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| Case Number: | CM14-0053573 | | |
| Date Assigned: | 07/07/2014 | Date of Injury: | 10/23/2001 |
| Decision Date: | 08/28/2014 | UR Denial Date: | 03/26/2014 |
| Priority: | Standard | Application Received: | 04/22/2014 |

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 Occupational 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:

The patient is a 59-year-old male who has submitted a claim for lumbar facet pain and lower extremity neuropathy associated with an industrial injury date of October 23, 2001. Medical records from 2013 through 2014 were reviewed, which showed that the patient complained of low back pain and bilateral leg pain. Physical examination revealed a normal gait and stance and swing phase with no analgic component. Lumbar spine range of motion testing revealed discomfort with extension and rotation. There was tenderness over the left sacroiliac joint noted. Motor strength was 5/5 for bilateral lower extremities. Sensation was decreased in the bilateral feet. Treatment to date has included medications, which include Colace 100mg, Gabapentin 300mg, Lidocaine 5% adhesive patch, Lidocaine 5% cream, Norco 10/325mg, Omeprazole 40mg, Tizanidine 4mg, and Tramadol 50 mg. Utilization review from March 26, 2014 denied the request for Norco 10/325mg 1 tab every 4 to 6 hours as needed, quantity 90, 15 day supply with no refills for weaning purposes and/or submission of supported documents, Tramadol 50 mg 1 every 4-6 hours as needed, quantity 180, 30 day supply, Total MED: 120, Lidoderm patch apply 1-2 patches 12 hours on & 12 hours off, quantity 60, 30 day supply, and Lidocaine Ointment 5% apply twice a day as directed, quantity 100gm, 30 day supply. The request for Tramadol was modified from 180 units to 120 units because there was no evidence given that the patient had failed a trial of first line medications for his pain. Guidelines further state that there are no long-term studies to allow for recommendations for longer than 3 months but the patient has been taking Tramadol since at least 7/2013. Records reviewed did not reflect significant pain reduction and there were no functional benefits noted. Modification was done for weaning purposes. The request for Lidoderm patch was denied because there was no evidence given that the patient had tried and failed first line therapy. In addition, there were no significant functional improvements reported due to the use of Lidoderm patch. The request for Lidocaine Ointment 5% was denied because guidelines state that topical Lidocaine is not recommended for nonneuropathic pain. In addition, there were no functional improvements noted for the patient due to Lidocaine ointment use. The request for Norco was modified from 180

units to 90 units because there was no evidence given that the patient had returned to work and there was no documentation submitted of the patient's improved functioning and pain relief due to the use of Norco. There were no functional benefits noted for the patient which could be objectively measured due to the use of Norco per guideline criteria.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10/325 mg 1 tab every 4 to 6 hours as needed, quantity 90, 15 day supply with no refills for weaning purposes and/or submission of supported documentation: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 78-80. Decision based on Non-MTUS Citation Washington, 2002; Colorado, 2002; Ontario, 2000; VA/DoD, 2003; Maddox-AAPM/APS, 1997; Wisconsin, 2004; Warfield, 2004.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-going Management Page(s): 78-81.

Decision rationale: According to pages 78-81 of the CA MTUS Chronic Pain Medical Treatment Guidelines, ongoing opioid treatment is not supported unless prescribed at the lowest possible dose and unless there is ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. The monitoring of these outcomes over time should affect therapeutic decision and provide a framework for documentation of the clinical use of these controlled drugs. In this case, the patient has been on Norco since at least October 2013. Specific measures of analgesia, objective improvement and functional improvements, such as improvements in activities of daily living were not documented in the recent progress reports. There was also no documentation of adverse effects or aberrant behaviors. No toxicology screenings are available. Additional information is needed as guidelines require clear and concise documentation for ongoing management. Therefore, the request for Norco 10/325 mg 1 tab every 4 to 6 hours as needed, quantity 90, 15 day supply with no refills for weaning purposes and/or submission of supported documentation is not medically necessary.

Tramadol 50 mg 1 every 4-6 hours as needed, quantity 180, 30 day supply, Total MED: 120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol Page(s): 113, 84, and 78-80. Decision based on Non-MTUS Citation Cepeda, 2006; Washington, 2002; Colorado, 2002; Ontario, 2000; VA/DoD, 2003; Maddox-AAPM/APS, 1997; Wisconsin, 2004; Warfield, 2004.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol; Tramadol (Ultram) Page(s): 93-94, 113.

Decision rationale: According to page 93-94 and 113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, Tramadol is a centrally acting synthetic opioid analgesic and is not recommended as a first-line oral analgesic. Tramadol is indicated for moderate to severe pain. In addition, guidelines do not support ongoing opioid treatment unless there is ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. In this case, the patient has been on Tramadol since at least October 2013 however there was no documentation of objective benefits from its use. Furthermore, the records do not clearly reflect continued analgesia, continued functional benefit, and a lack of adverse side effects. Request should document pain level, functional status and objective benefits of medications. Although opiates may be appropriate, additional information would be necessary, as the guidelines require clear and concise documentation for ongoing management. Therefore, the request for Tramadol 50 mg 1 every 4-6 hours as needed, quantity 180, 30 day supply, Total MED: 120 is not medically necessary.

Lidoderm patch apply 1-2 patches 12 hours on & 12 hours off, quantity 60, 30 day supply:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch) Page(s): 56-57.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (Lidocaine Patch) Page(s): 56-57.

Decision rationale: According to pages 56-57 of the CA MTUS Chronic Pain Medical Treatment Guidelines, topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tricyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. However, further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. In this case, the patient has been on Lidoderm patches since at least October 2013. However, records available did not document that he failed a trial of first-line therapy. There is also no documentation of functional benefits derived from the use of Lidoderm patches. Guidelines have not been met. Therefore the request for Lidoderm patch apply 1-2 patches 12 hours on & 12 hours off, quantity 60, 30 day supply is not medically necessary.

Lidocaine Ointment 5% apply twice a day as directed, quantity 100gm, 30 day supply:
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics: Lidocaine Page(s): 111-112. Decision based on Non-MTUS Citation Argoff, 2006; Dworkin, 2007; Khaliq-Chochrane, 2007; Knotkova, 2007; Lexi-Comp, 2008; Scudds, 1995.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, topical, Salicylate topicals, Topical Analgesics Page(s): 28, 105, 111-113.

Decision rationale: According to pages 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate

receptor antagonists, α -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor antagonists). Compounded products have limited published studies concerning its efficacy and safety. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Topical formulations of lidocaine and prilocaine (whether creams, lotions or gels) are not indicated for neuropathic or non-neuropathic pain complaints. Guidelines also state that no other commercially approved topical formulations of Lidocaine, other than Lidocaine dermal patch (Lidoderm), are indicated for neuropathic pain. In this case, the patient has been on Lidocaine ointment since at least October 2013 however the records provided did not document failure or intolerance to first-line oral pain medications, which is what guidelines recommend. The rationale of using a topical cream is to reduce the pain and decrease the need for oral medications however guidelines state that any compounded product that contains at least one drug or drug class that is not recommended is also not recommended. Lidocaine ointment contains lidocaine which is not recommended for topical use. Therefore, the request for Lidocaine Ointment 5% apply twice a day as directed, quantity 100gm, 30 day supply is not medically necessary.