MAXIMUS Federal Services

Case Number:	CM15-0030812		
Date Assigned:	02/24/2015	Date of Injury:	03/14/2014
Decision Date:	04/07/2015	UR Denial Date:	01/19/2015
Priority:	Standard	Application Received:	02/18/2015

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: Colorado
Certification(s)/Specialty: Family Practice

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 (IW) is a 45 year old male who sustained an industrial injury on 03/14/2014. He has reported injuries to the bilateral shoulders, left hip and right knee, with ongoing bilateral foot and ankle pain as well. Diagnoses include osteoarthritis-other specified sites (Bilateral knee, hip); Tenosynovitis, Bicipital; Osteoarthritis-Unspecified Bilateral Shoulder region. Treatment to date has included medications, physical therapy, a TENS Transcutaneous Electrical Nerve Stimulation) unit, injections, and surgery. A progress note from the treating provider dated12/16/2014 indicates the IW is following up on bilateral shoulder pain and knee pain. He reports increased knee pain of intermittent sharpness or numbness that increases with activity, especially with going up and down stairs, and complains of a new pain in his left foot within the prior week. The knee "pops" with movement. On examination non-weight bearing x-rays of the left knee were done. They showed subchondral sclerosis at the medial and lateral tibial plateau with minimal joint space narrowing. X-rays were non-weight bearing. The treatment plan was for bilateral knee cortisone injections which were done, continuation of modified duty, continuation of medications as taken prior including non-steroidal anti-inflammatories and Omeprazole and Lidopro, and use of a TENS unit. On 01/19/2015 Utilization Review non-certified a Retrospective request for Lidopro 121gm (DOS: 1/13/15). The MTUS Guidelines were cited. On 01/19/2015 Utilization Review non-certified a Retrospective request for Naproxen Sodium 550mg #60 (DOS: 1/13/15). The MTUS Guidelines were cited. On 01/19/2015 Utilization Review non-certified a Retrospective request for Omeprazole 20mg #60 (DOS: 1/13/15. The MTUS Guidelines were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective request for Naproxen Sodium 550mg #60 (DOS: 1/13/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Naproxen (Naprosyn).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 22 and 68.

Decision rationale: Per the MTUS Guidelines, non-steroidal anti-inflammatory drugs are recommended as second line agents for pain, after trial of Acetaminophen, (particularly for those patients at risk for gastrointestinal events, cardiac events, and renal disease), to be taken at the lowest effective dose for shortest period of time. Non-steroidal anti-inflammatory drugs may be first line for moderate to severe pain, based on available evidence, though studies cannot consistently confirm that non-steroidal anti-inflammatory drugs are superior to Acetaminophen. There is no evidence that any of the non-steroidal anti-inflammatory drugs are effective long term for pain relief or functional improvement. There is no consistent evidence that non-steroidal anti-inflammatory drugs are useful for long term management of neuropathic pain. For the patient of concern, the records supplied do not indicate improvement in pain with Non-steroidal anti-inflammatory drug as part of his regimen, with pain ratings consistently 8/10. The records are not entirely clear that patient has already been taking Naproxen sodium. The most recent records, 1/13/2015 and 2/17/2015, continue to list fenoprofen as patient's Non-steroidal anti-inflammatory drug, but then also indicate Naproxen sodium is a medication to be continued. There would be no clinical reason to take 2 non-steroidal anti-inflammatory medications. There is no documentation that patient ever tried Acetaminophen. There is no objective assessment of function and no indication the medications improved patient's function. Given the lack of evidence, per the Guidelines, to support long term use of non-steroidal anti-inflammatory drugs in pain treatment, and the lack of verifiable improvement in function or pain for this patient with non-steroidal anti-inflammatory drug, the request for Naproxen sodium is not medically necessary.

Retrospective request for Omeprazole 20mg #60 (DOS: 1/13/15: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 68.

Decision rationale: Per the MTUS Guidelines, non-steroidal anti-inflammatory drugs are recommended as second line agents for pain, after trial of Acetaminophen, (particularly for those patients at risk for gastrointestinal events, cardiac events, and renal disease), to be taken at the lowest effective dose for shortest period of time. Non-steroidal anti-inflammatory drugs may be

first line for moderate to severe pain, based on available evidence, though studies cannot consistently confirm that non-steroidal anti-inflammatory drugs are superior to Acetaminophen. There is no evidence that any of the non-steroidal anti-inflammatory drugs are effective long term for pain relief or functional improvement. There is no consistent evidence that non-steroidal anti-inflammatory drugs are useful for long term management of neuropathic pain. For the patient of concern, the records supplied do not indicate improvement in pain with Non-steroidal anti-inflammatory drug as part of his regimen, with pain ratings consistently 8/10. The records are not entirely clear that patient has already been taking Naproxen sodium. The most recent records, 1/13/2015 and 2/17/2015, continue to list fenoprofen as patient's Non-steroidal anti-inflammatory drug, but then also indicate Naproxen sodium is a medication to be continued. There would be no clinical reason to take 2 non-steroidal anti-inflammatory medications. There is no documentation that patient ever tried Acetaminophen. There is no objective assessment of function and no indication the medications improved patient's function. Given the lack of evidence, per the Guidelines, to support long term use of non-steroidal anti-inflammatory drugs in pain treatment, and the lack of verifiable improvement in function or pain for this patient with non-steroidal anti-inflammatory drug, the request for Naproxen sodium is not medically necessary.

Retrospective request for Lidopro 121gm (DOS: 1/13/15): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 111-113. Decision based on Non-MTUS Citation www.fda.gov.

Decision rationale: Lidopro cream is comprised of Methyl salicylate 27.5%, capsaicin 0.0325%, menthol 10% and lidocaine hydrochloride.Per the MTUS Guidelines, topical analgesics may be indicated for specific conditions when other therapies have failed. However, the guidelines make it clear that if a drug or drug class in a given topical compound is "not recommended," then the entire compounded topical is not recommended. Per the guidelines, capsaicin topical can only be recommended for those who have failed to respond to or are intolerant of other options for pain relief. Some good randomized studies suggest that capsaicin is useful for osteoarthritis, fibromyalgia and chronic non-specific back pain. However, higher doses of capsaicin (anything over 0.025% based on available studies) are considered experimental and have no studies to support use in the above conditions. It is noted that capsaicin has moderate to poor efficacy, but can work, alone or in compound, for patients whose pain has not been controlled with conventional therapies. Capsaicin produces "highly selective regional anesthesia by causing degeneration of capsaicin-sensitive nociceptive nerve endings, which can produce significant and long lasting increases in nociceptive thresholds." (Maroon, 2006) The above statements, it should be noted, support only the use of 0.025% dose capsaicin. Per the guidelines, Lidocaine, in the formulation of a dermal patch (Lidoderm), is recommended for " localized peripheral pain" (neuropathy) after failure of or contraindication to first line therapy (Tricyclic Antidepressants, SNRI Antidepressants or Anti-epilepsy drugs), and has FDA orphan status for that indication. No other topical formulations of Lidocaine (creams, lotions, gels) are indicated for neuropathic

pain. (Other formulations of Lidocaine can be used as local superficial anesthetics) Lidocaine, in any formulation, is not recommended for non-neuropathic pain due to lack of evidence for its efficacy and safety. Per the records for the patient of concern, there is not documentation of failed trial of first line therapies for pain (Tricyclic Antidepressants, SNRI Antidepressants or Anti-epilepsy drugs), and the requested formulation includes Lidocaine in a cream formulation which is not approved for use in neuropathic pain, or non-neuropathic pain. The Lidopro also contains capsaicin in a percentage (0.0325%) that has no quality evidence to support, so not recommended. The MTUS Guidelines do not address methyl salicylate or menthol topical preparations, which in this case is not relevant as the Lidocaine component and the capsaicin component are considered not recommended, so the entire topical analgesic compound, Lidopro, is not recommended or medically indicated.