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| Case Number: | CM15-0045177 | | |
| Date Assigned: | 04/07/2015 | Date of Injury: | 06/21/2001 |
| Decision Date: | 05/05/2015 | UR Denial Date: | 03/02/2015 |
| Priority: | Standard | Application Received: | 03/10/2015 |

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: Pennsylvania
 Certification(s)/Specialty: Internal 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 55 year old female who sustained an industrial injury on June 21, 2001. She reported injury of the low back. The injured worker was diagnosed as having cervical discopathy with disc displacement, lumbar discopathy with disc displacement, and lumbar radiculopathy. Treatment to date has included medications. At a visit on 12/6/14, the injured worker complained of low back pain radiating down the left leg with numbness and tingling, pain over the sacroiliac joint, and spasms of the paraspinal musculature of the low back. The documentation indicates that the injured worker had been using cyclobenzaprine 10%/tramadol 10% cream dispensed on September 29, 2014. Oral fexmid (cyclobenzaprine), nalfon, Prilosec, ultram ER (tramadol), and norco were dispensed and the injured worker was to continue to apply topical creams. Work status was noted as off work. On February 7, 2015, she was seen for continued low back pain with radiation into the left leg, sacroiliac joint pain, and associated numbness and tingling, with spasms of the paraspinal musculature. She indicates having to go to the emergency room for a bleeding issue related to her medications. Examination showed tenderness to palpation over the lumbar paraspinal musculature with decreased range of motion and positive straight leg raising on the left, with tenderness over the left sacroiliac joint with positive Faber and Patrick's maneuver, and normal strength and sensation. The treatment plan included holding all oral medications and continue with compound creams until she was cleared to use oral medications. Flurbiprofen 25%/Menthol 10%/Camphor 3%/Capsaicin 0.0375% cream and Cyclobenzaprine 10%/Tramadol 10% cream were dispensed. Work status remained off work. On 3/2/15, Utilization Review (UR) non-certified requests for Flurbiprofen

25%/Menthol 10%/Camphor 3%/Capsaicin 0.0375% cream 30 grams; Flurbiprofen 25%/Menthol 10%/Camphor 3%/Capsaicin 0.0375% cream 120 grams; Cyclobenzaprine 10%/Tramadol 10% cream 15 grams, and Cyclobenzaprine 10%/Tramadol 10% cream 60 grams. UR cited the MTUS.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retro (DOS 02/07/2015): Flurbiprofen 25%/ Menthol10%/ Camphor 0.0375%/Capsaicin 0.0375% cream 30gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics medications for chronic pain Page(s): 111-113, 60. Decision based on Non-MTUS Citation Uptodate: camphor and menthol: drug information. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. This injured worker has chronic low back pain. There is no documentation of trial and failure of anticonvulsant medication. Per the MTUS, topical nonsteroidal anti-inflammatory medications (NSAIDs) for short term pain relief may be indicated for pain in the extremities caused by osteoarthritis or tendonitis. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder. Topical NSAIDs are not recommended for neuropathic pain. There should be no concurrent use of an oral and topical NSAID. The only FDA approved topical NSAID is voltaren gel (diclofenac). There was no documentation of osteoarthritis or tendonitis. Flurbiprofen is not an FDA approved topical NSAID. The MTUS and ODG are silent with regard to menthol and camphor. They may be used for relief of dry, itchy skin. These agents carry warnings that they may cause serious burns. Capsaicin is recommended as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. It may be used for treatment of osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in high doses. Due to lack of documentation of trial and failure of antidepressants and anticonvulsants, lack of FDA approval of flurbiprofen, and lack of recommendation for multiple components in this compounded product, the request for this compounded topical cream is not medically necessary.

Flurbiprofen 25%, Menthol 10%, Camphor 3%, Capsaicin 0.0375% cream 120gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics medications for chronic pain Page(s): 111-113, 60. Decision based on Non-MTUS Citation Uptodate: camphor and menthol: drug information. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. This injured worker has chronic low back pain. There is no documentation of trial and failure of anticonvulsant medication. Per the MTUS, topical nonsteroidal anti-inflammatory medications (NSAIDs) for short term pain relief may be indicated for pain in the extremities caused by osteoarthritis or tendonitis. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder. Topical NSAIDs are not recommended for neuropathic pain. There should be no concurrent use of an oral and topical NSAID. The only FDA approved topical NSAID is voltaren gel (diclofenac). There was no documentation of osteoarthritis or tendonitis. Flurbiprofen is not an FDA approved topical NSAID. The MTUS and ODG are silent with regard to menthol and camphor. They may be used for relief of dry, itchy skin. These agents carry warnings that they may cause serious burns. Capsaicin is recommended as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. It may be used for treatment of osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in high doses. Due to lack of documentation of trial and failure of antidepressants and anticonvulsants, lack of FDA approval of flurbiprofen, and lack of recommendation for multiple components in this compounded product, the request for this compounded topical cream is not medically necessary.

Retro (DOS 02/07/2015): Cyclobenzaprine 10%, Tramadol 10% cream 15gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics medications for chronic pain Page(s): 111-113, 60.

Decision rationale: Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not

recommended. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. This injured worker has chronic low back pain. There was no documentation of trial and failure of antidepressant and anticonvulsant medication. Cyclobenzaprine is a muscle relaxant. The MTUS notes that there is no evidence for use of muscle relaxants as topical products. Tramadol is a centrally acting synthetic opioid analgesic. The MTUS and ODG do not address tramadol in topical form. This injured worker has been prescribed Cyclobenzaprine 10%/Tramadol 10% cream for four months without documentation of functional improvement. Work status remains off work, the documentation describes continued low back pain, and there was no discussion of activities of daily living. Due to lack of functional improvement and recommendation against one of the components in this compounded topical product, the request for Cyclobenzaprine 10%/Tramadol 10% cream is not medically necessary.

Cyclobenzaprine 10%, Tramadol 10% cream 60gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics medications for chronic pain Page(s): 111-113, 60.

Decision rationale: Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. This injured worker has chronic low back pain. There was no documentation of trial and failure of antidepressant and anticonvulsant medication. Cyclobenzaprine is a muscle relaxant. The MTUS notes that there is no evidence for use of muscle relaxants as topical products. Tramadol is a centrally acting synthetic opioid analgesic. The MTUS and ODG do not address tramadol in topical form. This injured worker has been prescribed Cyclobenzaprine 10%/Tramadol 10% cream for four months without documentation of functional improvement. Work status remains off work, the documentation describes continued low back pain, and there was no discussion of activities of daily living. Due to lack of functional improvement and recommendation against one of the components in this compounded topical product, the request for Cyclobenzaprine 10%/Tramadol 10% cream is not medically necessary.