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| <b>Case Number:</b>   | CM14-0146901 |                              |            |
| <b>Date Assigned:</b> | 09/15/2014   | <b>Date of Injury:</b>       | 11/06/2009 |
| <b>Decision Date:</b> | 10/15/2014   | <b>UR Denial Date:</b>       | 09/10/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 09/10/2014 |

### 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 Internal 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:

The injured worker is a 67 year old male who reportedly had a work related injury on 11/6/2009. He had an intracerebral hemorrhage that required evacuation surgically and resulted in right hemiparesis. He also has a chronic diagnosis of hypertension. He was seen by his primary treating provider on 8/14/2014. Subjectively, at this visit, he had knee pain, improved hemiparesis, blurred vision which was unchanged, and improvement in knee pain with topical creams. The patient was noted to have chronic diagnoses of hypertension and diabetes. The plan of care included Neurology consultation, Orthopedic consultation, Ophthalmology consultation, topical creams including gabpentin 10%/amitryptiline 10%/dextromethorphan 10%, 210 grams, another cream with coformulated flurbiprofen 20% and tramadol 20% as well as Senatra 60 units. Follow up was requested in four weeks. He was seen by a neurologist on 5/14/2014 and was noted to have dizziness, memory problems, and mild right hemiparesis. The request was for electronystagmogram and neuropsychological testing. In terms of his primary care provider's plan of care, the patient has also been referred to psychiatry for anxiety and depression. He has right knee pain and the concern is for osteoarthritis versus industrial injury. Consultation for an orthopedic specialist was submitted as well.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen 20%/ Tramadol 20% 210 gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** Although non-steroidal anti-inflammatory drug (NSAID) can be used for acute (first two weeks) osteoarthritis and minor sprains / strains, it is notable that efficacy does not last beyond the first two to four weeks. In addition, knee osteoarthritis is likely to not benefit from topical NSAID since the source of pain is deep within the knee while topical agents work superficially only. Further, topical agents are not the first line treatment of osteoarthritis. Finally, the physician has not documented a physical examination or imaging with X-rays to support the diagnosis of internal knee derangement or knee osteoarthritis. Such findings include provocative maneuvers (e.g. McMurray's test, Anterior and Posterior drawer test, Lachmann test), Laxity of ligaments laterally by varus and valgus maneuvers, crepitus, patellofemoral tenderness, and motor / vascular examination of the limb. Therefore, the diagnosis of osteoarthritis is not established on a clinical basis. For all these reasons, topical flurbiprofen would not be appropriate in this setting. Further, topical tramadol has no evidence to support its use. The agents that are used topically have minimal evidence of efficacy, other than NSAID and topical lidocaine. Topical analgesics are most useful in the management of neuropathy when first line therapies fail. As such, the request for topical coformulated flurbiprofen AND tramadol is not supported by the guidance cited.

**Gabapentin 10%/Amitriptyline 10 % Dextromethophan 10% 210 gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 113.

**Decision rationale:** Gabapentin is specifically not recommended in topical form (page 113) and if one component of a compounded product is not approved, the entire product is not recommended.

**Sentra AM:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Guidelines Pain (Chronic)

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

**Decision rationale:** Sentra is a combination of amino acids that is purported to be useful for fatigue and cognitive dysfunction. A search on Medline and Pubmed with the key word Sentra

produces no articles pertinent to "Sentra AM" and there is one small clinical trial for a related product called Sentra PM, which improves sleep reportedly. However, the evidence base even for that is minimal. Per ODG and prudent medical practice, the use of medical foods that are not supported by at least moderately robust data (multiple observational studies, or at least one clinical trial or multiple clinical trials) is not medically necessary.