

Case Number:	CM15-0096158		
Date Assigned:	05/28/2015	Date of Injury:	04/28/2004
Decision Date:	07/01/2015	UR Denial Date:	05/11/2015
Priority:	Standard	Application Received:	05/19/2015

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: New York
Certification(s)/Specialty: Internal Medicine

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 45-year-old male, who sustained an industrial injury on 4/28/2004. Diagnoses include lumbar discopathy with disc displacement and lumbar radiculopathy. Treatment to date has included medications including Fexmid, Prilosec, Ultram ER, Tylenol #3 and compound medicated creams. Per the Primary Treating Physician's Progress Report dated 3/23/2015 the injured worker reported low back pain radiating down to both legs that is associated with numbness and tingling. His pain rating has decreased from 8-9/10 to 6/10 after taking prescribed medications. Physical examination of the lumbar spine revealed tenderness to palpation over the lumbar paraspinal musculature. There as decreased range of motion secondary to pain and stiffness. The plan of care included oral and topical medications and authorization was requested for Tylenol #3 and Flurbiprofen 25%, menthol 10%, camphor 3%, capsaicin 0.0375% 15gm and 60gm topical cream.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tylenol #3 (Acetaminophen with codeine) 300mg/3mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74 - 82.

Decision rationale: MTUS recommends that ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects must be documented with the use of Opioids. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Guidelines recommend using key factors such as pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors, to monitor chronic pain patients on opioids. Assessment for the likelihood that the patient could be weaned from opioids is recommended if there is no overall improvement in pain or function, unless there are extenuating circumstances and if there is continuing pain with the evidence of intolerable adverse effects. The injured worker complains of chronic radicular low back pain. Documentation fails to demonstrate adequate improvement in level of function or quality of life, to support the medical necessity for continued use of opioids. In the absence of significant response to treatment, the request for Tylenol #3 (Acetaminophen with codeine) 300mg/3mg #120 is not medically necessary.

Compound Flurbiprofen 25%/ Menthol 10%/Camphor 3%/Capsaicin 0.0375% topical cream 15gm: Upheld

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

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

Decision rationale: MTUS states that use of topical analgesics is primarily recommended for neuropathic pain when trials of antidepressants and anti-convulsants have failed. There is little to no research to support the use of many of these agents. Flurbiprofen is not FDA approved for topical application and MTUS provides no evidence recommending the use of topical Menthol. Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post- mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Per guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The request for Compound Flurbiprofen 25%/ Menthol 10%/Camphor 3%/Capsaicin 0.0375% topical cream 15gm is not medically necessary by MTUS.

Compound Flurbiprofen 25%/Menthol 10%/Camphor 3%/Capsaicin 0.0375% topical cream 60gm: Upheld

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

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

Decision rationale: MTUS states that use of topical analgesics is primarily recommended for neuropathic pain when trials of antidepressants and anti-convulsants have failed. There is little to no research to support the use of many of these agents. Flurbiprofen is not FDA approved for topical application and MTUS provides no evidence recommending the use of topical Menthol. Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Per guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The request for Compound Flurbiprofen 25%/Menthol 10%/Camphor 3%/Capsaicin 0.0375% topical cream 60gm is not medically necessary by MTUS.

Urine Drug Screen (Toxicology): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, differentiation: dependence & addiction Page(s): 85. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Opioids, Urine drug tests.

Decision rationale: MTUS recommends screening patients to differentiate between dependence and addiction to opioids. Frequency of urine drug testing should be based on documented evidence of risk stratification. Patients at 'low risk' of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. Random collection is recommended. Quantitative urine drug testing is not recommended for verifying compliance without evidence of necessity. Documentation shows evidence of a recent urine drug screen. With the medical necessity for ongoing opioid use not having been established the recommendation for additional urine drug screening is no longer indicated. The request for Urine Drug Screen (Toxicology) is not medically necessary by MTUS.

Fexmid (cyclobenzaprine) 7.5mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63.

Decision rationale: Cyclobenzaprine (Flexeril) is a skeletal muscle relaxant and a central nervous system depressant recommended as a treatment option to decrease muscle spasm in conditions such as low back pain. Per MTUS guidelines, muscle relaxants are recommended for use with caution as a second-line option for only short-term treatment of acute exacerbations in patients with chronic low back pain. The greatest effect appears to be in the first 4 days of treatment and appears to diminish over time. Prolonged use can lead to dependence. The injured worker complains of chronic radicular low back pain. Documentation fails to indicate acute

exacerbation or significant improvement in the injured worker's pain or functional status to justify continued use of cyclobenzaprine. The request for Fexmid (cyclobenzaprine) 7.5mg #120 is not medically necessary per MTUS guidelines.

Nalfon (fenoprofen calcium) 400mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67.

Decision rationale: MTUS states that Non-steroidal anti-inflammatory drugs (NSAIDS) are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. There is no evidence of long-term effectiveness for pain or function. NSAIDS are recommended as a second-line treatment after acetaminophen for the treatment of acute exacerbations of chronic low back pain. The injured worker's symptoms are chronic and ongoing, without evidence of significant functional improvement or documentation of acute exacerbation. With MTUS guidelines not being met, the request for Nalfon (fenoprofen calcium) 400mg #90 is not medically necessary.

Prilosec (omeprazole DR) 20mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

Decision rationale: Proton Pump Inhibitors (PPIs) are used to treat gastrointestinal conditions such as Gastroesophageal reflux disease, Dyspepsia and Gastric ulcers, and to prevent ulcerations due to long term use of Non-steroidal anti-inflammatory drugs (NSAIDs). MTUS recommends the combination of NSAIDs and PPIs for patients at risk for gastrointestinal events, including age over 65 years of age, history of peptic ulcer, gastrointestinal bleeding, or perforation, concurrent use of ASA and high dose or multiple NSAIDs. Documentation does not support that the injured worker is at high risk of gastrointestinal events to establish the medical necessity of ongoing use of Omeprazole. The request for Prilosec (omeprazole DR) 20mg #90 is not medically necessary per MTUS guidelines.

Ultram ER (Tramadol) 150mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Tramadol Page(s): 77, 113.

Decision rationale: MTUS recommends that ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects must be documented with the use of Opioids. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Tramadol is a centrally acting analgesic

reported to be effective in managing neuropathic pain. Per MTUS guidelines, there are no long-term studies to allow use of Tramadol for longer than three months. The injured worker complains of chronic radicular low back pain. Documentation fails to demonstrate significant improvement in pain or function, to justify the ongoing use of Tramadol. With MTUS guidelines not being met, the request for Ultram ER (Tramadol) 150mg #90 is not medically necessary.