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| <b>Case Number:</b>   | CM14-0179449 |                              |            |
| <b>Date Assigned:</b> | 11/03/2014   | <b>Date of Injury:</b>       | 10/13/2011 |
| <b>Decision Date:</b> | 12/12/2014   | <b>UR Denial Date:</b>       | 10/09/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 10/29/2014 |

### 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 Management and is licensed to practice in Tennessee. 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:

This is a 61-year-old female with a 10/13/11 date of injury. The mechanism of injury occurred when she was descending some stairs and slipped and injured her cervico-thoracic spine, left shoulder, lumbar spine, and right ankle. According to a progress report dated 9/10/14, the patient complained of burning, radicular neck pain and muscle spasms, rated as an 8/10. She also complained of burning left shoulder pain radiating down the arm to the fingers rated as a 7/10, and mid and low back pain with muscle spasms, rated as an 8/10. Objective findings: tenderness to palpation of cervical spine with restricted range of motion, tenderness of left shoulder with restricted range of motion and crepitus noted upon motion, tenderness at bilateral thoracic paraspinal muscles with palpable spasms, restricted thoracic spine range of motion, tenderness at lumbar paraspinal muscles with restricted range of motion. Diagnostic impression: cervical spine and lumbar spine degenerative disc disease, cervical spine and lumbar spine radiculopathy, thoracic spine sprain/strain, arthrosis of left shoulder AC joint, right ankle internal derangement, status post right ankle Open Reduction Internal Fixation (ORIF). Treatment to date: medication management, activity modification, surgery, Localized Intense Neurostimulation Therapy (LINT) therapy, physical therapy. A Utilization Review (UR) decision dated 10/9/14 denied the request for Tabradol. CA MTUS guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Tabradol contains Methylsulfonylmethane (MSM), which is not FDA approved.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Tabradol 1mg-ml oral suspension 250 ml dosage 5ml quantity 1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines ANTISPASMODICS Page(s): 64.

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

**Decision rationale:** According to page 41 of the CA MTUS Chronic Pain Medical Treatment Guidelines, Cyclobenzaprine is recommended as an option, using a short course of therapy. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief. There is also a post-op use. The addition of cyclobenzaprine to other agents is not recommended. According to the medical records provided for review, Tabradol contains cyclobenzaprine, Methylsulfonylmethane and other proprietary ingredients to treat musculoskeletal conditions. However, according to the records reviewed, this patient has been taking Tabradol since at least 5/14/14, if not earlier. Guidelines do not support the long-term use of muscle relaxants. In addition, there is no documentation that the patient has had an acute exacerbation to his pain. Therefore, the request for Tabradol 1mg-ml oral suspension 250 ml dosage 5ml quantity 1 was not medically necessary.