MAXIMUS Federal Services

| Case Number: | CM14-0028262 | | |
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| Date Assigned: | 06/13/2014 | Date of Injury: | 02/19/2008 |
| Decision Date: | 08/22/2014 | UR Denial Date: | 02/25/2014 |
| Priority: | Standard | Application Received: | 02/28/2014 |

## 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 Tennessee. 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 is a 55-year-old female who has submitted a claim for herniated nucleus pulposus of the lumbosacral spine, cervical spine degenerative joint disease, bilateral carpal tunnel syndrome, left lower extremity radiculopathy, chronic pain syndrome, GERD, morbid obesity, and insomnia associated with an industrial injury date of 02/19/2008.Medical records from 2012 to 2014 were reviewed. Patient complained of low back pain radiating to the right lower extremity, graded 8/10 in severity. Patient likewise reported bilateral wrist pain, graded 4/10 in severity. Physical examination of the lumbar spine showed restricted motion and tenderness. Straight leg raise test was positive bilaterally. Sensation was diminished at L4 and L5 dermatomes. Weakness was noted at tibialis anterior and extensor halluces longus bilaterally, graded 4/5. Reflexes were 1+ at both knees and 2+ at both ankles. Left wrist swelling was noted. Finkelstein's test was positive on the right. Treatment to date has included right shoulder surgery in 2009, bilateral carpal tunnel surgery in 2011, use of H-wave unit, lumbar epidural steroid injection, and medications such as Ambien, Cymbalta, Neurontin, Senna, and Flexeril.Utilization review from 02/25/2014 denied the requests for H-wave stimulation device, TENS unit, ketoprofen 20% / 120gm / ketemine 10% gel, 120gm; gabapentin 10%/cyclobenzaprine 10%/capsaicin 0.375% 120 gm; and flurbiprofen 120% gel 120gm. Reasons for denial were not made available.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**H-WAVE STIMULATION DEVICE:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines H-wave Stimulation Page(s): 117-118.

**Decision rationale:** As stated on pages 117-118 of CA MTUS Chronic Pain Medical Treatment Guidelines, H-wave stimulation (HWT) is not recommended as an isolated intervention, but a trial may be considered as a non-invasive conservative option for chronic soft tissue inflammation if used as an adjunct to a program of evidence-based functional restoration. There is no evidence that H-Wave is more effective as an initial treatment when compared to TENS for analgesic effects. In this case, a progress report from 01/29/2014 cited that patient has been on H-wave therapy and provided her with 75% symptomatic relief. It likewise improved her range of motion. However, there was no evidence that patient has failed use of a TENS unit - a guideline criterion because H-wave was not found to be superior over TENS. Moreover, the request failed to specify body part to be treated, duration of intended use, and if the device is for rental or purchase. The request is incomplete; therefore, the request for H-wave stimulation device is not medically necessary.

**TENS UNIT:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS Page(s): 114, 116.

**Decision rationale:** As stated on page 114 of CA MTUS Chronic Pain Medical Treatment Guidelines, TENS units are not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration. In this case, patient has been using a TENS unit since March 2013 and reported beneficial effects from its use. It is unclear why another device is being requested at this time due to insufficient documentation. The request likewise failed to specify body part to be treated, duration of intended use, and if the device is for rental or purchase. The request is incomplete; therefore, the request for a TENS unit is not medically necessary.

**KETOPROFEN 20%, 120GM, KETEMINE 10% GEL, 120GM:** Upheld

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

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

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, ketoprofen is not recommended for topical use as there is a high incidence of photo contact dermatitis. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Ketamine is only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. In this case, the rationale provided for a topical product is to reduce the total amount of oral medications required, minimizing potential side effects. However, the compounded product contains ketoprofen, which is not recommended for topical use. Guidelines state that any compounded product that contains a drug class that is not recommended is not recommended. The medical necessity was not established. Therefore, the request for KETOPROFEN 20%, 120GM, KETAMINE 10% GEL, 120GM is not medically necessary.

**GABAPENTIN 10%/CYCLOBENZAPRINE 10%/CAPSAICIN 0.375% 120 GM:** Upheld

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

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

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Cyclobenzaprine is a skeletal muscle relaxant and there is no evidence for use of any muscle relaxant as a topical product. Gabapentin is not recommended for use as a topical analgesic. CA MTUS Chronic Pain Medical Treatment Guidelines identifies on page 28 that topical Capsaicin is only recommended as an option when there was failure to respond or intolerance to other treatments. Capsaicin in a 0.0375% formulation is not recommended for topical applications. In this case, the rationale provided for a topical product is to reduce the total amount of oral medications required, minimizing potential side effects. However, the compounded product contains cyclobenzaprine, capsaicin 0.0375%, and gabapentin, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class that is not recommended is not recommended. The medical necessity was not established. Therefore, the request for GABAPENTIN 10%/CYCLOBENZAPRINE 10%/CAPSAICIN 0.375% 120 GM is not medically necessary.

**FLURBIPROFEN 120% GEL 120GM:** Upheld

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

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

**Decision rationale:** According to CA MTUS Chronic Pain Medical Treatment Guidelines pages 111-113, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. There is little to no research as for the use of flurbiprofen in

compounded products. I In this case, the rationale provided for a topical product is to reduce the total amount of oral medications required, minimizing potential side effects. However, the compounded product contains cyclobenzaprine, capsaicin 0.0375%, and gabapentin, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class that is not recommended is not recommended. The medical necessity was not established. In this case, the rationale provided for a topical product is to reduce the total amount of oral medications required, minimizing potential side effects. However, Flurbiprofen is not recommended for topical use as stated above. The medical necessity was not established. Therefore, the request for FLURBIPROFEN 120% GEL 120GM is not medically necessary.