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| Case Number: | CM14-0204943 | | |
| Date Assigned: | 12/17/2014 | Date of Injury: | 08/22/1997 |
| Decision Date: | 02/04/2015 | UR Denial Date: | 11/07/2014 |
| Priority: | Standard | Application Received: | 12/08/2014 |

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 Emergency 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:

Patient with reported date of injury on 8/22/1997. Mechanism of injury is described as a lifting injury to back. Patient has a diagnosis of lumbar radiculitis, sciatica, myofascial pain syndrome and chronic pain syndrome. Medical reports reviewed. Last report available until 10/21/14. Patient complains of low back pain radiating to posterior legs to feet. Pain reportedly getting worst. Pain is 6/10. Objective exam reveals decreased lumbar range of motion. Pain on palpation especially L4 spinous process. Multiple trigger points. straight leg raise positive on R side. Decrease muscle strength in quadriceps, hamstrings and calf on R side. Was taking oral dilaudid with no improvement and plan was to start Butrans patch. MRI of lumbar spine(9/26/14) reported disc desiccation at L4-5, fracture of pars interarticularis of L4, L4-5 and L5-S1 with diffuse disc protrusion with effacement of thecal sac, spondylolisthesis, neural foraminal stenosis and encroachment of nerve roots. Current medications include ibuprofen and Norco. Was reportedly on Methadone but ran out. Patient has reportedly undergone epidural steroid injection with minimal improvement, physical therapy, chiropractic and TENS with no improvement. Independent Medical Review is for "Percura" #120, "Trepadone" #120, "Theramine" #120, "Gabadone" #120 and "B12" 2cc. Prior Utilization Review on 11/7/14 recommended non-certification. It approved Nucynta, Norco and Toradol.

IMR ISSUES, DECISIONS AND RATIONALES

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

Percura 2 p.o. b.i.d #120: 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)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Percura.

Decision rationale: Percura is a "medical food" from [REDACTED]. It is a blend of amino acids and other ingredients that the manufacturer claims will aid in pain and inflammation. It is not recommended with little to no evidence to support these claims by the manufacturer. It is marketed as a medical food/non-medicinal supplement. Similar to many of these "medical food" products, it makes multiple vague claims so as not to require FDA trials. There are no supporting good quality studies on the efficacy of this product. The studies often quoted are poorly designed studies. The provider has also decided to prescribe multiple non-medicinal compounds along with real medications with no documentation or awareness to review potential side effects or drug interactions between these non-FDA approved substances. Patient has no documented nutritional deficiency causing pain. A "medical food" is not indicated since there is no nutritional deficiency or documented nutritional special requirements. Percura is a non-evidenced based non-medicinal substance with unknown efficacy or safety profile and is not medically necessary.

Trepadone 2 p.o. b.i.d #120: 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)

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.

Decision rationale: Trepadone is a "medical food" from [REDACTED]. It is a blend of amino acids and other ingredients that the manufacturer claims will aid in pain and inflammation. It is not recommended with little to no evidence to support these claims by the manufacturer. It is marketed as a medical food/non-medicinal supplement. Similar to many of these "medical food" products, it makes multiple vague claims so as not to require FDA trials. There are no supporting good quality studies on the efficacy of this product. The studies often quoted are poorly designed studies. The provider has also decided to prescribe multiple non-medicinal compounds along with real medications with no documentation or awareness to review potential side effects or drug interactions between these non-FDA approved substances. Patient has no documented nutritional deficiency causing pain. A "medical food" is not indicated since there is no nutritional deficiency or documented nutritional special requirements. Trepadone is a non-evidence based non-medicinal substance with unknown efficacy or safety profile and is not medically necessary.

Theramine 2 p.o. b.i.d #120: 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)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter Medical Food.

Decision rationale: Theramine is a brand name product, being sold by [REDACTED], containing multiple non-prescription generic substances including "amino acids and polyphenol ingredients" claimed by its manufacturer to aid in various "inflammatory conditions" and pains. It is marketed as a medical food/non-medicinal supplement. Similar to many of these "medical food" products, it makes multiple vague claims so as not to require FDA trials. There are no supporting good quality studies on the efficacy of this product. The studies often quoted are poorly designed studies. There are no corresponding sections in ACOEM or MTUS concerning these substances. The ODG indicates medical food is defined as "a food which is formulated to be consumed or internally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles are established by medical evaluation." ODG reviewed each individual component in Theramine and found no evidence to support its use and does not recommend the use of Theramine. Patient has no documented nutritional deficiency causing pain. A "medical food" is not indicated since there is no nutritional deficiency or documented nutritional special requirements. Theramine is an unevidenced non-medicinal substance with unknown efficacy or safety profile and is not medically necessary.

Gabadone 2 p.o. q hs #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)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter Medical Food.

Decision rationale: Gabadone is a brand name product, being sold by [REDACTED], containing multiple non-prescription generic substances including "amino acids and polyphenol ingredients" claimed by its manufacturer to aid in various "sleep conditions" and anxiety. There is only marketing information available online. It is marketed as a medical food/non-medicinal supplement. Similar to many of these "medical food" products, it makes multiple vague claims so as not to require FDA trials. There are no supporting good quality studies on the efficacy of this product. The studies often quoted are poorly designed studies. There are no corresponding sections in ACOEM or MTUS concerning these substances. The ODG indicates medical food is defined as "a food which is formulated to be consumed or internally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles are established by medical evaluation." Patient has no documented nutritional deficiency causing sleep problems or anxiety. A "medical food" is not indicated since there is no nutritional deficiency or documented nutritional special requirements.

Gabapone is an unevidenced non-medicinal substance with unknown efficacy or safety profile and is not medically necessary.

B12 2 cc's: 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, Vitamin B.

Decision rationale: MTUS Chronic pain and ACOEM Guidelines do have any sections that relate to this topic. As per Official Disability Guidelines; Vitamin B is not recommended for chronic pain. There is limited to poor evidence to support such use for vitamin B. There is no rationale for why patient was given an intramuscular shot of Vitamin B12 as opposed to simple oral tablet. B12 2cc injection is not medically necessary.