

Case Number:	CM15-0090546		
Date Assigned:	05/14/2015	Date of Injury:	02/17/2012
Decision Date:	06/17/2015	UR Denial Date:	05/06/2015
Priority:	Standard	Application Received:	05/11/2015

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: Texas, New York, California
 Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 applicant is a represented 54-year-old who has filed a claim for chronic pain syndrome, fibromyalgia, and restless leg syndrome reportedly associated with an industrial injury of February 17, 2012. In a Utilization Review report dated May 6, 2015, the claims administrator failed to approve requests for Savella and modafinil. An RFA form received on April 23, 2015 was referenced in the determination. The claims administrator contended that the attending provider had failed to submit a progress note along with the RFA form and went on to deny the request on those grounds. The applicant's attorney subsequently appealed. In an undated RFA form apparently received on April 17, 2015, modafinil was sought for alleged chronic fatigue syndrome while a year supply of Savella was endorsed for fibromyalgia (FM). No clinical progress notes were seemingly attached to the RFA form. On November 7, 2014, a medical-legal evaluator declared the applicant permanent and stationary. The applicant was not working, the medical-legal evaluator reported, owing to issues with fibromyalgia. The applicant had been off work, on total temporary disability, between the dates of injury through November 7, 2014, the medical-legal evaluator reported. The applicant had developed various issues with chronic pain syndrome, fatigue, malaise, migraine headaches, and derivative issues of psychological stress. The applicant's medications included Levoxyl, Ambien, Lyrica, Savella, Provigil, Vicodin, Lipitor, Motrin, ropinirole, tizanidine, and Xifaxan. The applicant stated that walking, balancing, negotiating stairs remained problematic. The applicant had difficulty walking even to grocery store, it was suggested. Severe fatigue was preventing the applicant from driving, it was reported.

IMR ISSUES, DECISIONS AND RATIONALES

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

Savella 100mg #60 with 9 refills: 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 Functional Restoration Approach to Chronic Pain Management Page(s): 7. Decision based on Non-MTUS Citation Food and Drug Administration.

Decision rationale: The request for Savella, a SNRI medication, was not medically necessary, medically appropriate, or indicated here. While the Food and Drug Administration (FDA) does acknowledge that Savella is indicated in the treatment of fibromyalgia, i.e., the primary operating diagnosis here, this recommendation is, however, qualified by commentary made on page 7 of the MTUS Chronic Pain Medical Treatment Guidelines to the effect that an attending provider should incorporate some discussion of "efficacy of medication" into his choice of recommendations. Here, however, no clinical progress notes were attached to the handwritten RFA form received on April 17, 2015. It did not appear; however, that Savella had been particularly beneficial here, based on the historical notes on file. The applicant was off work, on total temporary disability, a medical-legal evaluator noted on November 7, 2014. The applicant was having difficulty performing activities of daily living as basic as grocery shopping, sitting, standing, walking, balancing, negotiating stairs, writing, typing, and the like, it was noted. The applicant was also apparently having difficulty dressing her at times. Ongoing usage of Savella seemingly failed to curtail the applicant's dependence on numerous other analgesic medications, including Vicodin, Motrin, and tizanidine, all of which the applicant was reportedly using on November 7, 2014. All of the foregoing, taken together, suggested a lack of functional improvement as defined in MTUS 9792.20e, despite ongoing usage of Savella. Therefore, the request was not medically necessary.

Modafinil 200mg #30 for 1 year: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Modafinil (Provigil).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Approach to Chronic Pain Management Page(s): 7-8. Decision based on Non-MTUS Citation NDA 20-717 PROVIGIL® (modafinil) Tablets FDA Approved Labeling dated August 17, 2007 PROVIGIL® (modafinil) Tablets [C-IV] The effectiveness of PROVIGIL in reducing excessive sleepiness has been established in the following sleep disorders:

narcolepsy, obstructive sleep apnea/hypopnea syndrome (OSAHS), and shift work sleep disorder (SWSD).

Decision rationale: Similarly, the request for modafinil was likewise not medically necessary, medically appropriate, or indicated here. As noted on pages 7 and 8 of the MTUS Chronic Pain Medical Treatment Guidelines, an attending provider using a drug for non-FDA labeled purposes has the responsibility to be well informed regarding usage of the same and should, furthermore, furnish compelling evidence to support such usage. While the Food and Drug Administration (FDA) notes that Provigil (modafinil) is indicated in the treatment of excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and/or shift-work disorder, here, however, there is no evidence that the applicant carry any such diagnosis. No clinical progress notes were attached to the RFA form received on April 17, 2015. A November 7, 2014 Medical-legal Evaluation made no mention of the applicant is having issues with either obstructive sleep apnea or narcolepsy. The applicant was off work, it was reported on that date, making any kind of shift-work disorder extremely unlikely. Ongoing usage of modafinil (Provigil), thus, amounted to usage of modafinil for what appeared to be a non-FDA labeled purpose, without any seeming discussion of medication efficacy present on the handwritten RFA form at issue. Therefore, the request was not medically necessary.