

<b>Case Number:</b>	CM14-0147401		
<b>Date Assigned:</b>	10/08/2014	<b>Date of Injury:</b>	11/05/2012
<b>Decision Date:</b>	11/19/2014	<b>UR Denial Date:</b>	08/21/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/10/2014

### 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 Anesthesiology, 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 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:

According to the records made available for review, this is a 45-year-old female with an 11/5/12 date of injury. At the time (8/21/14) of the decision for Urine drug screen; Toradol injections, unspecified dosage/amount; Terocin patches 4%-Menthol 4%, unspecified number; Gabacyclotram; Gabapentin 10%; Cyclobenzaprine 6%; Tramadol 10%; Flurbi-Cyclo-Bac-Lido 120ml; Soma 350mg, #60 2 bottles; and Somnicin (Melatonin 2-5HTO 50-L triptophan - pyridoxine 10-magnesiums 50), 2 bottles for insomnia, there is documentation of subjective (low back pain and difficulty falling asleep) and objective (positive Kemp's/facet test, positive straight leg raise, tenderness to palpation over the lumbar spine, and decreased lumbar spine range of motion) findings. The current diagnoses are discogenic back pain and lumbar spine disc protrusion. The treatment to date includes Toradol injections which take the edge off, Norco, Soma, Somnicin since at least 4/2/14 TENS unit, and lumbar epidural steroid injections. Regarding urine drug screen, there is no documentation of abuse, addiction, or poor pain control. Regarding Toradol injections, there is no documentation of moderately severe acute pain that requires analgesia at the opioid level; and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of previous injections. Regarding Soma, there is no documentation of acute muscle spasms, the intention to treat over a short course (less than two weeks), and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Soma use to date.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Urine drug screen:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines On-Going Management Page(s): 78.

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines identifies documentation of abuse, addiction, or poor pain control in patient under on-going opioid treatment, as criteria necessary to support the medical necessity of Urine Drug Screen. Within the medical information available for review, there is documentation of diagnoses of discogenic back pain and lumbar spine disc protrusion. In addition, there is documentation of ongoing treatment with opioids. However, there is no documentation of abuse, addiction, or poor pain control. Therefore, based on guidelines and a review of the evidence, the request for Urine drug screen is not medically necessary.

**Toradol injections, unspecified dosage/amount:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 72. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Ketorolac (Toradol); NSAIDs Other Medical Treatment Guideline or Medical Evidence: Title 8, California Code of Regulations, section 9792.20

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines identifies that Ketorolac (Toradol) is not indicated for minor or chronic painful conditions. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Official Disability Guidelines identifies that Ketorolac, when administered intramuscularly, may be used as an alternative to opioid therapy. In addition, Official Disability Guidelines identifies documentation of moderately severe acute pain that requires analgesia at the opioid level, as criteria necessary to support the medical necessity of Toradol injection. Within the medical information available for review, there is documentation of diagnoses of discogenic back pain and lumbar spine disc protrusion. However, despite documentation of pain, and given documentation of an 11/5/12 date of injury, there is no documentation of moderately severe acute pain that requires analgesia at the opioid level. In addition, despite documentation that Toradol injections take the edge off, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of previous injections. Furthermore, there is no documentation of the dosage/amount requested. Therefore, based on guidelines and a review of the evidence, the request for Toradol injections, unspecified dosage/amount is not medically necessary.

**Terocin patches 4%-Menthol 4%, unspecified number:** Upheld

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

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

**Decision rationale:** Terocin patch contains ingredients that include Lidocaine and Menthol. MTUS Chronic Pain Medical Treatment Guidelines identifies that many agents are compounded as monotherapy or in combination for pain control; that Ketoprofen, Lidocaine (in creams, lotion or gels), Capsaicin in a 0.0375% formulation, Baclofen and other muscle relaxants, and Gabapentin and other anti-epilepsy drugs are not recommended for topical applications; and that any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. Within the medical information available for review, there is documentation of diagnoses of discogenic back pain and lumbar spine disc protrusion. However, Terocin contains at least one drug (Lidocaine) that is not recommended. Therefore, based on guidelines and a review of the evidence, the request for Terocin patches 4%-Menthol 4%, unspecified number is not medically necessary.

**GabaCycloTram - Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%:** Upheld

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

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

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines identifies that many agents are compounded as monotherapy or in combination for pain control; that Ketoprofen, Lidocaine (in creams, lotion or gels), Capsaicin in a 0.0375% formulation, Baclofen and other muscle relaxants, and gabapentin and other anti-epilepsy drugs are not recommended for topical applications; and that any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. Therefore, based on guidelines and a review of the evidence, the request for Gabacyclotram is not medically necessary.

**Flurib-cylo-bac-lido 120ml:** Upheld

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

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

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines identifies that many agents are compounded as monotherapy or in combination for pain control; that Ketoprofen, Lidocaine (in creams, lotion or gels), Capsaicin in a 0.0375% formulation, Baclofen and other muscle relaxants, and Gabapentin and other anti-epilepsy drugs are not recommended for topical applications; and that any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. Therefore, based on guidelines and a review of the evidence, the request for Flurib-cylo-bac-lido 120ml is not medically necessary.

**Soma 350mg, #60 2 bottles:** 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 Carisoprodol (Soma) Page(s): 29. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Muscle relaxants (for pain) Other Medical Treatment Guideline or Medical Evidence: Title 8, California Code of Regulations, section 9792.20

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines identifies that Carisoprodol (Soma) is not recommended and that this medication is not indicated for long term use. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Official Disability Guidelines identifies that muscle relaxants are recommended as a second line option for short-term (less than two weeks) treatment of acute low back pain and for short-term treatment of acute exacerbations in patients with chronic low back pain. Within the medical information available for review, there is documentation of diagnoses of discogenic back pain and lumbar spine disc protrusion. However, there is no documentation of acute muscle spasms. In addition, given documentation of records reflecting prescriptions for Soma since at least 4/2/14, there is no documentation of the intention to treat over a short course (less than two weeks). Furthermore, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Soma use to date. Therefore, based on guidelines and a review of the evidence, the request for Soma 350mg, #60 2 bottles is not medically necessary.

**Somnicin (Melatonin 2-5HTO 50-L triptophan-pyridoxine 10-magnesiums 50), 2 bottles for insomnia:** 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) Pain Chapter, Medical Food

**Decision rationale:** Somnicin is a combination of ingredients that are all naturally-occurring within the body: Melatonin, 5-hydroxytryptophan, L-tryptophan, Vitamin B6, and Magnesium. MTUS does not address the issue. Official Disability Guidelines identifies 5-hydroxytryptophan as a medical food product, defined as a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. In addition, Official Disability Guidelines identifies that the product must be a food for oral or tube feeding; must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and must be used under medical supervision; as criteria to support the medical necessity of medical food. Within the medical information available for review, there is documentation of diagnoses of discogenic back pain and lumbar spine disc protrusion. In addition, there is documentation of a recommendation for Somnicin which contains 5-hydroxytryptophan, a medical food. However, there is no documentation identifying that the product is a food for oral or tube feeding; that is labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and that is used under medical supervision. Therefore, based on guidelines and a review of the evidence, the request for Somnicin (Melatonin 2-5HTO 50-L triptophan-pyridoxine 10-magnesiums 50), 2 bottles for insomnia is not medically necessary.