

<b>Case Number:</b>	CM15-0060445		
<b>Date Assigned:</b>	04/17/2015	<b>Date of Injury:</b>	08/16/2002
<b>Decision Date:</b>	07/16/2015	<b>UR Denial Date:</b>	03/21/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/30/2015

### 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: New York

Certification(s)/Specialty: Emergency Medicine

### 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 72 year old male who has reported shoulder pain after an injury on 8/16/02. The diagnoses have included impingement syndrome, status post arthroscopy and decompression bilaterally. Treatment has included two shoulder surgeries, physical therapy, TENS, and medications. Reports from the current primary treating physician from 2012-2015 reflect ongoing shoulder pain treated with diclofenac, Prilosec for "stomach irritation", Ultracet, Dendracin, naproxen, LidoPro, Terocin, and TENS. The blood pressure was significantly elevated at many of the office visits and this was not addressed in the context of the ongoing NSAID prescriptions. At each office visit there was limited shoulder range of motion. Reports refer to non-specific pain relief from unspecified medications. None of the reports adequately address the specific results of using any single medication or the TENS unit. No reports provide evidence of specific functional improvement. The injured worker is stated to be not working and to be limited in daily activities. Physical therapy was prescribed on 5/5/14. The report of 9/22/14 referred to an ulcer diagnosis and bleeding in the stool, for which Dexilant and Pylera had been prescribed. Physical therapy was never attended. On 3/9/15 the ulcer condition was "stabilized" and treated with the same medications. There was shoulder pain with limited range of motion. The treatment plan included physical therapy (no content specified), LidPro, Ultracet, tramadol ER, TENS, fenoprofen and pantoprazole (if approved by the family physician), cyclobenzaprine for pain, a urine drug screen, and fluoroscopy of the shoulder (no indications provided). On 3/21/15 Utilization Review partially certified a physical therapy prescription for 10 visits, and non-certified the remaining items that are appealed for this Independent Medical Review. The

MTUS and the Official Disability Guidelines were cited. Note was made of elevated blood pressure measurements and a diagnosed ulcer while taking NSAIDs. Dexilant had already been prescribed for the ulcer.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **1 TENS 4-lead unit with conductive garment: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS, chronic pain (transcutaneous electrical nerve stimulation).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS, chronic pain Page(s): 114-117.

**Decision rationale:** No physician reports address the specific medical necessity for a TENS unit. The MTUS for Chronic Pain lists the indications for TENS, which are primarily neuropathic pain, a condition not present in this patient. Other recommendations, including specific components of the treatment plan, are listed in the MTUS. The necessary kind of treatment plan is not present, including a focus on functional restoration with a specific trial of TENS alone. A 4-lead unit is not recommended absent specific documentation. Given the lack of clear indications in this injured worker (primary reason), the lack of any clinical trial or treatment plan per the MTUS (secondary reason), and the lack of apparent need for a 4-lead unit with a conductive garment, a TENS unit is not medically necessary.

#### **12 Physical therapy sessions: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Physical medicine. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Shoulder (Acute and Chronic).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Introduction, functional improvement, Physical Medicine Page(s): 9, 98-99.

**Decision rationale:** The treating physician has not provided an adequate prescription, which must contain diagnosis, duration, frequency, and treatment modalities, at minimum. Per the MTUS, Chronic Pain section, functional improvement is the goal rather than the elimination of pain. The maximum recommended quantity of Physical Medicine visits is 10, with progression to home exercise. The treating physician has not stated a purpose for the current physical therapy prescription. It is not clear what is intended to be accomplished with this physical therapy, given that it will not cure the pain and there are no other goals of therapy. This injured worker has had shoulder pain and limited range of motion for years. The current physical therapy prescription exceeds the quantity recommended in the MTUS. No medical reports identify specific functional deficits, or functional expectations for Physical Medicine. The Physical Medicine prescription is not sufficiently specific, and does not adequately focus on functional improvement. Given the completely non-specific prescription for physical therapy in this case, it is presumed that the therapy will use or even rely on passive modalities. Note that the MTUS recommends against therapeutic ultrasound and passive modalities for treating chronic pain. Physical Medicine for chronic pain should be focused on progressive exercise and self-care, with identification of functional deficits and goals, and minimal or no use of passive modalities. A non-specific

prescription for "physical therapy" in cases of chronic pain is not sufficient. The Physical Medicine is not medically necessary based on the MTUS, lack of sufficient emphasis on functional improvement, and the lack of a specific prescription.

**Tramadol ER 150mg #30:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid management, Opioids, steps to avoid misuse/addiction, indications, Chronic back pain, Mechanical and compressive etiologies, Medication trials, Tramadol Page(s): 77-81, 94, 80, 81, 60, 94, 113.

**Decision rationale:** There is insufficient evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, opioid contract, and there should be a prior failure of non-opioid therapy. None of these aspects of prescribing are in evidence. The prescribing physician does not specifically address function with respect to prescribing opioids, and has not addressed the other recommendations in the MTUS (other than a current prescription for a urine drug screen, discussed below). There is no evidence of significant and specific pain relief or increased function from the opioids used to date. None of the reports show the specific results of taking tramadol. This injured worker has failed the "return-to-work" criterion for opioids in the MTUS, and there is no evidence of an equivalent increase in function outside of work. The MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. There is no evidence of any drug tests in the reports from 2012-2015. As currently prescribed, this opioid does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary. This is not meant to imply that some form of analgesia is contraindicated; only that the opioids as prescribed have not been prescribed according to the MTUS and that the results of use do not meet the requirements of the MTUS.

**Cyclobenzaprine 7.5mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain), Flexeril (Cyclobenzaprine).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 63-66.

**Decision rationale:** The MTUS for Chronic Pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. This injured worker has chronic pain with no evidence of prescribing for flare-ups. The quantity prescribed implies long term use, not a short period of use for acute pain. The apparent rationale for prescribing cyclobenzaprine in this case is shoulder pain, which is not an accepted indication in the MTUS or other guidelines. Cyclobenzaprine, per the MTUS, is indicated for short term use only and is not recommended in combination with other agents. This injured worker has been prescribed multiple medications along with cyclobenzaprine. Per the MTUS, this muscle relaxant is not indicated and is not medically necessary.

## **1 10-panel drug screen: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, drug screens, steps to avoid misuse/addiction, urine drug screen to assess for the use or the presence of illegal drugs. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Urine Drug Testing (UDT) in patient-centered clinical situations, criteria for use.

**Decision rationale:** The treating physician has not provided any specific information regarding the medical necessity for a urine drug screen. Medical necessity for a urine drug screen is predicated on a chronic opioid therapy program conducted in accordance with the recommendations of the MTUS, or for a few other, very specific clinical reasons. There is no evidence in this case that opioids are prescribed according to the criteria outlined in the MTUS, as noted in prior Utilization Review and this Independent Medical Review, and there is no apparent medical necessity for any further opioids. The tests to be performed were not listed. The collection procedure was not specified. The MTUS recommends random drug testing, not at office visits or regular intervals. The details of testing have not been provided. The guidelines cited above make a number of detailed recommendations for testing, including the frequency and content of testing, and directions for interpreting drug test results. Potential problems with drug tests include: variable quality control, forensically invalid methods of collection and testing, lack of random testing, lack of MRO involvement, unnecessary testing, and improper utilization of test results. The treating physician would need to address these issues to ensure that testing is done appropriately and according to guidelines. Strict collection procedures must be followed, testing should be appropriate and relevant to this patient, and results must be interpreted and applied correctly. Given that the treating physician has not provided details of the proposed testing, the lack of an opioid therapy program in accordance with the MTUS, and that there are outstanding questions regarding the testing process, the urine drug screen is not medically necessary.

## **1 Fluoroscopy right shoulder: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 207. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Shoulder (Acute and Chronic).

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 207-209. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) shoulder chapter, steroid injections, ultrasound-diagnostic.

**Decision rationale:** The treating physician has provided no specific indications for fluoroscopy, and the indications are not apparent from the recent reports. Fluoroscopy of the shoulder would generally be an adjunct to a procedure, but no procedure was mentioned. If an injection is planned, imaging with ultrasound may be indicated per the Official Disability Guidelines citation above. Given the lack of any clear indications and the guideline recommendations, the fluoroscopy is not medically necessary.

**Fenoprofen Calcium 400mg #60: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, NSAIDs for Back Pain - Acute exacerbations of chronic pain, Back Pain - Chronic low back pain, NSAIDs, specific drug list & adverse effects Page(s): 60, 68, 68, 70-73.

**Decision rationale:** Per the MTUS for chronic pain, page 60, medications should be trialed one at a time, and there should be functional improvement with each medication. No reports show any specific benefit, functional or otherwise, from prior use of NSAIDs. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. There is no evidence that the prescribing physician is adequately monitoring for toxicity as recommended by the FDA and MTUS. The blood pressure has been consistently elevated and the treating physician has not address this in light of the ongoing use of NSAIDs. The injured worker has a diagnosis of an ulcer and is under treatment by another physician. There is insufficient evidence that the other physician has recommended that an NSAID be restarted, particularly when there is so little evidence of specific benefit from past use. This NSAID is not medically necessary based on the lack of specific functional and symptomatic benefit, prescription not in accordance with the MTUS and the FDA warnings, and the lack of sufficient indications to continue an NSAID in the face of a current peptic ulcer and hypertension.

**Pantoprazole 20mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Proton pump inhibitors (PPIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69.

**Decision rationale:** There are no medical reports which adequately describe the relevant signs and symptoms of possible gastrointestinal disease. The primary treating physician has suggested an ulcer diagnosis that is currently treated by another physician with Dexilant. The primary treating physician has prescribed an NSAID and a PPI without evidence of adequate consultation with the physician who has presumably diagnosed and treated the ulcer to date. Absent a clear and sufficient evaluation which takes into account the proven diagnosis, the current treatment, and the need for simultaneous treating physicians, the medical necessity to add a second PPI has not been established. Although a PPI may be indicated for an ulcer per the MTUS citation above and other guidelines, the PPI is apparently prescribed by another physician already, and the addition of a second PPI is not indicated.

**Lidopro cream 121g #1 bottle: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics, Salicylate topicals.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications, Salicylate topical Page(s): 60, 111-113, 105. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

**Decision rationale:** LidoPro is capsaicin, lidocaine, menthol, and methyl salicylate. No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state that "Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm." The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical lidocaine, only in the form of the Lidoderm patch, is indicated for neuropathic pain (which is not present in this case). The MTUS states that the only form of topical lidocaine that is recommended is Lidoderm. The topical lidocaine prescribed in this case is not Lidoderm. Capsaicin has some indications, in the standard formulations readily available without custom compounding. It is not clear what the indication is in this case, as the injured worker does not appear to have the necessary indications per the MTUS. The MTUS also states that capsaicin is only recommended when other treatments have failed. This injured worker has not received adequate trials of other, more conventional treatments. The treating physician did not discuss the failure of other, adequate trials of other treatments. Capsaicin is not medically necessary based on the lack of indications per the MTUS. Menthol is not discussed specifically in the MTUS. Topical salicylates in the standard formulations like BenGay are recommended in the MTUS. The topical compounded medication prescribed for this injured worker is not medically necessary based on the MTUS, the Official Disability Guidelines, lack of medical evidence, and lack of FDA approval.

**Ultracet 37.5mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Weaning of medications. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid management, Opioids, steps to avoid misuse/addiction, indications, Chronic back pain, Mechanical and compressive etiologies, Medication trials, Tramadol Page(s): 77-81, 94, 80, 81, 60, 94, 113.

**Decision rationale:** There is insufficient evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, opioid contract, and there should be a prior failure of non-opioid therapy. None of these aspects of prescribing are in evidence. The prescribing physician does not specifically address function with respect to prescribing opioids, and has not addressed the other recommendations in the MTUS (other than a current prescription for a urine drug screen, discussed below). There is no evidence of significant and

specific pain relief or increased function from the opioids used to date. None of the reports show the specific results of taking tramadol. This injured worker has failed the "return-to-work" criterion for opioids in the MTUS, and there is no evidence of an equivalent increase in function outside of work. The MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. There is no evidence of any drug tests in the reports from 2012-2015. As currently prescribed, this opioid does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary. This is not meant to imply that some form of analgesia is contraindicated; only that the opioids as prescribed have not been prescribed according to the MTUS and that the results of use do not meet the requirements of the MTUS.