

Case Number:	CM15-0030365		
Date Assigned:	02/23/2015	Date of Injury:	03/23/2009
Decision Date:	04/09/2015	UR Denial Date:	01/23/2015
Priority:	Standard	Application Received:	02/19/2015

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 56 year old female, who sustained an industrial injury on 3/23/09. She has reported left shoulder and right wrist pain after slipping and falling on a coffee spill and hitting a garbage container. The diagnoses have included sprain/strain of shoulder and upper arm, rotator cuff syndrome, chronic pain syndrome; Deep Venous Thrombosis (DVT) left upper extremity, anxiety and depression. Treatment to date has included medications, surgery, consultations with specialist, conservative measures, physical therapy and diagnostics. Surgery included status post left shoulder arthroscopy 9/25/13 with persistent left shoulder pain. Currently, the injured worker complains of increasing bilateral shoulder pain, anxiety and depression. She underwent shoulder surgery on 9/25/13 but has developed complications after surgery. She has had Deep Venous Thrombosis (DVT) of the left upper extremity. She is currently undergoing treatment with hematologist and he is currently requesting x-ray and ultrasound of bilateral upper extremities. The physical exam revealed tenderness to palpation to the left shoulder, limited range of motion, and positive Hawkin's test. The pain was rated 3/10 on pain scale. The pain is dull and associated with stiffness, worsens with activity, and improves partially with medication. The Magnetic Resonance Arthrogram of left shoulder dated 11/21/14 revealed mild tendinosis and no findings of tear. The medications included Norco, Butrans patch, Fanapt, Savella and polyethylene glycol. She is awaiting x-ray and ultrasound of the upper extremity. On 1/23/15 Utilization Review non-certified a request for Meds x1 Compound Butrans Patch 15mcg #4, noting the (MTUS) Medical Treatment Utilization Schedule chronic pain guidelines were cited. On 1/23/15 Utilization Review modified a request for Oral Norco

10/325mg #60 modified to Norco 10/325mg #30, Fanapt 6mg #30 modified to Fanapt 6mg #15 and Savella 50mg #60 modified to Savella 50mg #30 for weaning purposes, noting the (MTUS) Medical Treatment Utilization Schedule chronic pain guidelines were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Meds x1 Compound Butrans Patch 15mcg #4: Overturned
Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines
CRITERIA FOR USE OF OPIOIDS, Buprenorphine Page(s): 76-78, 88-89, 27.

Decision rationale: The patient presents with increasing unrated pain to the bilateral shoulders, anxiety, and depression. The patient's date of injury is 03/23/09. Patient is status post unspecified left shoulder surgery on 09/25/13, resulting in a post-operative deep vein thrombosis to the left upper extremity. The request is for MEDS X 1 COMPOUND BUTRANS PATCH 15MCG #4. The RFA is dated 01/15/15. Physical examination dated 01/14/15 reveals tenderness to palpation of the anterior aspect of the left shoulder, decreased range of motion of the left shoulder in all planes, and positive Hawkin's test to the left shoulder. The patient is currently prescribed Norco, Butrans, Fanapt, Savella, and Polyethylene glycol. Diagnostic imaging was not included. Patient's current work status is not provided. 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 4A's (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. Specifically addressing Buprenorphine, MTUS page 27 has the following: "Recommended. When used for treatment of opiate dependence, clinicians must be in compliance with the Drug Addiction Treatment Act of 2000. Buprenorphine's pharmacological and safety profile makes it an attractive treatment for patients addicted to opioids. Buprenorphine's usefulness stems from its unique pharmacological and safety profile, which encourages treatment adherence and reduces the possibilities for both abuse and overdose. Studies have shown that buprenorphine is more effective than placebo and is equally as effective as moderate doses of methadone in opioid maintenance therapy. Few studies have been reported on the efficacy of buprenorphine for completely withdrawing patients from opioids. In general, the results of studies of medically assisted withdrawal using opioids (-e.g., methadone-) have shown poor outcomes. Buprenorphine, however, is known to cause a milder withdrawal syndrome compared to methadone and for this reason may be the better choice if opioid withdrawal therapy is elected." In regards to the request for Butrans patches, the request appears reasonable. Progress reports indicate that this patient has been prescribed Butrans patches since at least 07/03/14. Progress report dated 02/09/15 states: "With her pain medication, she is able to at least do her activities of daily living and her pain is controlled... So far, the patient has been very compliant... She has good analgesia when she is on the Butrans patch... She does not have any side-effects or adverse reactions..." The provided documentation also includes a toxicology report dated

08/26/14 with consistent findings. Given documentation of analgesia, functional improvement, and a lack of adverse effects or aberrant behavior, continuation of this medication is substantiated. The request IS medically necessary.

Meds x4 Oral Norco 10/325mg #60: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CRITERIA FOR USE OF OPIOIDS, Buprenorphine Page(s): 76-78, 88-89, 27.

Decision rationale: The patient presents with increasing unrated pain to the bilateral shoulders, anxiety, and depression. The patient's date of injury is 03/23/09. Patient is status post unspecified left shoulder surgery on 09/25/13, resulting in a post-operative deep vein thrombosis to the left upper extremity. The request is for MEDS X4 ORAL NORCO 10/325MG #60. The RFA is dated 01/15/15. Physical examination dated 01/14/15 reveals tenderness to palpation of the anterior aspect of the left shoulder, decreased range of motion of the left shoulder in all planes, and positive Hawkin's test to the left shoulder. The patient is currently prescribed Norco, Butrans, Fanapt, Savella, and Polyethylene glycol. Diagnostic imaging was not included. Patient's current work status is not provided. 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 4A's (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. Specifically addressing Buprenorphine, MTUS page 27 has the following: "Recommended. When used for treatment of opiate dependence, clinicians must be in compliance with the Drug Addiction Treatment Act of 2000. Buprenorphine's pharmacological and safety profile makes it an attractive treatment for patients addicted to opioids. Buprenorphine's usefulness stems from its unique pharmacological and safety profile, which encourages treatment adherence and reduces the possibilities for both abuse and overdose. Studies have shown that buprenorphine is more effective than placebo and is equally as effective as moderate doses of methadone in opioid maintenance therapy. Few studies have been reported on the efficacy of buprenorphine for completely withdrawing patients from opioids. In general, the results of studies of medically assisted withdrawal using opioids (e.g., methadone) have shown poor outcomes. Buprenorphine, however, is known to cause a milder withdrawal syndrome compared to methadone and for this reason may be the better choice if opioid withdrawal therapy is elected." In regards to the request for Norco, the request appears reasonable. Progress reports indicate that this patient has been prescribed Norco since at least 07/03/14. Progress report dated 02/09/15 implies that this patient utilized Butrans patches and uses the Norco for breakthrough pain - one to two tablets/day. The same report states: "With her pain medication, she is able to at least do her activities of daily living and her pain is controlled... So far, the patient has been very compliant... She does not have any side-effects or adverse reactions..." The provided documentation also includes a toxicology report dated 08/26/14 with consistent findings. Given documentation of analgesia,

functional improvement, and a lack of adverse effects or aberrant behavior, continuation of this medication is substantiated. The request IS medically necessary.

Fanapt 6mg #30: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines, Mental Illness and Stress chapter, under Atypical Antipsychotic Drugs.

Decision rationale: The patient presents with increasing unrated pain to the bilateral shoulders, anxiety, and depression. The patient's date of injury is 03/23/09. Patient is status post unspecified left shoulder surgery on 09/25/13, resulting in a post-operative deep vein thrombosis to the left upper extremity. The request is for FANAPT 6MG #100. The RFA is dated 01/15/15. Physical examination dated 01/14/15 reveals tenderness to palpation of the anterior aspect of the left shoulder, decreased range of motion of the left shoulder in all planes, and positive Hawkin's test to the left shoulder. The patient is currently prescribed Norco, Butrans, Fanapt, Savella, and Polyethylene glycol. Diagnostic imaging was not included. Patient's current work status is not provided. MTUS guidelines do not discuss Fanapt, though ODG Mental Illness and Stress chapter, under Atypical Antipsychotic Drugs - the drug class to which Fanapt belongs - has the following: "Not recommended as a first-line treatment. There is insufficient evidence to recommend atypical antipsychotics for conditions covered in ODG. Adding an atypical antipsychotic to an antidepressant provides limited improvement in depressive symptoms in adults, new research suggests. The meta-analysis also shows that the benefits of antipsychotics in terms of quality of life and improved functioning are small to nonexistent, and there is abundant evidence of potential treatment-related harm. The authors said that it is not certain that these drugs have a favorable benefit-to-risk profile. Clinicians should be very careful in using these medications. The American Psychiatric Association has released a list of specific uses of common antipsychotic medications that are potentially unnecessary and sometimes harmful. Antipsychotic drugs should not be first-line treatment to treat behavioral problems. Antipsychotics should be far down on the list of medications that should be used for insomnia, yet there are many prescribers using quetiapine for instance, as a first line for sleep, and there is no good evidence to support this."In regards to the request for Fanapt - Iloperidone - the medication is not recommended as a first-line treatment for this patient's condition. This medication is an atypical antipsychotic medication, which is apparently prescribed to control this patient's significant anxiety and depression. Progress reports provided indicate that this patient has been taking Fanapt since sometime before 01/02/15, in which the treater prescribes a refill of this patient's prescription. However, the initiating prescription of this medication is not provided, and it does not appear in the previous note dated 10/20/14. It is possible this prescription originates from another physician - as this patient is being seen by a psychiatrist for anxiety and depression - though no progress reports from this provider are included. Owing to a lack of support of this medication for this patient's condition or a rationale as to why it is necessary, continued use cannot be substantiated. The request IS NOT medically necessary.

Savella 50mg #60: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines, Pain chapter, Milnacipran -Savella-.

Decision rationale: The patient presents with increasing unrated pain to the bilateral shoulders, anxiety, and depression. The patient's date of injury is 03/23/09. Patient is status post unspecified left shoulder surgery on 09/25/13, resulting in a post-operative deep vein thrombosis to the left upper extremity. The request is for SAVELLA 50MG #60. The RFA is dated 01/15/15. Physical examination dated 01/14/15 reveals tenderness to palpation of the anterior aspect of the left shoulder, decreased range of motion of the left shoulder in all planes, and positive Hawkin's test to the left shoulder. The patient is currently prescribed Norco, Butrans, Fanapt, Savella, and Polyethylene glycol. Diagnostic imaging was not included. Patient's current work status is not provided. Regarding Milnacipran -Savella, ODG states "FDA has now approved milnacipran for the management of fibromyalgia. As there is little to no evidence that the cause of fibromyalgia is related to industrial injuries, the use of Savella should be restricted to documented cases of fibromyalgia as part of an appropriate treatment plan." In regards to the request for Savella for the management of this patient's chronic pain, the patient's clinical diagnoses do not support the use of this medication. ODG guidelines indicate that Savella is an appropriate medication in those patients who possess a formal diagnosis of fibromyalgia as part of an appropriate treatment plan. This patient suffers from post-surgical pain, neuropathic pain, and chronic pain syndrome, but does not possess a formal diagnosis of fibromyalgia. Therefore, the request IS NOT medically necessary.