

| | | | |
|-----------------------|--------------|------------------------------|------------|
| Case Number: | CM15-0068824 | | |
| Date Assigned: | 05/21/2015 | Date of Injury: | 01/16/1996 |
| Decision Date: | 06/30/2015 | UR Denial Date: | 03/31/2015 |
| Priority: | Standard | Application Received: | 04/10/2015 |

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 60 year old female with an injury date of 01/16/1996. Her diagnoses included residual costoclavicular compression of brachial plexus, left with presumed extensive scarring, cervicogenic migraine headaches, cardiac arrhythmia with labile hypertension, abdominal pain, rule out compression of Batson's plexus and adjustment reaction of adult life with components of depression, fatigue and weight loss. Prior treatments included medications and radiofrequency ablation of atrial fibrillation on 07/18/2013. She presents on 02/17/2015 with a persistence of stomach upset with persisting abdominal cramping pain. She states a number of imaging studies have been done including ultrasound and CT scans suggesting chronic cholecystitis. She had a gastroenterology appointment on 02/24/2015. She reports feeling ascending numbness in her neck with a sense of pressure in her head. She was treated at the ER for a migraine. She complains of almost daily headaches and sleep disturbance. Associated symptoms included nausea, constipation, and lack of appetite, extreme fatigue and insomnia. Current medications included Norco, Fioricet, Edular, Soma, Ativan, Spironolactone, Inderal, Aspirin, Metoprolol and Uribel. Her physical appearance was cachectic and pale. Her weight was down 7 pounds. There was complete numbness of the entire left arm with external rotation. Exam of the arms showed no sensory deficits to pinprick with hyperesthesia and palms bilaterally. Treatment recommendations were physical therapy with a therapist specifically skilled in thoracic outlet treatment, Petrodolax, Cyrex #2 and Cyrex # 3 array testing, changing Norco to Hysingia ER 30 mg, Edular 10 mg, Ativan 1.0 mg and Fioricet for headache.

IMR ISSUES, DECISIONS AND RATIONALES

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

Physical Therapy, 156 Visits: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical Medicine Page(s): 98-99.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical medicine Page(s): 98-99.

Decision rationale: The patient presents on 02/17/15 with abdominal pain, and headache rated 5/10 with medications, 8/10 with medications. The patient's date of injury is 01/16/96. Patient has no documented surgical history directed at these complaints. The request is for 156 PHYSICAL THERAPY VISITS. The RFA was not provided. Physical examination dated 02/17/15 reveals complete numbness in the entire left arm with external rotation of the shoulder, prominent swelling and fullness in the left supraclavicular region, and wasting of the middle and lower trapezius muscles bilaterally. The patient is currently prescribed Norco, Fioricet, Edluar, Soma, Ativan, Spirolactone, Inderal, Aspirin, Metoprolol, and Uribel. Diagnostic imaging was not included. Patient's current work status is not provided. MTUS pages 98, 99 have the following: "Physical Medicine: recommended as indicated below. Allow for fading of treatment frequency from up to 3 visits per week to 1 or less, plus active self-directed home Physical Medicine." MTUS guidelines pages 98, 99 states that for "Myalgia and myositis, 9-10 visits are recommended over 8 weeks. For Neuralgia, neuritis, and radiculitis, 8-10 visits are recommended." In regard to the request for 156 physical therapy sessions, the provider has exceeded guidelines. There is no indication that this patient has had any physical therapy to date. Progress note dated 02/17/15 states that the provider wishes to have the patient seen by a physical therapist trained in thoracic outlet treatment 2-3 times per week for one year. MTUS guidelines do not support such a lengthy course of physical therapy, and the amount was modified by UR to 10 visits, which is in line with MTUS recommendations. The request for an entire year of physical therapy is excessive and cannot be substantiated. Therefore, the request IS NOT medically necessary.

Hysingla ER (extended release) 30 mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-95. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria For Use of Opioids Page(s): 88-89. Decision based on Non-MTUS Citation Official disability guidelines Pain (Chronic) chapter, Hysingla.

Decision rationale: The patient presents on 02/17/15 with abdominal pain, and headache rated 5/10 with medications, 8/10 with medications. The patient's date of injury is 01/16/96. Patient has no documented surgical history directed at these complaints. The request is for HYSINGLA

ER (EXTENDED RELEASE) 30MG QD HS. The RFA was not provided. Physical examination dated 02/17/15 reveals complete numbness in the entire left arm with external rotation of the shoulder, prominent swelling and fullness in the left supraclavicular region, and wasting of the middle and lower trapezius muscles bilaterally. The patient is currently prescribed Norco, Fioricet, Edluar, Soma, Ativan, Spirolactone, Inderal, Aspirin, Metoprolol, and Uribel. Diagnostic imaging was not included. Patient's current work status is not provided. ODG Guidelines regarding the Pain (Chronic) chapter under Hysingla states the following: "Not recommended for first-line use for treatment of acute or chronic non-malignant pain. Short-acting opioids are recommended prior to use of long-acting opioids. See Opioids, long-acting. The FDA approved the extended-release (ER) single-entity opioid analgesic hydrocodone bitartrate (Hysingla ER, Purdue Pharma) with abuse-deterrent properties. Hysingla ER has properties that are expected to reduce, but not totally prevent, abuse of the drug when chewed and then taken orally, or crushed and snorted or injected. The product is indicated for treatment of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Opioids are not recommended as a first-line treatment for chronic non-malignant pain in ODG. See Opioids for chronic pain. The FDA also approved another extended-release single-entity hydrocodone drug, Zohydro in October 2013." MTUS Guidelines pages 88 and 89 under Criteria For Use of Opioids (Long-Term Users of Opioids): "Pain should be assessed at each visit, and functioning should be measured at 6- month intervals using a numerical scale or validated instrument." MTUS page 78 under Criteria For Use of Opioids - Therapeutic Trial of Opioids, also requires documentation of the 4As - analgesia, ADLs, adverse side effects, and adverse behavior, as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. In regard to the Hysingla ER, the treater has not provided a reason for the request and has failed to document prior opioid efficacy. Progress note dated 02/17/15 states that the provider wishes to replace this patient's Norco prescription with Hysingla if covered by insurance, though does not provide a rationale for doing so. The same progress note does mention pain reduction attributed to medications, though does not provide functional improvements or consistent urine drug screens to date. MTUS requires documentation of analgesia via validated instrument, activity-specific functional improvements, consistent urine drug screens, and a lack of aberrant behavior to continue use of narcotic medications. Owing to a lack of complete 4A's documentation and a stated rationale as to why this patient requires Hysingla as opposed to traditional opiate medications, use of this medication cannot be substantiated. The request IS NOT medically necessary.

Edluar Sublingual 10 mg: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines Pain (Chronic) Chapter, Zolpidem (Ambien).

Decision rationale: The patient presents on 02/17/15 with abdominal pain, and headache rated 5/10 with medications, 8/10 with medications. The patient's date of injury is 01/16/96. Patient has no documented surgical history directed at these complaints. The request is for EDLUAR SUBLINGUAL 10MG PRN Q HS. The RFA was not provided. Physical examination dated 02/17/15 reveals complete numbness in the entire left arm with external rotation of the shoulder, prominent swelling and fullness in the left supraclavicular region, and wasting of the middle and lower trapezius muscles bilaterally. The patient is currently prescribed Norco, Fioricet, Edluar, Soma, Ativan, Spirolactone, Inderal, Aspirin, Metoprolol, and Uribel. Diagnostic imaging was not included. Patient's current work status is not provided. Edluar is the sublingual form of Zolpidem. ODG-TWC, Pain (Chronic) Chapter, Zolpidem (Ambien) Section states: "Zolpidem is a prescription short-acting nonbenzodiazepine hypnotic, which is recommended for short-term (7-10 days) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term." In regard to the request for Edluar (sublingual Zolpidem), the provider has exceeded guideline recommendations. The documentation provided indicates that this patient has been prescribed since at least 08/22/14. Progress note dated 02/17/15 notes that this patient reports some relief in her sleep complaints attributed to Edluar, however she reports that Lorazepam provides better results. Though the exact number of sublingual tablets to be filled by the pharmacy is not specified, the prescription as written implies nightly use of this medication. ODG does not recommend long-term use of nonbenzodiazepine hypnotic medications, generally limiting their use to 10 days duration - this patient has been taking Edluar for at least 6 months. The request as written specifies an excessive duration of therapy and cannot be substantiated. The request IS NOT medically necessary.

Soma Compound (unknown prescription): 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 Topical analgesic Page(s): 111-113.

Decision rationale: The patient presents on 02/17/15 with abdominal pain, and headache rated 5/10 with medications, 8/10 with medications. The patient's date of injury is 01/16/96. Patient has no documented surgical history directed at these complaints. The request is for SOMA COMPOUND (UNKNOWN PRESCRIPTION). The RFA was not provided. Physical examination dated 02/17/15 reveals complete numbness in the entire left arm with external rotation of the shoulder, prominent swelling and fullness in the left supraclavicular region, and wasting of the middle and lower trapezius muscles bilaterally. The patient is currently prescribed Norco, Fioricet, Edluar, Soma, Ativan, Spirolactone, Inderal, Aspirin, Metoprolol, and Uribel. Diagnostic imaging was not included. Patient's current work status is not provided. MTUS page 111 of the chronic pain section states the following regarding topical analgesics:

"Largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug or drug class that is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required." MTUS chronic pain medical treatment guidelines, pages 111-113, for "Topical Analgesics" states: "Any compounded product that contains at least one drug or drug class that is not recommended is not recommended." "There is no evidence for use of any other muscle relaxant as a topical product." In regard to the request for what appears to be a compounded cream containing Soma, topical formulations of muscle relaxants are not supported by guidelines. Per progress note dated 02/17/15 indicates that this patient reports a reduction in pain attributed to the "Soma compound." Regardless of reported efficacy, topical compound creams containing muscle relaxants lack guideline support and are not indicated. Therefore, the request IS NOT medically necessary.