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: Ohio, North Carolina, Virginia
Certification(s)/Specialty: Family Practice

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 37 year old female with a date of injury of 2-23-2006. The mechanism of injury is not given but she complains of lower back pain with radiation to the left lower extremity, a left foot drop, and right foot pain. She had a 2 level discectomy in 2006 and has had chiropractic care, physical therapy, and medications. She had lumbar epidural injections to the L5 and S1 nerve roots on 1-17-2014 with 50% pain relief and again on 10-3-2014 with 40% relief at 8 weeks. The physical exam reveals an antalgic gait, an AFO brace on the left, tenderness of the left lower paraspinal muscles, and diminished lumbar range of motion. There is diminished left great to dorsiflexion, diminished left sided sensation in the region of L4, L5, and S1. The left Achilles’ reflex is absent. Nerve conduction studies from 5-13-2014 reveal a left S1 radiculopathy. She had been taking Norco (Hydrocodone/acetaminophen) 5/325 mg 4 times daily before the 1st epidural injection. This was diminished to twice daily after the first injection. After the second injection, she was changed to Tramadol/APAP, at first once a day but more recently 4 times daily. Functional improvement is noted in terms of ability to do activities of daily living and to continue a home exercise program as a consequence of the medication specifically. No functional improvement has been independently attributed to the epidural steroid injections. At issue is a request for Tramadol/APAP 37.5mg #120, Cyclobenzaprine 7.5mg #30, and transforaminal epidural steroid Injection, bilateral L5-S1, L5 root, and S1 nerve roots. The epidural steroid injections were not certified because of a lack of demonstrated functional improvement after the first 2 injections. The tramadol/APAP was not certified because of a lack of functional improvement and the cyclobenzaprine was similarly denied for the same reason.
IMR ISSUES, DECISIONS AND RATIONALES

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

**Tramadol/APAP 37.5mg #120:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of opioids. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, Opioids, specific drug list

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

**Decision rationale:** Patients receiving opioid medication chronically require ongoing monitoring for pain relief, functionality, medication side effects, and any aberrant drug taking behavior. Opioids may generally be continued if there are improvements in pain and functionality as a consequence. In this instance, there is documentation of a recent pharmacy database inquiry and urine drug screen, both consistent. Pain relief has been verified via VAS scoring. Functional gains, although short-term, are noted because of medication. The overall daily opioid dose has generally been declining. Therefore, Tramadol/APAP 37.5mg #120 is medically necessary.

**Cyclobenzaprine 7.5mg #30:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-64.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-42.

**Decision rationale:** Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is marketed as Flexeril by [Company Name]. Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. Cyclobenzaprine is recommended as an option, using a short course of therapy for chronic pain. Cyclobenzaprine (Flexeril) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief and generally limited to 2-3 weeks. In this instance, the treating physician re-started the injured worker on cyclobenzaprine on 12-1-2014 after a period of abstinence for her low back spasm and leg cramps. The physician was specific about limiting the treatment to 2-3 weeks. Cyclobenzaprine 7.5mg #30 was therefore medically necessary under the guidelines. This opinion differs from utilization review. The guidelines do not specify that functional improvement must be shown with cyclobenzaprine which was the basis of denial.

**Transforaminal Epidural Steroid Injection, Bilateral L5-S1, L5 Root, and S1 Nerve Roots:** Overturned
**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Epidural steroid injections (ESIs).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Low Back

**Decision rationale:** Criteria for the use of Epidural steroid injections: Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, reduction of medication use and avoiding surgery, but this treatment alone offers no significant long-term functional benefit. (1) Radiculopathy (due to herniated nucleus pulposus, but not spinal stenosis) must be documented. Objective findings on examination need to be present. Radiculopathy must be corroborated by imaging studies and/or electrodiagnostic testing. (2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants). (3) Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance. (4) Diagnostic Phase: At the time of initial use of an ESI (formally referred to as the “diagnostic phase” as initial injections indicate whether success will be obtained with this treatment intervention), a maximum of one to two injections should be performed. A repeat block is not recommended if there is inadequate response to the first block (< 30% is a standard placebo response). A second block is also not indicated if the first block is accurately placed unless: (a) there is a question of the pain generator; (b) there was possibility of inaccurate placement; or (c) there is evidence of multilevel pathology. In these cases a different level or approach might be proposed. There should be an interval of at least one to two weeks between injections. (5) No more than two nerve root levels should be injected using transforaminal blocks. (6) No more than one interlaminar level should be injected at one session. Therapeutic phase: If after the initial block/blocks are given (see “Diagnostic Phase” above) and found to produce pain relief of at least 50-70% pain relief for at least 6-8 weeks, additional blocks may be supported. This is generally referred to as the “therapeutic phase.”

Indications for repeat blocks include acute exacerbation of pain, or new onset of radicular symptoms. The general consensus recommendation is for no more than 4 blocks per region per year. In this instance, the injured worker had 50% pain relief after the first epidural series lasting greater than 8 weeks and 40% pain relief lasting 8 weeks after the second series. Pain medication had been reduced following the first 2 series only to increase again recently with a flare. Therefore, Transforaminal Epidural Steroid Injection, Bilateral L5-S1, L5 Root, and S1 Nerve Roots is medically necessary.