

Case Number:	CM14-0126672		
Date Assigned:	08/27/2014	Date of Injury:	06/07/2013
Decision Date:	09/29/2014	UR Denial Date:	07/15/2014
Priority:	Standard	Application Received:	08/11/2014

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 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:

According to the records made available for review, this is a 38-year-old female with a 6/7/13 date of injury. At the time (7/15/14) of request for authorization for Gabadone #60 duration for two months and Trepadone #120 duration for two months, there is documentation of subjective (low back pain radiating down the left leg to the calf, pain rated 7/10 without medications and 5/10 with medications) and objective (blood pressure 120/70, pulse 52, BMI 32.8) findings, current diagnoses (lumbar radiculopathy, left sacroiliac dysfunction, myofascial syndrome, left sciatica, chronic pain related insomnia, and neuropathic pain), and treatment to date (medications including ongoing use of trepadone and gabadone). Regarding the requested Gabadone #60 duration for two months, there is no documentation of metabolic processes of sleep disorders associated with anxiety, and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Gabadone use to date. Regarding the requested Trepadone #120 duration for two months, there is no documentation of altered metabolic processes associated with pain and inflammation related to joint disorder, and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Trepadone use to date.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabadone #60 duration for two months: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Medical Food [and http://www.ptlcentral.com/medical-foods-products.php](http://www.ptlcentral.com/medical-foods-products.php).

Decision rationale: An online source identifies Gabadone as a Medical Food, consisting of a proprietary formulation of amino acids and polyphenol ingredients in specific proportions, for the nutritional management of the altered metabolic processes of sleep disorders associated with anxiety. MTUS does not address the issue. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. ODG identifies that the product must be a food for oral or tube feeding; must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and must be used under medical supervision; as criteria to support the medical necessity of medial food. Within the medical information available for review, there is documentation of diagnoses of lumbar radiculopathy, left sacroiliac dysfunction, myofascial syndrome, left sciatica, chronic pain related insomnia, and neuropathic pain. However, there is no documentation of metabolic processes of sleep disorders associated with anxiety. In addition, given medical records reflecting ongoing use of Gabadone, and despite documentation of decreased pain with medications from 7/10 to 5/10, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Gabadone use to date. Therefore, based on guidelines and a review of the evidence, the request for Gabadone #60 duration for two months is not medically necessary.

Trepadone #120 duration for two months: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.ptlcentral.com/medical-foods-products.php> Official Disability Guidelines (ODG) Pain, Medical Food.

Decision rationale: An online source identifies Trepadone as a Medical Food, consisting of a proprietary formulation of amino acids and polyphenol ingredients in specific proportions, for the dietary management of the altered metabolic processes associated with pain and inflammation related to joint disorder. MTUS does not address the issue. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. ODG identifies that the product must be a food for oral or tube feeding; must be labeled for dietary management of a specific

medical disorder, disease, or condition for which there are distinctive nutritional requirements; and must be used under medical supervision; as criteria to support the medical necessity of medical food. Within the medical information available for review, there is documentation of diagnoses of lumbar radiculopathy, left sacroiliac dysfunction, myofascial syndrome, left sciatica, chronic pain related insomnia, and neuropathic pain. However, there is no documentation of altered metabolic processes associated with pain and inflammation related to joint disorder. In addition, given medical records reflecting ongoing use of Trepadone, and despite documentation of decreased pain with medications from 7/10 to 5/10, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Trepadone use to date. Therefore, based on guidelines and a review of the evidence, the request for Trepadone #120 duration for two months is not medically necessary.