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 Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in Texas. 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 40 year old male injured on 08/27/12 while lifting an 80 pound bag of concrete from a container and putting them into a pick-up truck, when he felt a sharp pain in his upper to mid back. Current diagnoses include chronic lumbar back pain, and chronic neck pain. The injured worker underwent chiropractic therapy with no relief. Radiology reports dated 01/23/14 revealed minimal degenerative spurring on the thoracic spine, and cervical spine showed possible torticollis; may also represent muscle spasm. MRI of the thoracic area revealed multiple small disc protrusions; however, disc protrusions at T6-7 and T8-9 levels mildly compress the ventral aspect of the cord. Clinical note dated 04/23/14 the injured worker was seen for consult of his chronic mid and upper back pain, located in the thoracic spine. The pain was constant, described as sharp, aching, shooting, with spasms. Pain is worse with lifting, sitting, bending, twisting, weather change, walking. Pain was made better by changing positions. Pain level was rated as 8/10 with medication. Physical examination revealed decreased pinprick sensation in the left foot, dorsal and lateral. Straight leg raise was positive on the left at 60 degrees. Patrick's maneuver was positive on the left. Reflexes were decreased on bilateral biceps, triceps, and brachioradialis. There was worsened and reproducible concordant axial low back pain with rotation and hyperextension of the torso. Plan of management include recommendation for thoracic epidural steroid injection, trial of Cyclobenzaprine, Lidoderm, and Voltaren gel. Clinical notes dated 05/21/14 the injured worker reported pain located in the head, left arm, neck, shoulder and thoracic spine. Pain level was rated as 7/10, with the worst pain rated as 9/10. Clinical notes dated 06/24/14 the injured worker complained of bilateral low back pain, with pain level rated as 7/10, and worst pain level being 8/10. Pain was worse with physical activity and made better by rest and medication. Clinical note dated 07/23/14 indicated the injured worker has pain in the thoracic spine, bilateral hands, and left low back. He indicated there has
been no change since last visit. Pain level was rated as 8/10 with medications. Lumbosacral examination revealed spinal tenderness. Clinical notes dated 08/22/14 indicated the injured worker reported ongoing neck and low back pain. Pain was localized in the thoracic spine, bilateral hands, and bilateral low back, without any change since the last visit. The pain was described as intermittent, throbbing, electrical, made worse by stress, cold, walking, and made better by sleep. The injured worker indicated his pain level was 8/10 with medications, 8/10 on the average, and 10/10 at its worse. Examination of the lumbosacral range of motion revealed forward flexion of 60 degrees, hyperextension of 20 degrees, right lateral bending of 5 degrees, and left lateral bending of 15 degrees. Medications include Cyclobenzaprine HCL 7.5mg, Voltaren 1% gel, and Lidoderm 5% patch. The previous requests for Lidoderm patches 5% on 12/off 12hrs, max 3 patches at 1 time, 1 box, Voltaren 1% gel Diclofenac sodium apply 2gms BID prn 1 tube, and Cyclobenzaprine HCL 7.5mg 1-2 tabs BID prn #60 were non-certified on 07/28/14.

**IMR ISSUES, DECISIONS AND RATIONALES**

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

**Lidoderm Patches 5% on 12/off 12hours, Max 3 Patches at one Time, 1 Box:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (Lidocaine patch) Page(s): 56.

**Decision rationale:** As noted on page 56 of the Chronic Pain Medical Treatment Guidelines, topical Lidoderm may be recommended for localized neuropathic pain after there has been a trial of first line therapy (tri-cyclic or SNRI anti-depressants or an anti-epilepsy drug such as Gabapentin or Lyrica). Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no indication in the documentation that these types of medications have been trialed and/or failed. In addition, Lidoderm is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. As such, the request for Lidoderm patches 5% on 12/off 12hrs, max 3 patches at one time, 1 box, cannot be recommended as medically necessary as it does not meet established and accepted medical guidelines.

**Voltaren 1% Gel Diclofenac Sodium Apply 2 Grams to Affected Area twice time as needed 1 Tube:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Diclofenac (Voltaren) Page(s): 43.
**Decision rationale:** As noted on page 43 of the Chronic Pain Medical Treatment Guidelines, Voltaren is not recommended as first line treatment due to increased risk profile. Post marketing surveillance has revealed that treatment with all oral and topical Diclofenac products may increase liver dysfunction, and use has resulted in liver failure and death. The United States Federal Drug Administration advised physicians to measure transaminases periodically in patients receiving long-term therapy with Diclofenac and issued warnings about the potential for elevation in liver function tests during treatment with all products containing Diclofenac sodium. With the lack of data to support superiority of Diclofenac over other NSAIDs and the possible increased hepatic and cardiovascular risk associated with its use, alternative analgesics and/or non-pharmacological therapy should be considered. As such, the request for Voltaren 1% gel, Diclofenac Sodium apply 2gms to affected area twice as needed 1 tube, cannot be established as medically necessary.

**Cyclobenzaprine HCL 7.5mg 1-2 Tablets by mouth twice per day as needed #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines
Cyclobenzaprine Page(s): 41.

**Decision rationale:** As noted on page 41 of the Chronic Pain Medical Treatment Guidelines, cyclobenzaprine is recommended as a second-line option for short-term (less than two weeks) treatment of acute low back pain and for short-term treatment of acute exacerbations in patients with chronic low back pain. Studies have shown that the efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Based on the clinical documentation, the patient has exceeded the 2-4 week window for acute management also indicating a lack of efficacy if being utilized for chronic flare-ups. As such, the medical necessity of Cyclobenzaprine HCL 7.5mg 1-2 tabs by mouth twice per day as needed #60 cannot be established at this time.