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| Case Number: | CM13-0047495 | | |
| Date Assigned: | 12/27/2013 | Date of Injury: | 11/03/2008 |
| Decision Date: | 06/15/2015 | UR Denial Date: | 11/01/2013 |
| Priority: | Standard | Application Received: | 11/04/2013 |

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: New York
 Certification(s)/Specialty: Emergency 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 53 year old male who has reported knee pain after an injury on 11/3/2008. He reported left knee pain initially. The injured worker was diagnosed with internal derangement of the knees. He has not worked since 2011 due to a non-industrial illness. Treatment to date has included medications, a brace, a hot/cold device, physical therapy, and a TENS unit. Per the report of 10/24/13, there was ongoing knee pain. Activities of daily living were performed adequately. There was no discussion of the specific results of using any medication, and no discussion of the ingredients in the topical agents. LidoPro, Terocin, diclofenac, and Protonix were appealed. Protonix was stated to be for stomach upset. The other medications were for inflammation and managing symptoms. Per the report of 12/11/2013, there was ongoing knee pain. The injured worker was stated to be unable to take NSAIDs due to renal problems. Flector was prescribed. The injured worker was retired. LidoPro and Terocin were dispensed. The specific results of using any medication were not discussed. On 11/1/13 Utilization Review certified Hyalgan injections and non-certified LidoPro, Terocin, Voltaren, and Protonix. Ca MTUS was cited in support of the decisions.

IMR ISSUES, DECISIONS AND RATIONALES

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

LIDOPRO 4OZ: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

Decision rationale: No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. LidoPro is capsaicin, lidocaine, menthol, and methyl salicylate. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. 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. The Official Disability Guidelines state that "Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm." The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical lidocaine, only in the form of the Lidoderm patch, is indicated for neuropathic pain (which is not present in this case). The MTUS states that the only form of topical lidocaine that is recommended is Lidoderm. The topical lidocaine prescribed in this case is not Lidoderm. Topical anesthetics like the ones dispensed are not indicated per the FDA, are not FDA approved, and place injured workers at an unacceptable risk of seizures, irregular heartbeats and death. Capsaicin has some indications, in the standard formulations readily available without custom compounding. It is not clear what the indication is in this case, as the injured worker does not appear to have the necessary indications per the MTUS. The MTUS also states that capsaicin is only recommended when other treatments have failed. This injured worker has not received adequate trials of other, more conventional treatments. The treating physician did not discuss the failure of other, adequate trials of other treatments. Capsaicin is not medically necessary based on the lack of indications per the MTUS. The topical compounded medication prescribed for this injured worker is not medically necessary based on the MTUS, the Official Disability Guidelines, lack of medical evidence, and lack of FDA approval.

TEROCIN PATCHES #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Analgesics Page(s): 60, 111-113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: December 5, 2006 FDA Alert, FDA Warns Five Firms To Stop Compounding Topical Anesthetic Creams.

Decision rationale: The treating physician has not discussed the ingredients of Terocin and the specific indications for this injured worker. Per the manufacturer, Terocin is Methyl Salicylate 25%, Menthol 10%, Capsaicin 0.025%, Lidocaine 2.5%, Aloe, Borage Oil, Boswellia Serrata, and other inactive ingredients. Per page 60 of the MTUS, medications should be trialed one at a time. Regardless of any specific medication contraindications for this patient, the MTUS recommends against starting 3-7 medications simultaneously. Per the MTUS, any compounded product that contains at least one drug that is not recommended, is not recommended. Boswellia serrata resin and topical lidocaine other than Lidoderm are not recommended per the MTUS. Topical lidocaine in the form of the Lidoderm patch is indicated for neuropathic pain (not present in this case). The MTUS does not recommend topical anesthetics other than Lidoderm for neuropathic pain (a condition not present in this case). Note the FDA warning cited above. Topical lidocaine like that in Terocin is not indicated per the FDA, and places patients at an unacceptable risk of seizures, irregular heartbeats and death. Capsaicin alone in the standard formulation readily available OTC may be indicated for some patients. The indication in this case is unknown, as the patient has not failed adequate trials of other treatments. Capsaicin is also available OTC, and the reason for compounding the formula prescribed is not clear. Terocin is not medically necessary based on lack of specific medical indications, the MTUS, lack of medical evidence, FDA directives, and inappropriate prescribing.

VOLTAREN (DICLOFENAC) 100MG #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-73.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, NSAIDs, specific drug list & adverse effects Page(s): 60, 70.

Decision rationale: Per the MTUS for chronic pain, page 60, medications should be trialed one at a time, and there should be functional improvement with each medication. No reports show any specific benefit, functional or otherwise. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. There is no evidence that the prescribing physician is adequately monitoring for toxicity as recommended by the FDA and MTUS. Diclofenac has a higher cardiovascular risk profile than many other NSAIDs, and should not be the first choice for an NSAID. The treating physician has not provided any indications for using diclofenac rather than other, safer NSAIDs. The treating physician has stated that this injured worker should not be taking NSAIDs due to a renal condition. Diclofenac is not indicated for this reason alone. The MTUS states that NSAIDs for arthritis are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Given the lack of specific benefit there is not a sufficient necessity to continue this NSAID for the long term. This NSAID is not medically necessary based on the MTUS recommendations against chronic use, lack of specific functional and symptomatic benefit, and prescription not in accordance with the MTUS and the FDA warnings.

PROTONIX 20MG #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69.

Decision rationale: There are no medical reports which adequately describe the relevant signs and symptoms of possible gastrointestinal disease. There is no examination of the abdomen. Stomach upset is not a diagnosis and is not a sufficient reason to continue a PPI for the long term. Sufficient indications have not been described and no reports describe the specific, NSAID-related risk factors present in this case, as presented in the MTUS. PPIs are not benign. The MTUS, FDA, and recent medical literature have described a significantly increased risk of hip, wrist, and spine fractures; pneumonia, Clostridium-difficile-associated diarrhea, and hypomagnesemia in patients on proton pump inhibitors. This PPI is not medically necessary based on lack of medical necessity and risk of toxicity.