

<b>Case Number:</b>	CM15-0111423		
<b>Date Assigned:</b>	06/17/2015	<b>Date of Injury:</b>	02/25/2011
<b>Decision Date:</b>	07/16/2015	<b>UR Denial Date:</b>	06/04/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/09/2015

### 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: Maryland

Certification(s)/Specialty: Physical Medicine & Rehabilitation, Neuromuscular 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 injured worker is a 44-year-old female, who sustained an industrial injury on 2/25/2011. The mechanism of injury is a trip and fall injury. The injured worker was diagnosed as having lumbar sprain/strain with lumbar radiculopathy. There is no record of a recent diagnostic study. Treatment to date has included therapy and medication management. In a progress note dated 5/7/2015, the injured worker complains of low back pain radiating to the left lower extremity with numbness and tingling of the left leg rated 4/10. Physical examination showed decreased lumbar range of motion. The treating physician is requesting Gabadone #60 and Trepadone #90.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Gabadone #60:** 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) 11th edition, Web Pain Chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain-GABADone ½ and Other Medical Treatment Guidelines Updated ACOEM Guidelines, Pain section; Complementary, alternative treatments, or dietary supplements, etc., page 135.

**Decision rationale:** Gabadone #60 is not medically necessary per ODG and the updated ACOEM guidelines. The ACOEM guidelines state that complementary and alternative treatments, or dietary supplements, etc., are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The ODG states that Gabadone is not recommended. The ODG states that "GABAdone" is a medical food that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. It is noted that there is no peer-reviewed research in humans to support the use of choline or glutamic acid for treatment of either anxiety or sleep disorder. There is inconclusive evidence for the use of 5-hydroxy tryptophan as a treatment for anxiety. GABA does not cross the blood-brain barrier so this supplement will not replace drugs that work in the brain by a GABA-related mechanism. There is no quality evidence to support use in anxiety. The documentation does not indicate extenuating circumstances which would necessitate going against guideline recommendations and using this product. The request for Gabadone is not medically necessary.

**Trepadone #90:** 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) 11th edition, Web Pain Chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain-Trepadone and Other Medical Treatment Guidelines Updated ACOEM Guidelines, Pain section; Complementary, alternative treatments, or dietary supplements, etc., page 135.

**Decision rationale:** Trepadone #90 is not medically necessary per the ODG Guidelines and the updated ACOEM guidelines. The updated ACOEM states that complementary and alternative treatments, or dietary supplements, etc., are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The ODG states that Trepadone is not recommended. Trepadone is a medical food that is suggested for use in the management of joint disorders associated with pain and inflammation. It is a proprietary blend of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, L-serine, gamma-aminobutyric acid, grape seed extract, cinnamon bark, cocoa, omega-3 fatty acids, histidine, whey protein hydrolysate, glucosamine, chondroitin and cocoa. The ODG states that for 5-hydroxytryptophan, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine and GABA all indicate there is no role for these supplements as treatment for chronic pain and that there is insufficient evidence to support use for osteoarthritis or for neuropathic pain. The documentation does not indicate a dietary deficiency or extenuating circumstances which would necessitate going against guideline recommendations and using this product. The request for Trepadone is not medically necessary.

