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| Case Number: | CM15-0100357 | | |
| Date Assigned: | 06/02/2015 | Date of Injury: | 03/05/2002 |
| Decision Date: | 07/09/2015 | UR Denial Date: | 05/06/2015 |
| Priority: | Standard | Application Received: | 05/26/2015 |

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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 37 year old male, who sustained an industrial injury on 3/5/02. He reported a back injury. The injured worker was diagnosed as having status post anterior and posterior lumbar fusion for lumbar discogenic pain L5-S1. Treatment to date has included lumbar fusion, lumbar injections, physical therapy, home exercise program, oral medications including Voltaren, Cymbalta and Baclofen and topical Lidoderm patches. Currently, the injured worker complains of low back pain with increased pain in legs, he rates the pain 7/10 without medications, 5-6/10 with medications and 5/10 after injection. He is currently working 2-3 days a week. Physical exam noted tenderness to palpation of lumbar spine with sacroiliac tenderness and limited lumbar range of motion. A request for authorization was submitted for Voltaren, Baclofen, Cymbalta and Lidoderm patches.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lidoderm patch 5%, Qty 30 with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm patches Topical analgesic Page(s): 56-57, 111-113. Decision based on Non-MTUS Citation Official disability guidelines Pain chapter, Lidoderm patch.

Decision rationale: The patient presents on 04/07/15 with lower back pain rated 5-6/10 with medications, 7/10 without medications, which radiates into the bilateral lower extremities (right greater than left). The patient's date of injury is 03/05/02. Patient is status post anterior and posterior lumbar decompression and fusion at L5-S1 levels in March 2011, and status post lumbar ESI at the site of the posterior hardware in July 2014. The request is for LIDODERM PATCH 5%, QTY 30 WITH 2 REFILLS. The RFA is dated 04/29/15. Physical examination dated 04/07/15 reveals moderate tenderness to palpation of the lumbar spine, sacroiliac tenderness bilaterally, and decreased sensation to pinprick on the right in the L4 and L5 dermatomal distributions. Straight leg raise is noted to be negative bilaterally, and the provider also documents absent patellar reflexes, absent Babinski reflexes, and reduced gastrocnemius reflexes bilaterally. The patient is currently prescribed Voltaren, Cymbalta, and Baclofen. Diagnostic imaging was not included, though progress note dated 04/07/15 references X-ray of the lumbar spine dated 02/26/12 showing: "stable fixation anteriorly at L5 to S1 and stable pedicle screws L5 to S1. There are signs of progressive bone growth within the interbody of L5-S1. Patient is currently working. MTUS Chronic Pain Medical Treatment guidelines, page 57 states: "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." Page 112 also states, "Lidocaine indication: neuropathic pain. Recommended for localized peripheral pain." When reading ODG guidelines, it specifies that Lidoderm patches are indicated as a trial if there is "evidence of localized pain that is consistent with a neuropathic etiology." ODG further requires documentation of the area for treatment, trial of a short-term use with outcome documented for pain and function. In regard to the request for Lidoderm patches for this patient's chronic lower back pain, such patches are not indicated for this patient's chief complaint. MTUS guidelines state that Lidocaine patches are appropriate for localized peripheral neuropathic pain. This patient presents with lower back pain which radiates into the bilateral lower extremities, not a localized neuropathic pain amenable to Lidocaine patches. There is no documentation of other complaints for which this medication would be considered appropriate, either. Therefore, the request is not medically necessary.

Cymbalta 30 mg, Qty 30 with 2 refills: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Duloxetine (Cymbalta).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-16.

Decision rationale: The patient presents on 04/07/15 with lower back pain rated 5-6/10 with medications, 7/10 without medications, which radiates into the bilateral lower extremities (right greater than left). The patient's date of injury is 03/05/02. Patient is status post anterior and posterior lumbar decompression and fusion at L5-S1 levels in March 2011, and status post lumbar ESI at the site of the posterior hardware in July 2014. The request is for CYMBALTA

30MG, QTY 30 WITH 2 REFILLS. The RFA is dated 04/29/15. Physical examination dated 04/07/15 reveals moderate tenderness to palpation of the lumbar spine, sacroiliac tenderness bilaterally, and decreased sensation to pinprick on the right in the L4 and L5 dermatomal distributions. Straight leg raise is noted to be negative bilaterally, and the provider also documents absent patellar reflexes, absent Babinski reflexes, and reduced gastrocnemius reflexes bilaterally. The patient is currently prescribed Voltaren, Cymbalta, and Baclofen. Diagnostic imaging was not included, though progress note dated 04/07/15 references X-ray of the lumbar spine dated 02/26/12 showing: "stable fixation anteriorly at L5 to S1 and stable pedicle screws L5 to S1. There are signs of progressive bone growth within the interbody of L5-S1. Patient is currently working. MTUS Chronic Pain Medical Treatment Guidelines, pg 13-16 for Antidepressants for chronic pain states: Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. For Cymbalta specifically, MTUS states it is FDA- approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Used off-label for neuropathic pain and radiculopathy." In regard to the continuation of Cybalta, the request is appropriate. Progress note dated 04/07/15 notes that this patient is able to achieve adequate pain control through the utilization of Cymbalta daily in addition to other prescribed medications. Addressing functionality, this patient has been able to return to work and is currently working as a truck driver and general laborer. Given this patient's lower back pain with a neuropathic component, documented analgesia, and apparent functionality; continuation of this medication is substantiated. The request is medically necessary.

Baclofen 20 mg, Qty 30 with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Baclofen (Lioresal, generic available).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 63-66.

Decision rationale: The patient presents on 04/07/15 with lower back pain rated 5-6/10 with medications, 7/10 without medications, which radiates into the bilateral lower extremities (right greater than left). The patient's date of injury is 03/05/02. Patient is status post anterior and posterior lumbar decompression and fusion at L5-S1 levels in March 2011, and status post lumbar ESI at the site of the posterior hardware in July 2014. The request is for BACLOFEN 20MG, QTY 30 WITH 2 REFILLS. The RFA is dated 04/29/15. Physical examination dated 04/07/15 reveals moderate tenderness to palpation of the lumbar spine, sacroiliac tenderness bilaterally, and decreased sensation to pinprick on the right in the L4 and L5 dermatomal distributions. Straight leg raise is noted to be negative bilaterally, and the provider also documents absent patellar reflexes, absent Babinski reflexes, and reduced gastrocnemius reflexes bilaterally. The patient is currently prescribed Voltaren, Cymbalta, and Baclofen. Diagnostic imaging was not included, though progress note dated 04/07/15 references X-ray of the lumbar spine dated 02/26/12 showing: "stable fixation anteriorly at L5 to S1 and stable pedicle screws L5 to S1. There are signs of progressive bone growth within the interbody of L5-S1. Patient is currently working. Regarding muscle relaxants for pain, MTUS Guidelines page 63 states, "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbation in patients with chronic LBP. 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. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone,

methocarbamol, dantrolene and baclofen." In regard to the continuation of Baclofen for this patient's lower back pain and associate muscle spasms, the requesting provider has exceeded guideline recommendations. Progress notes indicate that this patient has been receiving Baclofen since at least 04/29/14 with noted benefits. However, MTUS guidelines do not support the use of muscle relaxants such as Baclofen long term. The requested 30 tablets with 2 refills in addition to prior use does not imply the intent to limit this medication to short term use. Therefore, the request is not medically necessary.

Voltaren 100 mg Qty 60 with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Diclofenac Sodium (Voltaren, Voltaren-XR) generic available: (Voltaren, diclofenac sodium enteric-coated tablet Package Insert), (Voltaren-XR, diclofenac sodium extended release tablets Package Insert).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines Pain chapter, under Diclofenac sodium (Voltaren®, Voltaren-XR®).

Decision rationale: The patient presents on 04/07/15 with lower back pain rated 5-6/10 with medications, 7/10 without medications, which radiates into the bilateral lower extremities (right greater than left). The patient's date of injury is 03/05/02. Patient is status post anterior and posterior lumbar decompression and fusion at L5-S1 levels in March 2011, and status post lumbar ESI at the site of the posterior hardware in July 2014. The request is for VOLTAREN 100MG QTY 60 WITH 2 REFILLS. The RFA is dated 04/29/15. Physical examination dated 04/07/15 reveals moderate tenderness to palpation of the lumbar spine, sacroiliac tenderness bilaterally, and decreased sensation to pinprick on the right in the L4 and L5 dermatomal distributions. Straight leg raise is noted to be negative bilaterally, and the provider also documents absent patellar reflexes, absent Babinski reflexes, and reduced gastrocnemius reflexes bilaterally. The patient is currently prescribed Voltaren, Cymbalta, and Baclofen. Diagnostic imaging was not included, though progress note dated 04/07/15 references X-ray of the lumbar spine dated 02/26/12 showing: "stable fixation anteriorly at L5 to S1 and stable pedicle screws L5 to S1. There are signs of progressive bone growth within the interbody of L5-S1. Patient is currently working. ODG Pain chapter, under Diclofenac sodium (Voltaren ‚, Voltaren- XR‚) has the following: "Not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients as did rofecoxib (Vioxx), which was taken off the market. According to the authors, this is a significant issue and doctors should avoid diclofenac because it increases the risk by about 40%." It goes onto state that there is substantial increase in stroke. In this case, the provider is requesting a continuation of Voltaren for this patient's chronic lower back pain. This patient has been prescribed Voltaren since at least 04/29/14 with documented benefits. While this patient reports benefits from this medication and exhibits increased functionality, NSAIDs such as Voltaren are not recommended by MTUS as a first line medication owing to significant cardiovascular risks (equivalent to the risks posed by Vioxx, which has itself been withdrawn from the market). No rationale is provided as to why this patient is unable to tolerate other NSAID medications. The requesting provider would be advised to switch this patient to a different NSAID medication for future pain control, as the chronic use of Voltaren cannot be substantiated. Therefore, the request is not medically necessary.