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| Case Number: | CM14-0125434 | | |
| Date Assigned: | 08/11/2014 | Date of Injury: | 03/13/2013 |
| Decision Date: | 10/20/2014 | UR Denial Date: | 06/30/2014 |
| Priority: | Standard | Application Received: | 08/07/2014 |

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:

Patient is a 48-year-old male who has a submitted a claim for lumbar radiculopathy, lumbar sprain/strain, sleep disturbance, anxiety, depression, and hypertension associated with an industrial injury date of 3/13/2013. Medical records from 2014 were reviewed. Patient complained of constant severe low back pain, associated with stiffness and weakness. Aggravating factors included lifting 10 pounds, sitting, standing, walking, and bending. Patient also suffered from symptoms of depression, anxiety, and irritability. Physical examination of the lumbar spine showed trigger points, muscle spasm, and painful/restricted range of motion. Sensation was diminished at bilateral lower extremities. Treatment to date has included chiropractic care, aquatic therapy, and medications such as orphenadrine, omeprazole, naproxen, and topical creams. Utilization review from 6/30/2014 denied the Retrospective request for Compounded Gabapentin 10%/Dextromethorphan 10%/Amitriptyline 10% in Mediderm Base, qty 30gm, DOS 05/27/2014, Retrospective request for Compounded Gabapentin 10%/Dextromethorphan 10%/Amitriptyline 10% in Mediderm Base, qty 210gm, DOS 05/27/2014, Retrospective request for Compounded Flurbiprofen 20%/Tramadol 20% in Mediderm Base, qty 30gm, DOS 05/27/2014, and Retrospective request for Compounded Flurbiprofen 20%/Tramadol 20% in Mediderm Base, qty 210gm, DOS 05/27/2014 because of lack of published studies concerning its efficacy and safety.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective request for Compounded Gabapentin 10%/Dextromethorphan 10%/Amitriptyline 10% in Mediderm Base, qty 30gm, DOS 05/27/2014: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin; Salicylate; Topical Analgesics Page(s): 28; 105; 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Section, Topical Salicylates

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. CA MTUS does not support the use of opioid medications and gabapentin in a topical formulation. Dextromethorphan is not addressed in the guidelines. Amitriptyline is a tricyclic antidepressant considered first-line agents, but there is no discussion regarding topical application of this drug. Medi-Derm base contains methyl salicylate 20%, menthol 5%, and capsaicin 0.035%. According to the guideline, topical salicylate is significantly better than placebo in chronic pain. Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. Regarding the capsaicin component, the guideline states there is no current indication that an increase over a 0.025% formulation would provide any further efficacy. Guidelines state that capsaicin in a 0.0375% formulation is not recommended for topical applications. In this case, topical cream is prescribed as adjuvant therapy to oral medications. However, the prescribed medication contains gabapentin, amitriptyline, and capsaicin in 0.035% formulation, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class, which is not recommended, is not recommended. Therefore, the Retrospective request for Compounded Gabapentin 10%/Dextromethorphan 10%/Amitriptyline 10% in Mediderm Base, qty 30gm, DOS 05/27/2014 is not medically necessary.

Retrospective request for Compounded Flurbiprofen 20%/Tramadol 20% in Mediderm Base, qty 210gm, DOS 05/27/2014: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin ; Salicylate ; Topical Analgesics Page(s): 28; 105; 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Section, Topical Salicylates

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. Topical NSAIDs formulation is only supported for diclofenac in the California MTUS. In addition, there is little to no research as for the use of flurbiprofen in compounded products. The topical formulation of tramadol does not show

consistent efficacy. Medi-Derm base contains methyl salicylate 20%, menthol 5%, and capsaicin 0.035%. According to the guideline, topical salicylate is significantly better than placebo in chronic pain. Regarding the Menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. Regarding the capsaicin component, the guideline states there is no current indication that an increase over a 0.025% formulation would provide any further efficacy. Guidelines state that capsaicin in a 0.0375% formulation is not recommended for topical applications. In this case, topical cream is prescribed as adjuvant therapy to oral medications. However, the prescribed medication contains flurbiprofen, tramadol, and capsaicin in 0.035% formulation, which are not recommended for topical use. Guidelines state that any compounded product that contains a drug class, which is not recommended, is not recommended. Therefore, the Retrospective request for Compounded Flurbiprofen 20%/Tramadol 20% in Mediderm Base, qty 210gm, DOS 05/27/2014 is not medically necessary.

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