

| | | | |
|-----------------------|--------------|------------------------------|------------|
| Case Number: | CM14-0184847 | | |
| Date Assigned: | 11/12/2014 | Date of Injury: | 05/09/2013 |
| Decision Date: | 12/31/2014 | UR Denial Date: | 10/16/2014 |
| Priority: | Standard | Application Received: | 11/06/2014 |

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 Orthopedic Surgery 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 65 year old female who sustained a work related injury May 9, 2013. Past medical history included diagnoses of hypertension and a thyroid condition unspecified. At an orthopedic evaluation performed June 16, 2014, the treating physician documents an MRI dated 1/10/2014, reveals; L5-S1 right paracentral foraminal 4mm disc protrusion contacting the transversing right S1 nerve root and narrowing the right foramen resulting in contact of the exiting right L5 nerve root with a 10mm fissure associated with the protrusion; L4-L5 mild canal stenosis and narrowing of the lateral recessed of both transversing L5 nerve root. (MRI report is not contained in this case file). The physician documents the diagnosis as lumbosacral sprain/strain with multiple level disc disease however the clinical examination does not show any stenosis. The recommendation is for Naprosyn or Motrin but not both, an exercise program to include walking up to two miles a day with crunches or half sit ups on a regular basis, and a stool supplied for work. Work was modified at that time was to work for an 8 hour day and that the stool be supplied. On initial orthopedic evaluation performed July 14, 2014, the injured worker complains of persistent low back pain with locking and catching that radiates to the left leg with weakness, numbness and tingling. Physical examination reveals; normal posture with loss of lumbar lordosis, forward flexion limited to 60 degrees with fingertips failing to touch toes by 30cm, reversal of lumbar lordosis is full, rising is difficult with pain, lateral bending is 40 degrees bilaterally with pain, extension is 30 degrees with pain, palpation of the lumbar spine is tender without spasm, leg lengths and circumferences are equal bilaterally and supine and active straight leg raising are positive at 60 degrees on the left. X-rays of the lumbar spine 3 views reveals disc herniation of the lumbar spine at the L5-S1 space. (X-ray report is not contained in this case file). Treatment plan is documented as aqua therapy program. Work status is temporary total disability. On re-evaluation October 2, 2014, the treating orthopedic physician documents

the injured worker visited with progressive low back pain with radiation to her legs. Physical examination reveals a well-developed, well-nourished female in moderate distress, with tenderness about her lumbar spine, and a positive leg raise testing. He further documents x-rays of the lumbar spine (undated), three views, loss of lumbar lordosis and clinical and MRI scan (undated) evidence of a disc herniation of the lumbar spine. There are no reports of x-rays or MRI included in this case file. The plan is documented as; request authorization for a spine specialist consultation, and prescriptions for; Orphenadrine/caffeine, Gabapentin/Pyridoxine, Hydrocodone/Ondansetron, Omeprazole/Flurbiprofen/Cyclo/Mentho cream, Keratek Gel, and Diclofenac/Lidocaine and urine toxicology screen. According to utilization review performed October 16, 2014, Orphenadrine/caffeine 50/10mg cap #60 is non-certified as there is no documentation of decreasing the injured workers pain or improving function and is a combination medication and not supported by MTUS guidelines. Gabapentin/Pyridoxine 250/10mg #60 is non-certified as there is no documentation noting objective or imaging findings revealing radiculopathy and is not supported by MTUS guidelines. Omeprazole/Flurbiprofen 10/100mg cap #60 is non-certified as there is no indication of GI upset. It is recommended for short term use without documentation of improved symptoms with its use, it is not supported by MTUS guidelines. Hydrocodone 10/325mg/APAP/ Ondansetron/300/2mg #60 is non-certified as there is no quantified documentation of increase in pain or if this has been taken in the past with functional improvement and not supported by MTUS guidelines. Flurbiprofen/Cyclo/Mentho 20%/10%/14% cream 180gm is non-certified, as any compound product that contains at least one drug or drug class that is not recommended is not recommended per MTUS guidelines. Keratex Gel 4 ounce bottle is non-certified as it's largely experimental and not supported by MTUS guidelines. Diclofenac/Lidocaine 3%/5% 180gm is non-certified as there is no documentation noting the safety and efficacy of this drug and no documentation of failure of oral medications according to MTUS guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Orphenadrine/Caffeine 50/10mg caps #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Page(s): 63-64. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Muscle relaxants (for pain) Title 8, California Code of Regulations

Decision rationale: MTUS Chronic Pain Medical Treatment Guidelines identifies documentation of acute exacerbation of chronic low back pain and used as a second line option for short-term treatment, as criteria necessary to support the medical necessity of muscle relaxant. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. ODG identifies that muscle relaxants are recommended for short-term (less than two weeks) treatment. Within the medical information available for review, there is documentation of a diagnosis of

disc herniation of the lumbar spine. In addition, given ongoing treatment with NSAIDS, there is documentation of Orphenadrine used as a second line agent. However, there is no documentation of acute muscle spasm. In addition, given documentation of ongoing treatment with Orphenadrine/Caffeine, and a request for Orphenadrine/caffeine 50/10mg caps #60, there is no documentation of short-term (less than two weeks) treatment and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Orphenadrine/Caffeine use to date. Therefore, based on guidelines and a review of the evidence, the request for Orphenadrine/Caffeine 50/10mg caps #60 is not medically necessary.

Gabapentin/Pyridoxine 250/10mg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin (Neurontin) Page(s): 18-19. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Vitamin B

Decision rationale: Specifically regarding Gabapentin, MTUS Chronic Pain Medical Treatment Guidelines identifies documentation of neuropathic pain, as criteria necessary to support the medical necessity of Neurontin (gabapentin). Specifically regarding Pyridoxine (Vitamin B), MTUS does not address this issue. ODG identifies that vitamin B is not recommended; that it is frequently used for treating peripheral neuropathy but its efficacy is not clear. Within the medical information available for review, there is documentation of a diagnosis of disc herniation of the lumbar spine. However, the requested Gabapentin/Pyridoxine 250/10mg #60 contains at least one drug (Pyridoxine) that is not recommended. Therefore, based on guidelines and a review of the evidence, the request for 120 capsules of Gabapentin/Pyridoxine 250/10mg #60 is not medically necessary.

Omeprazole/Flurbiprofen 10/100mg cap # 60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (Non-Steroidal Anti-Inflammatory Drugs), GI Symptoms & Cardiovascular Risk Page(s): 68-69. Decision based on Non-MTUS Citation Title 8, California Code of Regulations

Decision rationale: Specifically regarding Flurbiprofen, MTUS Chronic Pain Medical Treatment Guidelines identifies documentation of moderate to severe osteoarthritis pain, acute low back pain, chronic low back pain, or exacerbations of chronic pain, as criteria necessary to support the medical necessity of NSAIDs. Specifically regarding Omeprazole, MTUS Chronic Pain Medical Treatment Guidelines identifies that risk for gastrointestinal event includes age > 65 years; history of peptic ulcer, GI bleeding or perforation; concurrent use of ASA, corticosteroids, and/or an anticoagulant; and/or high dose/multiple NSAID. ODG identifies

documentation of risk for gastrointestinal events and preventing gastric ulcers induced by NSAIDs, as criteria necessary to support the medical necessity of PPIs. In addition, MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Within the medical information available for review, there is documentation of a diagnosis of disc herniation of the lumbar spine. In addition, there is documentation of pain. However, despite documentation of ongoing treatment with NSAID, there is no documentation of risk for gastrointestinal events (high dose/multiple NSAID). In addition, given documentation of ongoing treatment with Flurbiprofen, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Flurbiprofen use to date. Therefore, based on guidelines and a review of the evidence, the request for pharmacy purchase of Omeprazole/Flurbiprofen 10/100mg cap # 60 is not medically necessary.

Hydrocodone 10/325mg/APAP/Ondansetron/300/2mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-80. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Antiemetics (for opioid nausea). Title 8, California Code of Regulations

Decision rationale: Specifically regarding Hydrocodone/APAP, MTUS Chronic Pain Medical Treatment Guidelines necessitate documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is being prescribed; and there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects, as criteria necessary to support the medical necessity of opioids. Specifically regarding Ondansetron, ODG identifies documentation of nausea and vomiting secondary to chemotherapy and radiation treatment, postoperative use, or acute use for gastroenteritis, as criteria necessary to support the medical necessity of Ondansetron (Zofran). MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Within the medical information available for review, there is documentation of a diagnosis of disc herniation of the lumbar spine. However, there is no documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is being prescribed; there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. In addition, there is no documentation of nausea and vomiting secondary to chemotherapy and radiation treatment, postoperative use, or acute use for gastroenteritis. Furthermore, given documentation of ongoing treatment with Hydrocodone/APAP/Ondansetron, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications with Hydrocodone/APAP/Ondansetron use to date.

Therefore, based on guidelines and a review of the evidence, the request for 40 Tablets of Hydrocodone 10/325mg/APAP/Ondansetron/300/2mg #60 is not medically necessary.

Flurbiprofen/ Cyclo/ Mentho 20%/10%/14% cream 180gm: Upheld

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

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

Decision rationale: MTUS Chronic Pain Medical Treatment Guidelines identifies that many agents are compounded as monotherapy or in combination for pain control; that any compounded medications containing ketoprofen, lidocaine (in creams, lotion or gels), capsaicin in a 0.0375% formulation, baclofen and other muscle relaxants, and gabapentin and other antiepilepsy drugs are not recommended for topical applications; and that any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. Within the medical information available for review, there is documentation of a diagnosis of disc herniation of the lumbar spine. However, Flurbiprofen/ Cyclo/ Mentho 20%/10%/14% cream 180gm contains at least one drug class (muscle relaxants (Cyclobenzaprine)) that is not recommended. Therefore, based on guidelines and a review of the evidence, the request for Flurbiprofen/ Cyclo/ Mentho 20%/10%/14% cream 180gm is not medically necessary.

Keratex Gel 4 ounce bottle: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

Decision rationale: Keratex contains menthol and methyl salicylate gel. MTUS Chronic Pain Medical Treatment Guidelines identifies that topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed, as criteria necessary to support the medical necessity of topical analgesics. Within the medical information available for review, there is documentation of a diagnosis of disc herniation of the lumbar spine. In addition, there is documentation of neuropathic pain. However, there is no documentation that trials of antidepressants and anticonvulsants have failed. Therefore, based on guidelines and a review of the evidence, the request for Keratex Gel 4 ounce bottle is not medically necessary.

Diclofenac/Lidocaine 3%, 5% 180gm: Upheld

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

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

Decision rationale: MTUS Chronic Pain Medical Treatment Guidelines identifies that many agents are compounded as monotherapy or in combination for pain control; that any compounded medications containing ketoprofen, lidocaine (in creams, lotion or gels), capsaicin in a 0.0375% formulation, baclofen and other muscle relaxants, and gabapentin and other antiepilepsy drugs are not recommended for topical applications; and that any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. Within the medical information available for review, there is documentation of a diagnosis of disc herniation of the lumbar spine. However, Diclofenac/Lidocaine 3%, 5% 180gm contains at least one drug (Lidocaine) that is not recommended. Therefore, based on guidelines and a review of the evidence, the request for Diclofenac/Lidocaine 3%, 5% 180gm is not medically necessary.