

Case Number:	CM14-0134171		
Date Assigned:	08/25/2014	Date of Injury:	05/11/2011
Decision Date:	10/23/2014	UR Denial Date:	08/06/2014
Priority:	Standard	Application Received:	08/19/2014

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 Emergency Medicine and is licensed to practice in Florida. 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:

This patient is a 36 year-old with a date of injury of 05/11/11. A progress report associated with the request for services, dated 06/26/14, identified subjective complaints of low back pain. Physical findings were not documented. Diagnoses included (paraphrased) a variety of ICD-9 codes. Treatment had included a home exercise program. A Utilization Review determination was rendered on 08/06/14 recommending non-certification of "Flurbiprofen/Cyclo/Menth Cream 20%/10%/4%: #180mg and Keratek Gel: #4oz".

IMR ISSUES, DECISIONS AND RATIONALES

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

Flurbiprofen/Cyclo/Menth Cream 20%/10%/4%: #180mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 71.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics

Decision rationale: The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are "Largely experimental in use with few randomized

controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Flurbiprofen 20% is an NSAID being used as a topical analgesic. The MTUS Guidelines note that the efficacy of topical NSAIDs in clinical trials has been inconsistent and most studies are small and of short duration. Recommendations primarily relate to osteoarthritis where they have been shown to be superior to placebo during the first two weeks of treatment, but either not afterward, or with diminishing effect over another two-week period. The Guidelines also state that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. They are indicated for relief of osteoarthritis pain in joints that lend themselves to treatment (ankle, elbow, foot, hand, knee, and wrist). In neuropathic pain, they are not recommended as there is no evidence to support their use. The Official Disability Guidelines (ODG) also does not recommend them for widespread musculoskeletal pain. The only FDA approved topical NSAID is Diclofenac. Cyclobenzaprine 10% is a muscle relaxant being used as a topical analgesic. The MTUS Guidelines specifically state that there is no evidence for baclofen or any other muscle relaxant as a topical product. Therefore, there is no necessity for the addition of Cyclobenzaprine in the topical formulation for this patient. The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, in this case, there is no documentation of the failure of conventional therapy, documented functional improvement, or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation.

Keratek Gel: #4oz: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 71.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals; Topical Analgesics, Page(s): 105, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain; Low Back: Topical Analgesics; Salicylate Topicals; Biofreeze Cryotherapy Gel

Decision rationale: Keratek gel is a combination topical consisting of Methyl Salicylate 28% and menthol 16%. The MTUS Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Methyl Salicylate is a non-steroidal anti-inflammatory being used as a topical analgesic. The Chronic Pain Guidelines do recommend topical salicylates as being significantly better than placebo in chronic pain. In osteoarthritis, salicylates are superior to placebo for the first two weeks, with diminishing effect over another two-week period. The Official Disability Guidelines also recommend topical salicylates as an option and note that they are significantly better than placebo in acute and chronic pain. They further note however, that neither salicylates nor capsaicin have shown significant efficacy in the treatment of osteoarthritis. Menthol is a topical form of cooling. The Medical Treatment Utilization Schedule (MTUS) does not specifically address menthol as a topical analgesic. However, at-home applications of local heat or cold to the low back are considered optional. The Official Disability

Guidelines (ODG) state that Biofreeze (menthol) is recommended as an optional form of cryotherapy for acute pain. Studies on acute low back pain showed significant pain reduction after each week of treatment. There is no recommendation related to the use of menthol for chronic pain. In this case, there is documentation of chronic pain not completely responsive to other therapies. The rationale for the non-certification was not specified. It is recommended at least for acute pain and a study found significant pain reduction after each week of treatment. Therefore, there is documented medical necessity for Keratek gel.