MAXIMUS Federal Services

Case Number:	CM15-0137033		
Date Assigned:	07/27/2015	Date of Injury:	06/07/2005
Decision Date:	09/24/2015	UR Denial Date:	07/03/2015
Priority:	Standard	Application Received:	07/15/2015

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: 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 62 year old male who sustained an industrial injury on 06/07/2005 resulting in injury to the low back after slipping and falling. Treatment provided to date has included: right knee replacement (2006); L4-5 bilateral medial branch block (2014); physical therapy (4); lumbar radiofrequency ablation (04/2015) resulting in increased pain; medications (Voltaren gel, naproxen, and Ultracet); and conservative therapies/care. Diagnostic testing was not available for review or discussed in the progress notes. There were no noted comorbidities or other dates of injury noted. On 05/14/2015, physician progress report (PR) noted complaints of low back and left leg pain. The pain was rated 7/10 in severity, and was described as constant, sharp, throbbing, and numbness and tingling. Current medications include Hysingla ER which was reported to not be controlling the pain, Norco, gabapentin, and Anaprox. The PRs for the last 6 months have consistently showed a pain severity level of 7/10 without improvement or changes. The physical exam revealed full active flexion of the lumbar spine with extension to 20° with pain coming from the forward flexion upright position, and increased pain with extension. Lumbar facet stress test is positive with the left more so than the right. Sensation, motor strength and reflexes in the lower extremities were all normal. The provider noted diagnoses of lumbar facet arthropathy, left lumbar radiculitis, lumbar strain and sprain, right knee status post knee replacement in 2006, and tapering of opioids. The PR indicates that the injured worker was "trailed" on Ultram (taking 4 per day) without pain relief; therefore was changed to Norco. Plan of care includes starting physical therapy, continued to adjust opioid by increasing Hysingla ER to 50mg daily, increase gabapentin to 900mg per day, continued

Anaprox, and follow-up in 4 weeks. The injured worker's work status is unemployed and permanent and stationary. The request for authorization and IMR (independent medical review) includes: Hysingla ER 30mg #30 and Norco 10/325mg #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Hysingla ER 30mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines When to Continue Opioids, Weaning of Medications.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, criteria for use of opioids Page(s): 60, 61, 76-78, 88, 89. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) chapter under Hysingla.

Decision rationale: The 62 year old patient complains of low back pain, rated at 6/10, as per progress report dated 06/17/15. The request is for Hysingla ER 30mg #30. The RFA for this case is dated 06/17/15, and the patient's date of injury is 06/07/05. Diagnoses, as per progress report dated 06/17/15, included lumbar facet arthropathy, left knee lumbar radiculitis, and lumbar sprain and strain. The patient is status post total left knee replacement in 2006. Requested medications included Norco, Hysingla, Tylenol and Gabapentin. The patient is off work, as per the same progress report. MTUS Guidelines pages 88 and 89 states, "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 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. MTUS p77 states, "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." ODG Guidelines, Pain (Chronic) chapter under Hysingla states: 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. In this case, a prescription for Hysingla is first noted in progress report dated 04/15/15. Prior progress reports document the use of Norco. In the 04/15/15 report, the treater states that since the patient is taking "Norco around the clock, we would like to switch him over to Hysingla and this will eliminate Tylenol in his medication and will give him 24-hour coverage." In subsequent report dated 05/14/15, the treater states that Hysingla is not noted to

control his pain. As per progress report dated 06/17/15, the patient is taking Tylenol again along Hysingla. The treater, therefore, reduced the dose and Hysingla and started the patient back on Norco. In progress report dated 07/17/15 (after the UR date), the treater states that the patient did not find Hysingla beneficial, hence it was discontinued and patient went back to the Norco regimen. MTUS requires a clear discussion regarding the impact of Hysingla on 4As, including analgesia, ADLs, adverse side effects, and aberrant behavior, for continued opioid use. Additionally, ODG guidelines do not support the use Hysingla for first-line use. Hence, this request is not medically necessary.

Norco 10/325mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines When to Continue Opioids, Weaning of Medications.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, criteria for use of opioids Page(s): 60, 61, 76-78, 88, 89.

Decision rationale: The 62 year old patient complains of low back pain, rated at 6/10, as per progress report dated 06/17/15. The request is for Norco 10/325mg #60. The RFA for this case is dated 06/17/15, and the patient's date of injury is 06/07/05. Diagnoses, as per progress report dated 06/17/15, included lumbar facet arthropathy, left knee lumbar radiculitis, and lumbar sprain and strain. The patient is status post total left knee replacement in 2006. Requested medications included Norco, Hysingla, Tylenol and Gabapentin. The patient is off work, as per the same progress report. MTUS Guidelines pages 88 and 89 states, "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 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. MTUS p77 states, "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." MTUS p90 states, "Hydrocodone has a recommended maximum dose of 60mg/24hrs." In this case, a prescription for Norco is first noted in progress report dated 08/01/14. As per the report, the patient has used this medication in the past. It is, however, not clear when the opioid regimen was initiated. As per progress report dated 03/09/15, the patient is using Norco without any side effects and he is able to be functional with this medication. CURES report is consistent and the patient has been using Norco conservatively. The patient discontinued Norco for a brief period to trial Hysingla but is now back on Norco. The treater, however, does not use a pain scale to demonstrate a measurable reduction in pain nor does the treater provide specific examples that indicate improvement in function before and after medication. No UDS reports are available for review. MTUS requires a clear discussion regarding the impact of Norco on 4As, including analgesia, ADLs, adverse side effects, and aberrant behavior, for continued opioid use. Hence, the request is not medically necessary.