

<b>Case Number:</b>	CM13-0023318		
<b>Date Assigned:</b>	03/14/2014	<b>Date of Injury:</b>	07/14/2011
<b>Decision Date:</b>	05/21/2014	<b>UR Denial Date:</b>	08/19/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/11/2013

### 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 Occupational Medicine and is licensed to practice in California. 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 patient is an employee of [REDACTED] and has submitted a claim for L5-S1 disc injury with bilateral S1 radiculopathy associated with an industrial injury date of 07/14/2011. Treatment to date has included L5-S1 transforaminal interbody fusion on 02/14/2013, lumbar spine brace, chiropractic care, aquatic therapy, physical and occupational therapy sessions, and epidural steroid injections with lumbar facet blocks. Utilization review from 08/19/2013 denied the request for Tabradol 1mg/mL oral suspension 250mL dosage 5mL (1 tsp) 2-3 times daily because medical records did not demonstrate that the patient had failed adjuvant analgesics prior to starting this medication which would be the recommendation. Furthermore, cyclobenzaprine, which is a constituent of this drug, is not recommended in its topical form. Medical records from 2011 to 2013 were reviewed showing that patient has been complaining of constant sharp pain in his right lower back graded 8/10 associated with stiffness and radicular symptoms to the right lower extremity. Pain was aggravated by prolonged sitting and standing, repetitive lifting, carrying and pulling objects over 20 pounds. He also complained of back pain while getting dressed and performing personal hygiene. He denied any bowel or bladder incontinence. Intake of medications alleviated his symptoms. Objective findings showed paraspinal tenderness, right greater than left, at T12-S1 levels. Range of motion of lumbar spine elicited pain at end-range towards all directions. Motor strength was decreased at bilateral lower extremities secondary to pain. Deep tendon reflexes were equal and symmetric. There was positive pain bilaterally upon Valsalva, Kemp's test/Facet, Yeoman's test and Iliac compression test. There was diminished sensation to pin-prick and light touch at the L4, L5 and S1 dermatomes, bilaterally. MRI of lumbar spine without contrast, dated 08/16/2011, revealed mild-to-moderate central stenosis of L4-5, mild central stenosis of L3-4. Repeat MRI of lumbar spine, dated 02/11/2013, showed L4-L5 4-5mm posterior and central disc protrusion abutting the adjacent nerve roots in the lateral

corners of the central canal, but no neural foraminal narrowing. A focal high intensity zone suggests annular tear just to the right of midline. L2-L3 far right lateral mild (2-3mm) disc bulge along with linear high signal intensity focus suggesting annular tear. Current medications include compounded Ketoprofen 20% in PLO Gel, compounded Cyclophene 5% in PLO Gel, Synapryn 10mg/1mL oral suspension, Tabradol 1mg/mL oral suspension, Deprezine 15mg/mL oral suspension, Dicopanol (diphenhydramine) 5mg/mL oral suspension, and gabapentin (Fanatrex) 25mg/mL oral suspension.

### **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 250ML DOSAGE 5ML (1 TSP) 2-3 TIMES A DAY:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41, 111.

**Decision rationale:** Page 111 of CA MTUS Chronic Pain Medical Treatment Guidelines state that any compounded product that contains at least one drug (drug class) that is not recommended is not recommended. Tabradol contains cyclobenzaprine. Page 41 of the CA MTUS states that cyclobenzaprine is more effective than placebo in the management of back pain; however, the addition of this drug to other agents is not recommended. There is no indication or evidence that a suspension formulation would be more superior to a tablet formulation. Therefore, the request for Tabradol 1mg/mL oral suspension 250mL dosage 5mL (1 tsp) 2-3 times a day is not medically necessary and appropriate.