical, psychological, daily and work activities." There are no specific discussions regarding aberrant behavior, adverse reactions, ADLs, etc. No UDS's, opioid pain agreement or CURES reports. No return to work, or change in work status, either. MTUS requires appropriate discussion of the 4As. Given the lack of documentation as required by guidelines, the request IS NOT medically necessary.