

Case Number:	CM15-0149299		
Date Assigned:	08/12/2015	Date of Injury:	04/15/2011
Decision Date:	09/23/2015	UR Denial Date:	07/01/2015
Priority:	Standard	Application Received:	07/31/2015

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 49 year old female who sustained an industrial injury on 4-15-11. Treatments include: medication, physical therapy, nerve block, cervical epidural and injections. Progress report dated 6-4-15 reports complaints of constant low back pain that radiates into the right lower extremity and is associated with tingling, numbness, cramps and burning. Epidural injection given on 4-17-12 provided 50% improvement in back and radiating leg pain. She also has complaints of constant neck pain with right sided headaches that start from the back and radiates to the front with constant right upper extremity pain into fingers with numbness, tingling and weakness. The neck pain is rated 3-9 out of 10. Post cervical epidural, she had 50% improvement. She has right upper extremity pain, right shoulder pain and right lower extremity pain. Diagnoses include: possible cervical and lumbar discogenic pain, possible right lumbar facet pain, lumbar sprain and strain, right lumbosacral radicular pain, cervical discogenic pain, status post right shoulder rotator cuff repair. Plan of care includes: continue conservative care, recommend and continue medications; flexeril, nabumetone, prilosec, topical creams, zanaflex and Ultram ER continue urine toxicology screens. Work status: working regular job duties. Follow up in 6 weeks.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ultram ER 150mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain Criteria for use of Opioids Page(s): 60,61, 76-78, 88,89.

Decision rationale: The patient presents with low back pain radiating to the right lower extremity, with tingling and numbness. The request is for Ultram ER 150 MG #60. Physical examination to the lumbar spine on 06/04/15 revealed tenderness to palpation over the L-4-S1 area. Per 06/04/15 Request For Authorization, patient's diagnosis include possible lumbar discogenic pain/possible right lumbar facet pain L4-L5, right lumbosacral radicular pain (constant) L5-S1 (abnormal electrodiagnostic study May 17), possible cervicgia discogenic pain/possible right cervical facet pain C2-C3, stabilized right cervical radicular pain C6, status post right shoulder rotator cuff repair, and resolved right occipital neuralgia. Patient's medications, per 06/04/15 Request for Authorization include Ultram, Zanaflex, Relafen, and Prilosec. Patient is permanent and stationary. 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." Pages 80, 81 of MTUS also states "There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant radiculopathy," and for chronic back pain, it "appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." MTUS Chronic Pain Medical Treatment Guidelines for Tramadol, 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. The treater has not specifically discussed this request. It is not clear how long the patient has been on this medication, as only one progress report was available in which the treater states that the patient remains on Ultram ER 150 mg, one a day. However, treater has not discussed how Ultram decreases pain and significantly improves patient's activities of daily living. There are no UDS's, no opioid pain agreement, or CURES reports addressing aberrant behavior; no discussions with specific adverse effects, aberrant behavior, ADL's, etc. MTUS requires appropriate discussion of the 4A's. Given the lack of documentation as required by guidelines, the request is not medically necessary.

Zanaflex 4mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 66.

Decision rationale: The patient presents with low back pain radiating to the right lower extremity, with tingling and numbness. The request is for Zanaflex 4 mg. Physical examination to the lumbar spine on 06/04/15 revealed tenderness to palpation over the L-4-S1 area. Per 06/04/15 Request For Authorization, patient's diagnosis include possible lumbar discogenic pain/possible right lumbar facet pain L4-L5, right lumbosacral radicular pain (constant) L5-S1 (abnormal electrodiagnostic study May 17), possible cervicgia discogenic pain/possible right cervical facet pain C2-C3, stabilized right cervical radicular pain C6, status post right shoulder rotator cuff repair, and resolved right occipital neuralgia. Patient's medications, per 06/04/15 Request for Authorization include Ultram, Zanaflex, Relafen, and Prilosec. Patient is permanent and stationary. MTUS Chronic Pain Medical Treatment Guidelines for Muscle Relaxants for pain, pg 66: "Antispasticity/Antispasmodic Drugs: Tizanidine (Zanaflex, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain." The treater has not specifically discussed this request. It is not clear how long the patient has been on this medication, as only one progress report was available in which the treater states that the patient takes Zanaflex only on as needed basis during flare-up. However, there is no discussion of its efficacy in terms of pain reduction and functional improvement. MTUS page 60 require that medication efficacy in terms of pain reduction and functional gains must be discussed when using for chronic pain. Therefore, this request is not medically necessary.

Relafen (Nabumetone) 750mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS (Non-Steroidal Anti-Inflammatory Drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Nabumetone (Relafen) Page(s): 72 and 73.

Decision rationale: The patient presents with low back pain radiating to the right lower extremity, with tingling and numbness. The request is for Relafen (Nabumetone) 750 MG #60. Physical examination to the lumbar spine on 06/04/15 revealed tenderness to palpation over the L-4-S1 area. Per 06/04/15 Request For Authorization, patient's diagnosis include possible lumbar discogenic pain/possible right lumbar facet pain L4-L5, right lumbosacral radicular pain (constant) L5-S1 (abnormal electrodiagnostic study May 17), possible cervicgia discogenic pain/possible right cervical facet pain C2-C3, stabilized right cervical radicular pain C6, status post right shoulder rotator cuff repair, and resolved right occipital neuralgia. Patient's medications, per 06/04/15 Request for Authorization include Ultram, Zanaflex, Relafen, and Prilosec. Patient is permanent and stationary. MTUS Chronic Pain Guidelines page 72 & 73 states, "Nabumetone (Relafen, generic available): 500, 750 mg. Dosing: Osteoarthritis: The recommended starting dose is 1000 mg PO. The dose can be divided into 500 mg PO twice a day. Additional relief may be obtained with a dose of 1500 mg to 2000 mg per day. The

maximum dose is 2000 mg/day. Patients weighing less than 50 kg may be less likely to require doses greater than 1000 mg/day. The lowest effective dose of nabumetone should be sought for each patient. Use for moderate pain is off-label.” (Relafen Package Insert) 72 & 73 Regarding NSAID's, MTUS page 22 and Anti-inflammatory Medications section, supports it for chronic low back pain, at least for short-term relief. MTUS p60 also states, "A record of pain and function with the medication should be recorded," when medications are used for chronic pain. The treater has not addressed this request. It is not clear how long the patient has been on this medication, as only one progress report was available in which the treater states that the patient remains on Relafen. However, the treater has not documented the efficacy of this medication, in terms of pain relief and functional improvement. MTUS page 60 require that medication efficacy in terms of pain reduction and functional gains must be discussed when using for chronic pain. Therefore, this request is not medically necessary.

Prilosec 20mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS (Non-Steroidal Anti-Inflammatory Drugs) GI (Gastrointestinal) Symptoms & Cardiovascular Risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular Page(s): 69.

Decision rationale: The patient presents with low back pain radiating to the right lower extremity, with tingling and numbness. The request is for Prilosec 20 mg #30. Physical examination to the lumbar spine on 06/04/15 revealed tenderness to palpation over the L-4-S1 area. Per 06/04/15 Request For Authorization, patient's diagnosis include possible lumbar discogenic pain/possible right lumbar facet pain L4-L5, right lumbosacral radicular pain (constant) L5-S1 (abnormal electrodiagnostic study May 17), possible cervicgia discogenic pain/possible right cervical facet pain C2-C3, stabilized right cervical radicular pain C6, status post right shoulder rotator cuff repair, and resolved right occipital neuralgia. Patient's medications, per 06/04/15 Request for Authorization include Ultram, Zanaflex, Relafen, and Prilosec. Patient is permanent and stationary. MTUS page 69 under NSAIDs, GI symptoms & cardiovascular risk Section states, Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. Recommendations: Patients with no risk factor and no cardiovascular disease: Non- selective NSAIDs OK (e.g., ibuprofen, naproxen, etc.). Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 ?g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease:

If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxen plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007) The treater does not specifically discuss this request. It is not clear how long the patient has been on this medication, as only one progress report was available. In this case, the treater has not documented any gastrointestinal upset or irritation. There is no history of ulcers, either. Additionally, the patient is under 65 years of age, and there is no documented use of ASA, corticosteroids, and/or an anticoagulants concurrently. The treater does not provide GI risk assessment required to make a determination based on MTUS. Therefore, the request is not medically necessary.

Urine compliance testing every 3-4 months: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Procedure Summary, Pain, Urine drug testing (UDT).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Urine Drug Testing Page(s): 43.

Decision rationale: The patient presents with low back pain radiating to the right lower extremity, with tingling and numbness. The request is for Urine compliance testing every 3-4 months. Physical examination to the lumbar spine on 06/04/15 revealed tenderness to palpation over the L-4-S1 area. Per 06/04/15 Request For Authorization, patient's diagnosis include possible lumbar discogenic pain/possible right lumbar facet pain L4-L5, right lumbosacral radicular pain (constant) L5-S1 (abnormal electrodiagnostic study May 17), possible cervicalgia discogenic pain/possible right cervical facet pain C2-C3, stabilized right cervical radicular pain C6, status post right shoulder rotator cuff repair, and resolved right occipital neuralgia. Patient's medications, per 06/04/15 Request for Authorization include Ultram, Zanaflex, Relafen, and Prilosec. Patient is permanent and stationary. MTUS Chronic Pain Medical Treatment Guidelines, for Testing, pg 43 states: Recommended as an option, using a urine drug screen to assess for the use or the presence of illegal drugs. ODG-TWC Guidelines, online, Pain chapter for Urine Drug Testing states: Patients at "low risk" of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. There is no reason to perform confirmatory testing unless the test is inappropriate or there are unexpected results. If required, confirmatory testing should be for the questioned drugs only. Per 06/04/15 RFA, treater is requesting urine drug testing for compliance every 3-4 months as per guidelines while the patient remains on prescribed pain medications. Review of the records did not indicate a prior urine drug test. The patient is on Ultram and a urine drug test would be indicated and supported by the guidelines. However, the request is for a test every 3-4 months and guidelines do not support routine urine drug testing. Therefore, the request is not medically necessary.

Retrospective request for Ultram ER 150mg, #60, date of service: 06/04/15: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain Criteria for use of Opioids Page(s): 60, 61, 76-78, 88,89.

Decision rationale: The patient presents with low back pain radiating to the right lower extremity, with tingling and numbness. The request is for Retrospective request for Ultram ER 150 mg, #60, Date of Service: 06/04/15. Physical examination to the lumbar spine on 06/04/15 revealed tenderness to palpation over the L-4-S1 area. Per 06/04/15 Request For Authorization, patient's diagnosis include possible lumbar discogenic pain/possible right lumbar facet pain L4-L5, right lumbosacral radicular pain (constant) L5-S1 (abnormal electrodiagnostic study May 17), possible cervicgia discogenic pain/possible right cervical facet pain C2-C3, stabilized right cervical radicular pain C6, status post right shoulder rotator cuff repair, and resolved right occipital neuralgia. Patient's medications, per 06/04/15 Request for Authorization include Ultram, Zanaflex, Relafen, and Prilosec. Patient is permanent and stationary. 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." Pages 80, 81 of MTUS also states "There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant radiculopathy," and for chronic back pain, it "appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." MTUS Chronic Pain Medical Treatment Guidelines for Tramadol, page113 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. The treater has not specifically discussed this request. It is not clear how long the patient has been on this medication, as only one progress report was available in which the treater states that the patient remains on Ultram ER 150 mg, one a day. However, treater has not discussed how Ultram decreases pain and significantly improves patient's activities of daily living. There are no UDS's, no opioid pain agreement, or CURES reports addressing aberrant behavior; no discussions with specific adverse effects, aberrant behavior, ADL's, etc. MTUS requires appropriate discussion of the 4A's. Given the lack of documentation as required by guidelines, the request is not medically necessary.