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| Case Number: | CM14-0165061 | | |
| Date Assigned: | 10/10/2014 | Date of Injury: | 11/27/2002 |
| Decision Date: | 11/10/2014 | UR Denial Date: | 10/02/2014 |
| Priority: | Standard | Application Received: | 10/07/2014 |

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 Pain Management 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 57 year old female with a date of injury on 11/27/2002. As per 6/23/14 report, she presented with low back pain, as well as left leg numbness and weakness. An exam revealed tightness and tenderness of bilateral lumbosacral paraspinal muscles. On 3/30/10 discogram revealed disc tears at L3-L4 and L4-L5, and 10/10 concordant low back pain at L5-S1. She had posterior lumbar fusion with instrumentation on 08/03/10. She is currently on Norco, Lidoderm, Senokot, Prilosec, Ketoprofen ointment, Ambien, Limbrel, and morphine sulfate immediate release (MSIR) 15mg. She has a long history of methamphetamine use and she went through 3 weeks of a drug rehab program recently but quit and left the program before completion due to a conflict with a staff member. Methadone, Norco, and Lidoderm helped some with pain control. Senokot helped with constipation. Prilosec had been helping with medication-related gastrointestinal (GI) upset. Her back brace continues to help with daily function. Currently she was recommended for topical non-steroidal anti-inflammatory drugs (NSAID)/analgesics for topical control of pain and inflammation. Diagnoses include chronic low back pain, chronic pain syndrome, and lumbosacral radiculopathy. The request for Gabapentin powder, Ketoprofen powder, Lidocaine hydrogen chloride (HCL) powder, Professional Compounding Centers of America (PCCA) Lidoderm base dispensed on 4/30/14 quantity: 120, refills: 3 and Ketoprofen powder, Professional Compounding Centers of America (PCCA) Lidoderm base dispensed on 4/30/14, quantity: 120 refills: 3, was denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabapentin powder, Ketoprofen powder, Lidocaine HCL powder, PCCA Lidoderm base dispensed on 4/30/2014 quantity : 120 refills: 3: 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 Page(s): 111.

Decision rationale: According to the California Medical Treatment Utilization Schedule (MTUS) guidelines, topical analgesics are an option with specific indications, many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents. Ketoprofen is not currently Food and Drug Administration (FDA) approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Absorption of the drug depends on the base it is delivered in. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for injured workers at risk, including those with renal failure. Lidocaine is indicated in localized Neuropathic pain after there has been evidence of a trial of first-line therapy (tri-cyclic or serotoninnorepinephrine reuptake inhibitors [SNRI] anti-depressants or an anti-epileptic [AED] such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the Food and Drug Administration (FDA) for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. The California Medical Treatment Utilization Schedule (MTUS), the Official Disability Guidelines (ODG) states that the only non-steroidal anti-inflammatory drugs (NSAID) that is Food and Drug Administration (FDA) approved for topical application is diclofenac (Voltaren 1% Gel). In this case, there is no evidence of neuropathic pain. Per guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Thus, the request is considered not medically necessary according to guidelines; non-certified.

Ketoprofen powder, PCCA Lipodermbase dispensed on 4/30/2014 quantity : 120 refills: 3: 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 Page(s): 111.

Decision rationale: According to the California Medical Treatment Utilization Schedule (MTUS) guidelines, topical analgesics are an option with specific indications, many agents are compounded as monotherapy or in combination for pain control. There is little to no research to support the use of many of these agents. Ketoprofen is not currently Food and Drug Administration (FDA) approved for a topical application. It has an extremely high incidence of

photo contact dermatitis. Absorption of the drug depends on the base it is delivered in. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for injured workers at risk, including those with renal failure. Lidocaine is indicated in localized Neuropathic pain after there has been evidence of a trial of first-line therapy (tri-cyclic or serotonin-norepinephrine reuptake inhibitors [SNRI] anti-depressants or an anti-epileptic drugs [AED] such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the Food and Drug Administration (FDA) for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. The California Medical Treatment Utilization Schedule (MTUS) the Official Disability Guidelines (ODG) states that the only non-steroid anti-inflammatory drugs (NSAID) that is Food and Drug Administration (FDA) approved for topical application is diclofenac (Voltaren 1% Gel). In this case, there is no evidence of neuropathic pain. Per guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Thus, the request is considered not medically necessary according to guidelines; non-certified.