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| Case Number: | CM15-0115716 | | |
| Date Assigned: | 06/23/2015 | Date of Injury: | 05/24/1995 |
| Decision Date: | 09/18/2015 | UR Denial Date: | 05/18/2015 |
| Priority: | Standard | Application Received: | 06/15/2015 |

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: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

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 62-year-old male with an industrial injury dated 05/24/1995. The injured worker's diagnoses include right shoulder pain, status post rotator repair, left medial and lateral epicondylitis -compensatory, left first carpometacarpal joint pain, right carpal tunnel syndrome, right elbow pain and lumbar spine pain, status post laminectomy and discectomy. Treatment consisted of diagnostic studies, prescribed medications, and periodic follow up visits. In a progress note dated 04/23/2015, the injured worker reported low back, right shoulder and right leg pain. Objective findings revealed tenderness in the paraspinous musculature of the thoracic and lumbar with muscle spasm of the lumbar region and decrease lumbar range of motion. The treating physician prescribed 60 Naprosyn 500mg with 3 refills, Tizanidine 4 mg with 3 refills, 60 Lidoderm Patches 5% with 3 refills, 30 Ambien 10mg with 2 refills, Tramadol 50mg with 2 refills now under review.

IMR ISSUES, DECISIONS AND RATIONALES

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

60 Naprosyn 500mg with 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Naproxen, NSAIDs (non-steroidal anti-inflammatory drugs).

Decision rationale: MTUS specifies four recommendations regarding NSAID use: 1) Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. 2) Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. 3) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. 4) Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. The medical documents do not indicate that the patient is being treated for osteoarthritis. Additionally, the treating physician does not document failure of primary (Tylenol) treatment. Progress notes indicate how long the patient has been on naproxen since 2011, which the MTUS guidelines recommend against long-term use. The medical records fail to indicate significant improvement while taking this medication. As such, the request for 60 Naprosyn 500mg with 3 refills is not medically necessary.

90 Tizanidine 4 mg with 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants, Zanaflex Page(s): 63-67.

Decision rationale: Zanaflex is the brand name version of tizanidine, which is a muscle relaxant. MTUS states concerning muscle relaxants "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (VanTulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Homik, 2004) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou, 2004) According to a recent review in American Family Physician, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the

primary drug class of choice for musculoskeletal conditions. (See2, 2008)." MTUS further states, "Tizanidine (Zanaflex, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. (Malanga, 2008) Eight studies have demonstrated efficacy for low back pain. (Chou, 2007) One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. (Malanga, 2002) May also provide benefit as an adjunct treatment for fibromyalgia. (ICSI, 2007)." Refills are not appropriate for Zanaflex due to the need for medical monitoring. As such, the request for 90 Zanaflex 4mg with 3 refills is not medically necessary.

60 Lidoderm Patches 5% with 3 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm patches Page(s): 56-57. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical analgesics and Other Medical Treatment Guidelines UpToDate.com, Lidocaine (topical).

Decision rationale: Chronic Pain Medical Treatment Guidelines state "Lidoderm is the brand name for a lidocaine patch produced by Endo Pharmaceuticals. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. For more information and references, see Topical analgesics." ODG further details, "Criteria for use of Lidoderm patches: (a) Recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology. (b) There should be evidence of a trial of first-line neuropathy medications (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). (c) This medication is not generally recommended for treatment of osteoarthritis or treatment of myofascial pain/trigger points. (d) An attempt to determine a neuropathic component of pain should be made if the plan is to apply this medication to areas of pain that are generally secondary to non-neuropathic mechanisms (such as the knee or isolated axial low back pain). One recognized method of testing is the use of the Neuropathic Pain Scale. (e) The area for treatment should be designated as well as number of planned patches and duration for use (number of hours per day). (f) A Trial of patch treatment is recommended for a short-term period (no more than four weeks). (g) It is generally recommended that no other medication changes be made during the trial period. (h) Outcomes should be reported at the end of the trial including improvements in pain and function, and decrease in the use of other medications. If improvements cannot be determined, the medication should be discontinued. (i) Continued outcomes should be intermittently measured and if improvement does not continue, lidocaine patches should be discontinued." Medical documents provided do not indicate that the use would be for post-herpetic neuralgia. Additionally, treatment notes did not detail other first-line therapy used and what the clinical outcomes resulted. The records fail to document significant improvement while using the patches. As such, the request for 60 Lidoderm Patches 5% with 3 refills is not medically necessary.

30 Ambien 10mg with 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Ambien.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Zolpidem, insomnia treatment.

Decision rationale: The CA MTUS silent regarding this topic. ODG states that zolpidem is a prescription short acting non-benzodiazepine hypnotic, which is approved for short-term treatment of insomnia. In this case, the patient has been taking this medication several months. There has been no discussion of the patient's sleep hygiene or the need for variance from the guidelines, such as "(a) Wake at the same time everyday; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping." Medical documents also do not include results of these first line treatments, if they were used in treatment of the patient's insomnia. ODG additionally states "The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning." Medical documents provided do not detail these components. As such, the request for 30 Ambien 10mg with 2 refills is not medically necessary at this time.

90 Tramadol 50mg with 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Tramadol, Ultram Page(s): 74-96, 113, 123. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram®).

Decision rationale: Ultram is the brand name version of Tramadol, which is classified as central acting synthetic opioids. MTUS states regarding Tramadol, "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." ODG further states, "Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/acetaminophen." "The treating physician did not provide sufficient documentation that the patient has failed a trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of Tramadol prior to the initiation of this medication. There is no evidence of functional improvement while taking this medication. The original utilization review recommended weaning and modified the request, which is appropriate. As such, the request for 90 Tramadol 50mg with 2 refills not medically necessary.