

<b>Case Number:</b>	CM13-0011983		
<b>Date Assigned:</b>	09/30/2013	<b>Date of Injury:</b>	03/27/2012
<b>Decision Date:</b>	02/27/2014	<b>UR Denial Date:</b>	08/08/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/15/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Physical Medicine and Rehabilitation, has a subspecialty in Pain Management 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 physician 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:

This is a female patient with the date of injury of March 27, 2012. A utilization review determination dated August 8, 2013 recommends non-certification of Terocin cream 4oz, Flexeril 7.5mg #60, Acetadryl 25/500mg #50, Medrox patches #20, Tramadol ER 150mg #30, carpal tunnel brace, hot/cold wrap, retro Dendracin cream 4oz, retro Terocin cream, retro Flexeril 7.5mg #60, retro Acetadryl 25/500mg #50, retro Medrox patches #20, and retro Tramadol ER 150mg #60. The previous reviewing physician recommended non-certification of Terocin, Medrox patches, and Dendracin cream due to lack of documentation of failed first-line therapy of antidepressants and anticonvulsants and the patient's intolerance of these or similar medications to be taken on an oral basis; non-certification of Flexeril due to lack of documentation of muscle spasms on the physical exam; non-certification of Acetadryl due to lack of documentation of failed first-line opiate trials; non-certification of carpal tunnel brace due to lack of documentation of a current diagnosis of carpal tunnel syndrome or any documented objective findings consistent with carpal tunnel syndrome; and non-certification of a hot/cold wrap due to lack of documentation indicating that the patient is in a post-operative setting and local heat not recommended after the acute phase of injury. A letter dated August 26, 2013 identifies, "We previously requested Terocin lotion 4 ounces to apply in small amounts two to three times daily as needed for topical pain relief, Flexeril 7.5 mg, #60 for muscle spasms, tightness and stiffness, Acetadryl 25/500 mg, #50 for insomnia, as she is having difficulty sleeping related to chronic pain and wakes up several times at night as well as Medrox patch #20, one patch 12 hours on and 12 hours off for topical relief to alternate with Terocin lotion which helps during the daytime to help manage her pain, tramadol ER 150 mg, #30 for nonnarcotic pain medication as well as replacement of hot and cold wrap for the wrist and carpal tunnel brace, as her previous brace has worn out. Please kindly authorize carpal tunnel brace to use for nighttime,

to avoid repetitive wrist flexion, extension, to help with numbness, tingling and weakness." A Request for Authorization dated July 26, 2013 identifies Subjective Complaints of constant pain, motion loss, stiffness, and weather effects. She has sense of swelling, locking, and clicking. She has limitations with push off. She drops things. She describes element of depression and headaches. Objective Findings identify tenderness along the wrist is exquisite. Wrist motion in extension is 60 degrees with quite a bit of difficulty. She has positive Watson sign and clicking on it. Diagnoses include wrist joint inflammation with evidence of regional reflex sympathetic dystrophy, but with MRI missing and element of depression. Treatment Plan identifies the patient wants to avoid injection. Medication was provided.

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

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

**Terocin cream 4 oz.:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** Regarding request for Terocin cream 4 oz., Terocin is a combination of methyl salicylate, menthol, lidocaine and capsaicin. Chronic Pain Medical Treatment Guidelines state that any compounded product that contains at least one drug or drug class that is not recommended, is not recommended. Regarding the use of topical non-steroidal anti-inflammatory, guidelines state that the efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the 1st 2 weeks of treatment osteoarthritis, but either not afterwards or with the diminishing effect over another two-week period. Regarding use of capsaicin, guidelines state that it is recommended only as an option for patients who did not respond to or are intolerant to other treatments. Regarding the use of topical lidocaine, guidelines the state that it is recommended for localized peripheral pain after there is evidence of a trial of first-line therapy. Within the documentation available for review, there is no indication that the patient is unable to tolerate oral NSAIDs. Oral NSAIDs have significantly more guideline support compared with topical NSAIDs. Additionally, there is no indication that the topical NSAID is going to be used for short duration. Furthermore, there is no documentation of localized peripheral pain with evidence of failure of first-line therapy as recommended by guidelines prior to the initiation of topical lidocaine. Finally, there is no indication that the patient has been intolerant to or did not respond to other treatments prior to the initiation of capsaicin therapy. In the absence of clarity regarding those issues, the currently requested Terocin cream 4 oz. is not medically necessary.

**Flexeril 7.5mg #60:** Upheld

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

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

**Decision rationale:** Regarding the request for Flexeril 7.5mg #60, Chronic Pain Medical Treatment Guidelines support the use of non-sedating muscle relaxants to be used with caution as a 2nd line option for the short-term treatment of acute exacerbations of pain. Guidelines go on to state that muscle relaxants are recommended for a short course of therapy. Within the documentation available for review, there is no identification of a specific analgesic benefit or objective functional improvement as a result of the Flexeril. Additionally, it does not appear that this medication is being prescribed for the short-term treatment of an acute exacerbation, as recommended by guidelines. In the absence of such documentation, the currently requested Flexeril 7.5mg #60 is not medically necessary.

**Acetadryl 25/500mg #50:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 12. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

**Decision rationale:** Regarding the request for Acetadryl 25/500mg #50, a search of the internet reveals that Acetadryl is a combination of acetaminophen/diphenhydramine. Chronic Pain Medical Treatment Guidelines state acetaminophen is recommended for treatment of chronic pain & acute exacerbations of chronic pain. Guidelines do not contain criteria for the use of diphenhydramine. Drugs.com states that diphenhydramine is indicated for the treatment of sneezing, runny nose, watery eyes, hives, skin rash, itching, and other cold or allergy symptoms. Diphenhydramine is also used to treat motion sickness, to induce sleep. Regarding the use of sleep aids, California MTUS guidelines are silent regarding the use of sedative hypnotic agents. ODG recommends the short-term use (usually two to six weeks) of pharmacological agents only after careful evaluation of potential causes of sleep disturbance, and determination as to whether the insomnia is primary or secondary. They go on to state the failure of sleep disturbances to resolve in 7 to 10 days, may indicate a psychiatric or medical illness. Within the documentation available for review, there is discussion regarding how frequently the insomnia complaints occur or how long they have been occurring, no statement indicating what behavioral treatments have been attempted for the condition of insomnia. Finally, there is no indication that diphenhydramine is being used for short term use as recommended by guidelines. In the absence of such documentation, the currently requested Acetadryl 25/500mg #50 is not medically necessary.

**Medrox patches #20:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

**Decision rationale:** Regarding the request for Medrox patches #20, Chronic Pain Medical Treatment Guidelines state topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. It is primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The Guidelines also state there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In addition, the Guidelines state there have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. An online search identifies that Medrox contains 0.0375% Capsaicin, 20% Menthol, and 5% Methyl Salicylate. As such, the currently requested Medrox patches #20 is not medically necessary.

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

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 75-79.

**Decision rationale:** Regarding the request for Tramadol ER 150mg #30, California Pain Medical Treatment Guidelines state that Tramadol is a short acting opiate pain medication. Due to high abuse potential, close follow-up is recommended with documentation of analgesic effect, objective functional improvement, side effects, and discussion regarding any aberrant use. Guidelines go on to recommend discontinuing opioids if there is no documentation of improved function and pain. Within the documentation available for review, there is no indication that the Tramadol is improving the patient's function or pain, no documentation regarding side effects, and no discussion regarding aberrant use. In the absence of such documentation, the currently requested Tramadol ER 150mg #30 is not medically necessary.

**Carpal Tunnel brace:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 264. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Carpal Tunnel Syndrome, Splinting

**Decision rationale:** Regarding the request for carpal tunnel brace, Occupational Medicine Practice Guidelines state initial treatment of Carpal Tunnel Syndrome (CTS) should include night splints. Day splints can be considered for patients comfort as needed to reduce pain, along with work modifications. ODG recommends splinting of wrist in neutral position at night & day

prn, as an option in conservative treatment. Use of daytime wrist splints has positive, but limited evidence. Within the medical information made available for review, there is documentation that the previous brace has worn out and carpal tunnel brace is requested to use for nighttime, to avoid repetitive wrist flexion, extension, to help with numbness, tingling and weakness. The Guidelines do support night splints in the management of CTS. As such, the requested carpal tunnel brace is medically necessary.

**Hot/cold wrap:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 265. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Carpal Tunnel Syndrome Chapter, Cold packs and Heat therapy

**Decision rationale:** Regarding the request for a hot/cold wrap, Occupational Medicine Practice Guidelines state physical modalities, such as massage, diathermy, cutaneous laser treatment, "cold" laser treatment, transcutaneous electrical neurostimulation (TENS) units, and biofeedback have no scientifically proven efficacy in treating acute hand, wrist, or forearm symptoms. Limited studies suggest there are satisfying short- to medium-term effects due to ultrasound treatment in patients with mild to moderate idiopathic CTS, but the effect is not curative. Patients' at-home applications of heat or cold packs may be used before or after exercises and are as effective as those performed by a therapist. ODG recommends at-home local applications of cold packs first few days of acute complaints; thereafter, applications of heat therapy. Within the medical information made available for review, there is no documentation of acute complaints. In the absence of such documentation, the currently requested hot/cold wrap is not recommended.

**Retrospective request for Dendracin cream 4oz. 1 bottle:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-112.

**Decision rationale:** Regarding request for Dendracin cream 4oz. 1 bottle, dispensed 7/26/13, Dendracin is a combination of methyl salicylate, menthol, and benzocaine (according to drugs.com). Chronic Pain Medical Treatment Guidelines state that any compounded product that contains at least one drug or drug class that is not recommended, is not recommended. Regarding the use of topical non-steroidal anti-inflammatory, guidelines state that the efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the 1st 2 weeks of treatment osteoarthritis, but either not afterwards or with the diminishing effect over another two-week period. Regarding the use of topical local anesthetics (benzocaine),

guidelines state that they are recommended for localized peripheral pain after there is evidence of a trial of first-line therapy. Within the documentation available for review, there is no indication that the patient is unable to tolerate oral NSAIDs. Oral NSAIDs have significantly more guideline support compared with topical NSAIDs. Additionally, there is no indication that the topical NSAID is going to be used for short duration. Additionally, there is no documentation of localized peripheral pain with evidence of failure of first-line therapy as recommended by guidelines prior to the initiation of topical benzocaine. In the absence of clarity regarding those issues, the currently requested Dendracin cream 4oz. 1 bottle, dispensed 7/26/13 is not medically necessary.

**Retrospective request for Terocin cream, dispensed 7/26/13: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

**Decision rationale:** Regarding request for Terocin cream, dispensed 7/26/13, Terocin is a combination of methyl salicylate, menthol, lidocaine and capsaicin. Chronic Pain Medical Treatment Guidelines state that any compounded product that contains at least one drug or drug class that is not recommended, is not recommended. Regarding the use of topical non-steroidal anti-inflammatory, guidelines state that the efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the 1st 2 weeks of treatment osteoarthritis, but either not afterwards or with the diminishing effect over another two-week period. Regarding use of capsaicin, guidelines state that it is recommended only as an option for patients who did not respond to or are intolerant to other treatments. Regarding the use of topical lidocaine, guidelines the state that it is recommended for localized peripheral pain after there is evidence of a trial of first-line therapy. Within the documentation available for review, there is no indication that the patient is unable to tolerate oral NSAIDs. Oral NSAIDs have significantly more guideline support compared with topical NSAIDs. Additionally, there is no indication that the topical NSAID is going to be used for short duration. Furthermore, there is no documentation of localized peripheral pain with evidence of failure of first-line therapy as recommended by guidelines prior to the initiation of topical lidocaine. Finally, there is no indication that the patient has been intolerant to or did not respond to other treatments prior to the initiation of capsaicin therapy. In the absence of clarity regarding those issues, the currently requested Terocin cream 4 oz. is not medically necessary.

**Retrospective request for Flexeril 7.5mg #60, dispensed 7/26/13: Upheld**

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

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

**Decision rationale:** Regarding the request for Flexeril 7.5mg #60, dispensed 7/26/13, Chronic Pain Medical Treatment Guidelines support the use of non-sedating muscle relaxants to be used with caution as a 2nd line option for the short-term treatment of acute exacerbations of pain. Guidelines go on to state that muscle relaxants are recommended for a short course of therapy. Within the documentation available for review, there is no identification of a specific analgesic benefit or objective functional improvement as a result of the Flexeril. Additionally, it does not appear that this medication is being prescribed for the short-term treatment of an acute exacerbation, as recommended by guidelines. In the absence of such documentation, the currently requested Flexeril 7.5mg #60, dispensed 7/26/13 is not medically necessary.

**Retrospective request for Acetadryl 25/500mg #50, dispensed 7/26/13: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Sleep Medication.

**Decision rationale:** Regarding the request for Acetadryl 25/500mg #50, a search of the internet reveals that Acetadryl is a combination of acetaminophen/diphenhydramine. Chronic Pain Medical Treatment Guidelines state acetaminophen is recommended for treatment of chronic pain & acute exacerbations of chronic pain. Guidelines do not contain criteria for the use of diphenhydramine. Drugs.com states that diphenhydramine is indicated for the treatment of sneezing, runny nose, watery eyes, hives, skin rash, itching, and other cold or allergy symptoms. Diphenhydramine is also used to treat motion sickness, to induce sleep. Regarding the use of sleep aids, California MTUS guidelines are silent regarding the use of sedative hypnotic agents. ODG recommends the short-term use (usually two to six weeks) of pharmacological agents only after careful evaluation of potential causes of sleep disturbance, and determination as to whether the insomnia is primary or secondary. They go on to state the failure of sleep disturbances to resolve in 7 to 10 days, may indicate a psychiatric or medical illness. Within the documentation available for review, there is discussion regarding how frequently the insomnia complaints occur or how long they have been occurring, no statement indicating what behavioral treatments have been attempted for the condition of insomnia. Finally, there is no indication that diphenhydramine is being used for short term use as recommended by guidelines. In the absence of such documentation, the currently requested Acetadryl 25/500mg #50 is not medically necessary.

**Retrospective request for Medrox patches #20, dispensed 7/26/13: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** Regarding the request for Medrox patches #20, dispensed 7/26/13, Chronic Pain Medical Treatment Guidelines state topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. It is primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The Guidelines also state there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In addition, the Guidelines state there have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. An online search identifies that Medrox contains 0.0375% Capsaicin, 20% Menthol, and 5% Methyl Salicylate. As such, the currently requested Medrox patches #20, dispensed 7/26/13 is not medically necessary.

**Retrospective request for Tramadol ER 150mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 75-79.

**Decision rationale:** Regarding the request for Tramadol ER 150mg #60, dispensed 7/26/13, California Pain Medical Treatment Guidelines state that Tramadol is a short acting opiate pain medication. Due to high abuse potential, close follow-up is recommended with documentation of analgesic effect, objective functional improvement, side effects, and discussion regarding any aberrant use. Guidelines go on to recommend discontinuing opioids if there is no documentation of improved function and pain. Within the documentation available for review, there is no indication that the Tramadol is improving the patient's function or pain, no documentation regarding side effects, and no discussion regarding aberrant use. In the absence of such documentation, the currently requested Tramadol ER 150mg #60, dispensed 7/26/13 is not medically necessary.