

| | | | |
|-----------------------|--------------|------------------------------|------------|
| Case Number: | CM15-0141665 | | |
| Date Assigned: | 07/31/2015 | Date of Injury: | 02/12/2014 |
| Decision Date: | 09/21/2015 | UR Denial Date: | 07/17/2015 |
| Priority: | Standard | Application Received: | 07/21/2015 |

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 42 year old male with an industrial injury dated 02-12-2014. His diagnoses included lumbar spine strain and sprain, lumbar spondylosis and low back pain. Prior treatment included physical therapy, acupuncture, exercise and medications. He presents on 07-06-2015 for monthly visit for "flaring" low back pain. He had completed 12/12 physical therapy sessions with short-term benefits and had completed 5/6 acupuncture treatments with some improvement in range of motion but with no change in pain level. He reported low back pain was radiating down to the left lower extremity with stiffness and causing difficulty in sleeping and daily activity. Physical exam noted positive straight leg raising bilateral and positive trendelenburg test bilateral. The provider documents the following tests results: MRI (08-21-2014) of lumbar spine revealed lumbar spondylosis on lumbar 4-5 with annular bulge and 2 mm broad central protrusion with annular fissure. The formal MRI report is not in the submitted records. EMG-NCS (02-26-2015) of bilateral lower extremities showed no electro diagnostic evidence of radiculopathy in the areas tested. Treatment plan included medications (Voltaren gel, Flector patch, Diclofenac ER and Soma), physical therapy and neurosurgery consult for lumbar spine disc protrusion and persistent low back pain. Work status was full duty. The request for physical therapy, lumbar quantity 6 was authorized. The treatment request for review is: Diclofenac extended release 100 mg (with three refills), quantity 120; Flector Patches (1 patch twice a day) quantity 60; Soma 350 mg quantity 30; Voltaren Gel 1%, 200 g (with three refills) quantity 4.

IMR ISSUES, DECISIONS AND RATIONALES

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

Voltaren Gel 1%, 200g (with three refills) quantity 4: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non Steroidal Anti Inflammatory Drugs Page(s): 111-112.

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

Decision rationale: This patient present with a flare-up of his lower back pain. The current request is for Voltaren Gel 1%, 200g (with three refills) quantity 4. Prior treatment included physical therapy, acupuncture, exercise and medications. The patient may return to full duty. MTUS Chronic Pain Medical Treatment Guidelines page 111 states the following regarding topical analgesics: "largely experimental and used with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents." Regarding topical NSAIDs, page 111-113 states, "indications: Osteoarthritis and tendonitis, in particular that of the knee, and elbow or other joints that are amenable to topical treatment: Recommended for short term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder. Neuropathic pain, not recommended as there is no evidence to support use." Per report 07/06/15, the patient reported low back pain, radiating down to the left lower extremity with stiffness noted. Physical examination noted positive straight leg raising bilaterally and positive Trendelenburg test bilateral. Treatment plan was for refill of medications. The patient does not suffer from peripheral joint arthritis or tendinitis for which topical NSAIDs are recommended. MTUS does not support the use of topical NSAIDs such as Voltaren for axial or spinal pain. The requested Voltaren gel IS NOT medically necessary.

Flector Patches (1 patch twice a day) quantity 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non Steroidal Anti Inflammatory Drugs Page(s): 111-112.

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

Decision rationale: This patient present with a flare-up of his lower back pain. The current request is for Flector Patches (1 patch twice a day) quantity 60. Prior treatment included physical therapy, acupuncture, exercise and medications. The patient may return to full duty. The Flector patch is Diclofenac in a topical patch. Regarding topical NSAIDs, MTUS under Topical Analgesics, pages 111-113 states, "Indications: Osteoarthritis and tendonitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks)." ODG Guidelines, under the Pain Chapter, has the following regarding Flector patch: "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. In

addition, there is no data that substantiate Flector efficacy beyond two weeks." Per report 07/06/15, the patient reported low back pain, radiating down to the left lower extremity with stiffness noted. Physical examination noted positive straight leg raising bilaterally and positive Trendelenburg test bilateral. Treatment plan was for refill of medications. MTUS does not support topical NSAID medications for this patient's chief complaint. MTUS guidelines indicate that topical NSAID medications are considered appropriate for peripheral joint complaints, and specifically state that there is little evidence to utilize topical NSAIDs for osteoarthritis of the spine, hip, or shoulder. This patient presents with chronic low back pain, not a peripheral joint complaint amenable to topical NSAIDs. Without discussion of a peripheral joint complaint or other condition for which Flector patches are considered appropriate, the request cannot be substantiated. Therefore, the request IS NOT medically necessary.

Diclofenac extended release 100mg (with three refills), quantity 120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Diclofenac Sodium Page(s): 71.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications Page(s): 22.

Decision rationale: This patient present with a flare-up of his lower back pain. The current request is for Diclofenac extended release 100mg (with three refills), quantity 120. Prior treatment included physical therapy, acupuncture, exercise and medications. The patient may return to full duty. MTUS Guidelines page 22 on anti-inflammatory medications states that anti-inflammatories are the traditional first-line treatment to reduce pain, so activity and functional restoration can resume, but long-term use may not be warranted. For medication use in chronic pain, MTUS page 60 also requires documentation of the pain assessment and function as related to the medication use. Specific to Voltaren, ODG Guidelines, Pain Chapter, under Diclofenac Sodium states, "Not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients as did rofecoxib (Vioxx), which was taken off the market." Specific to Voltaren, ODG Guidelines, Pain Chapter, under Diclofenac Sodium states, "Not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients as did rofecoxib (Vioxx), which was taken off the market." Per report 07/06/15, the patient reported low back pain, radiating down to the left lower extremity with stiffness noted. Physical examination noted positive straight leg raising bilaterally and positive Trendelenburg test bilateral. Treatment plan was for refill of medications. The patient has been prescribed Diclofenac since at least 01/26/15. MTUS page 60 requires recording of pain assessment and functional changes when medications are used for chronic pain. None of the reports provided discuss how Diclofenac has impacted the patient's pain and function. Due to lack of documentation of medication efficacy, the requested Diclofenac IS NOT medically necessary.

Soma 350mg quantity 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol Page(s): 65.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-66.

Decision rationale: This patient present with a flare-up of his lower back pain. The current request is for Soma 350mg quantity 30. Prior treatment included physical therapy, acupuncture, exercise and medications. The patient may return to full duty. MTUS Chronic Pain Guidelines pages 63-66 states: "Muscle relaxants (for pain): Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbation in patients with chronic LBP. The most commonly prescribed antispasmodic agents are Carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Cyclobenzaprine (Flexeril, Amrix, Fexmid, generic available): Recommended for a short course of therapy." MTUS, Chronic Pain Medication Guidelines, Muscle Relaxants, page 63-66: "Carisoprodol (Soma, Soprodal 350, Vanadom, generic available): Neither of these formulations is recommended for longer than a 2 to 3 week period." Abuse has been noted for sedative and relaxant effects. Per report 07/06/15, the patient reported low back pain, radiating down to the left lower extremity with stiffness noted. Physical examination noted positive straight leg raising bilaterally and positive Trendelenburg test bilateral. Treatment plan was for refill of medications. The patient has been prescribed Soma since at least 01/26/15 and MTUS recommends this medication only for a short period, no more than 2-3 weeks. This request is not in accordance with guidelines. Therefore, the request IS NOT medically necessary.