

Case Number:	CM14-0161945		
Date Assigned:	10/07/2014	Date of Injury:	01/20/2003
Decision Date:	11/07/2014	UR Denial Date:	09/24/2014
Priority:	Standard	Application Received:	10/02/2014

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 Occupational Medicine 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 claimant was injured on 01/20/03. Butrans patch, Pennsaid, Subsys, and Amrix are under review. On 07/01/14, she was evaluated for headaches, bilateral neck pain, mid thoracic pain, bilateral scapular pain, low back pain, and bilateral arm pain. She was diagnosed with thoracic outlet syndrome and had complex regional pain syndrome. She had received opioid medications as well as therapy but still had swelling of the forearms worse on the left side. She had sharp pain in the occipital area when she turned her head. She was taking Morphine ER, Hydrocodone/APAP, Gabapentin, Docusate, Senna, Magnesium, and Cymbalta. She was status post scalene blocks in 2004 and 2013 but they did not help. She had tried suicide in the past due to pain. She did not sign a pain packet and did not give a urine drug screen at that time. She was to follow-up with another physician. She reported that ice packs to the neck helped as well as Botox injections, biofeedback, and medications but she continued to have significant pain. Acupuncture had aggravated it, biofeedback helped some, and chiropractic made it worse. She had first rib decompression with slight relief. Electrodiagnostic studies in May 2003 showed bilateral ulnar entrapment at the elbow. MRI of the cervical spine on 06/04/03 showed mild central stenosis at C4-5 and C6-7 due to disc bulges. She underwent left thoracic outlet decompression, anterior and medial scalenectomy, left first rib resection, and brachial plexus neurolysis in November 2005 and got significant relief. She has also had stellate ganglion blocks. A functional restoration program was recommended. She was found to be permanent and stationary and was to continue with an independent gym program. She did not want to return to work. She was stable on Morphine ER TID and Norco twice a day. She had decreased range of motion with positive Spurling's bilaterally. Her strength was intact. She was also diagnosed with fibromyalgia. The claimant was prescribed Butrans patch, Norco, and Cymbalta on 09/04/14. On 09/09/14, she had increasing thoracic pain. The thoracic area was not

examined but her neck was. She was to discontinue Lyrica, Gabapentin and Amrix which all caused confusion and depression. She was started on Pennsaid, Butrans patch, Subsys, and Norco, and Cymbalta was started again. On 09/12/14, she reported neck pain radiating to the left upper extremity. She complained of increasing neck pain since 2002. The only alleviating factors were doing nothing and oral pain medications. She had decreased range of motion of the cervical spine with significant point tenderness along the muscles and deep cervical fascia. Extension caused facet pain and she had facet tenderness. Radicular pain was noted in her arms. She was also prescribed a cervical ESI at C5-6. On 10/09/14, she stated that physical activity made her worse and alleviating factors were the same as before. Subsys decreased her pain so she could get out of bed and take care of her basic hygiene. A drug screen was done. She had decreased range of motion of the cervical spine. There was severe spasm and twitching of the muscle bellies and significant tenderness. Motor function was mildly weak. There were no neurologic deficits. She had myofascial pain and spasm with trigger points about the neck and shoulders.

IMR ISSUES, DECISIONS AND RATIONALES

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

Butrans Patch 10mcg/hr. #4 with 5 refills: 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 Butrans

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Buprenorphine Page(s): 57. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Formulary: Butrans.

Decision rationale: The history and documentation do not objectively support the request for Butrans patch 10 mcg/hr. #4 with 5 refills. The MTUS p. 57 state "Buprenorphine may be recommended for treatment of opiate addiction, also recommended as an option for chronic pain, especially after detoxification in patients who have a history of opiate addiction." The ODG formulary states buprenorphine may be "recommended as an option for treatment of chronic pain (consensus based) in selected patients (not first-line for all patients). Suggested populations: (1) Patients with a hyperalgesic component to pain; (2) Patients with centrally mediated pain; (3) Patients with neuropathic pain; (4) Patients at high-risk of non-adherence with standard opioid maintenance; (5) For analgesia in patients who have previously been detoxified from other high-dose opioids. Use for pain with formulations other than Butrans is off-label. Due to complexity of induction and treatment the drug should be reserved for use by clinicians with experience." There is no clear evidence that the claimant has tried and failed all other reasonable first line drugs and the benefit to her of the use of this medication is unclear. There is no evidence that the ODG criteria have been met, in particular, that the claimant has a hyperalgesic component to her pain, centrally mediated pain, neuropathic pain (she describes and has findings of soft tissue/muscular tenderness but no focal neurologic deficits) or is at high risk of non-adherence with standard opioid maintenance which she has used in the past. There is no history of detoxification. She has been prescribed oral medications but the results are not clear, including

side effects and ineffectiveness. The medical necessity of this request for Butrans patch 10 mcg/hr. #4 with 5 refills has not been demonstrated.

Pennsaid 2% 2 Bottles: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 143.

Decision rationale: The history and documentation do not objectively support the request for the topical agent Pennsaid 2%, 2 bottles. The MTUS state "topical agents may be recommended as an option [but are] largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily is recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004)." There is no evidence of failure of all other first line drugs. The claimant was also using multiple other pain medications with no documentation of intolerance or lack of effectiveness. The medical necessity of this request for the topical compound pain medication Pennsaid 2%, 2 bottles has not been clearly demonstrated.

Subsys 400mcg/hr #90: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Formulary - Subsys

Decision rationale: The history and documentation do not objectively support the request for Subsys 400 mcg/hr., #90. The MTUS do not address its use. The ODG state it is "not recommended for musculoskeletal pain. FDA has approved Subsys Fentanyl sublingual spray, from Insys Therapeutics, only for breakthrough cancer pain." There is no evidence of cancer pain and the medical necessity of the use of Subsys 400 mcg/hr. #90, frequency unknown, in this case of chronic musculoskeletal pain has not been demonstrated.

Amrix #15: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-spasmodics Page(s): 98.

Decision rationale: The history and documentation do not objectively support the request for Amrix #15. The MTUS states regarding antispasmodics, "used to decrease muscle spasm in conditions such as LBP although it appears that these medications are often used for the treatment of musculoskeletal conditions whether spasm is present or not. The mechanism of action for most of these agents is not known. (Chou, 2004) Cyclobenzaprine (Flexeril, Amrix, Fexmid, generic available): Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment." Also, "before prescribing any medication for pain, the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication to be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medication should show effects within 1 to 3 days. A record of pain and function with the medication should be recorded. (Mens 2005)" There is no indication of significant spasm for which this type of medication appears to be indicated and the benefit to the claimant, including functional improvement, has not been described. The medical necessity of the use of Amrix #15 has not been clearly demonstrated.