

Case Number:	CM15-0122825		
Date Assigned:	07/07/2015	Date of Injury:	12/11/2008
Decision Date:	08/11/2015	UR Denial Date:	06/11/2015
Priority:	Standard	Application Received:	06/25/2015

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, Arizona, Maryland
Certification(s)/Specialty: Psychiatry

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 57 year old female with an industrial injury dated 12/11/2008. The injured worker's diagnoses include reactive depression, rupture of radial collateral ligament of right thumb, traumatic degenerative arthritis of carpometacarpal joint of thumb, unspecified disorder of autonomic nervous system and pain in upper limb. Treatment consisted of diagnostic studies, prescribed medications, psychotherapy and periodic follow up visits. In a progress note dated 04/03/2015, the injured worker presented for a follow up evaluation. The treating physician reported that the injured worker was not getting her pain management prescriptions regularly. The treating physician reported that the injured worker was afraid of interventional procedures but will use meds as given. The treating physician reported positive response to Savella. In a progress note dated 06/05/2015, the injured worker reported right extremity pain. Objective findings revealed tenderness in the right trapezius, positive right Spurling test, positive impingement sign, decrease right wrist range of motion , decreased grip, pain in forearm, positive Carpal Tinel's and positive Finkelstein test. Treatment plan consisted of medication management. The treating physician prescribed a retrospective request for Savella 100 mg Qty 60 and Hydroxyzine 25 mg Qty 90 (prescribed on 4/3/15).

IMR ISSUES, DECISIONS AND RATIONALES

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

Savella 100 mg Qty 60 (retrospective prescribed 4/3/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Milnacipran (Ixel) Page(s): 62-63.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Milnacipran Page(s): 62. Decision based on Non-MTUS Citation ODG - Mental & Stress-Antidepressants for treatment of MDD (major depressive disorder).

Decision rationale: MTUS states "Milnacipran (Ixel(R)) Not Recommended as it is not FDA approved and not available in the US at this time. Under study as a treatment for fibromyalgia syndrome. An FDA Phase III study demonstrated "significant therapeutic effects" of milnacipran for treatment of fibromyalgia syndrome. Milnacipran ([REDACTED]) has been approved for the treatment of depression outside of the U.S. and is in a new class of antidepressants known as Norepinephrine Serotonin Reuptake Inhibitors (or NSRIs). What makes Milnacipran different from the Selective Serotonin Reuptake Inhibitors (SSRIs) - drugs like Prozac(R) - and Selective Norepinephrine Reuptake Inhibitors (SNRIs) - drugs like Effexor(R) - is that Milnacipran affects two neurotransmitters, norepinephrine and serotonin. (Rooks, 2007) ODG states "Milnacipran, one of the pioneer SNRIs, was designed from theoretic considerations to be more effective than SSRIs and better tolerated than TCAs, and with a simple pharmacokinetic profile. Milnacipran has the most balanced potency ratio for reuptake inhibition of the two neurotransmitters compared with other SNRIs (1:1.6 for milnacipran, 1:10 for duloxetine, and 1:30 for venlafaxine), and in some studies milnacipran has been shown to inhibit norepinephrine uptake with greater potency than serotonin (2.2:1). Clinical studies have shown that milnacipran has efficacy comparable with the TCAs and is superior to SSRIs in severe depression. In addition, milnacipran is well tolerated, with a low potential for pharmacokinetic drug-drug interactions. Milnacipran is a first-line therapy suitable for most depressed patients. It is frequently successful when other treatments fail for reasons of efficacy or tolerability. (Kasper, 2010) Note: In the US the FDA has approved milnacipran (Savella) for fibromyalgia, but not for depression. (FDA, 2009)" The injured worker suffers from chronic pain secondary to rupture of radial collateral ligament of right thumb, traumatic degenerative arthritis of carpometacarpal joint of thumb, unspecified disorder of autonomic nervous system and pain in upper limbs. According to the guidelines quoted above, Savella is not FDA approved in U.S for treatment of depression. The only FDA approval it has at this time is for Fibromyalgia. The injured worker has been prescribed Savella for treatment of depression and chronic pain. He has not been diagnosed with fibromyalgia. The request for Savella 100 mg Qty 60 (retrospective prescribed 4/3/15) is not medically necessary.

Hydroxyzine 25 mg Qty 90 (retrospective prescribed 4/3/15): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation URL [www.ncbi.nlm.nih.gov/pubmed/2188436].

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

Decision rationale: FDA states that Atarax is indicated for symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested. The effectiveness of hydroxyzine as an anti anxiety agent for long term use, that is more than 4 months, has not been assessed by systematic clinical studies. The physician should reassess periodically the usefulness of the drug for the individual patient. The injured worker has been on several psychotropic medications including Klonopin, Wellbutrin, Effexor, Remeron, Savella. There is no evidence of objective functional improvement with the hydroxyzine. The guidelines state that the physician should reassess periodically the usefulness of the drug for the individual patient. Thus the request for Hydroxyzine 25 mg Qty 90 (retrospective prescribed 4/3/15) is not medically necessary.