

<b>Case Number:</b>	CM14-0216149		
<b>Date Assigned:</b>	02/10/2015	<b>Date of Injury:</b>	07/28/2008
<b>Decision Date:</b>	04/15/2015	<b>UR Denial Date:</b>	12/09/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/24/2014

### 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. 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: Anesthesiology

### 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 50 year old female, who sustained an industrial injury reported on 7/28/2008. She reported a history of severe, chronic pain to the right shoulder, along with no change in abdominal pain, depression, anxiety, sleep or weight gain. The diagnoses were noted to include carpal tunnel syndrome; other affections of shoulder region with right shoulder surgery (2011); non-allopathic lesion of upper extremities; sprain/strain of tibiofibular; abdominal pain (currently asymptomatic); obesity; sleep disorder; and a history of shortness of breath, syncopal events and seizures, per stated chemical exposure. Treatments to date have included consultations; diagnostic imaging studies; and medication management. The work status classification for this injured worker (IW) was noted to be that she remains on permanent disability, as per the 7/13/2014 disability report. On 12/9/2014, Utilization Review (UR) non-certified, for medical necessity, the request, made on 12/2/2014, for the topical application of Amitriptyline 10%, Dextr 10%, Gabapentin 10%, quantity 210, dispensed on 3/24/14, 4/24/14, 5/26/14, 6/26/14 & 8/11/14. The Medical Treatment Utilization Schedule, chronic pain medical treatment guidelines, topical, was cited.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen 20%, Trama 20%, QTY 210 dispensed 3/24/2014: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Topical Analgesics.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the topical analgesic compound requested is Flurbiprofen 20%/Tramadol 20%. Tramadol is not FDA approved for a topical application. In addition, there are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). It is evident from the records that the patient is able to use oral medications and there is no rationale provided for the use of a topical analgesic compound. Medical necessity for the requested topical analgesic has not been established. The retrospective request for this topical analgesic treatment of Flurbiprofen 20/Tramadol 20 is not medically necessary.

**Flurbiprofen 20%, Trama 20%, QTY: 210 dispensed 4/24/2014: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Topical Analgesics.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the topical analgesic compound requested is Flurbiprofen 20%/Tramadol 20%. Tramadol is not FDA approved for a topical application. In addition, there are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). It is evident from the records that the patient is able to use oral medications and there is no rationale provided for the use of a topical analgesic compound. Medical necessity for the requested topical analgesic has not been established. The

retrospective request for this topical analgesic treatment of Flurbiprofen 20/Tramadol 20 is not medically necessary.

**Flurbiprofen 20%, Trama 20%, QTY 210 dispensed 5/26/2014: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Topical Analgesics.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the topical analgesic compound requested is Flurbiprofen 20%/Tramadol 20%. Tramadol is not FDA approved for a topical application. In addition, there are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). It is evident from the records that the patient is able to use oral medications and there is no rationale provided for the use of a topical analgesic compound. Medical necessity for the requested topical analgesic has not been established. The retrospective request for this topical analgesic treatment of Flurbiprofen 20/ Tramadol 20 is not medically necessary.

**Flurbiprofen 20%, Trama 20%, QTY 210 dispensed 6/26/2014: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Topical Analgesics.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the topical analgesic compound requested is Flurbiprofen 20%/Tramadol 20%. Tramadol is not FDA approved for a topical

application. In addition, there are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). It is evident from the records that the patient is able to use oral medications and there is no rationale provided for the use of a topical analgesic compound. Medical necessity for the requested topical analgesic has not been established. The retrospective request for this topical analgesic treatment of Flurbiprofen 20/Tramadol 20 is not medically necessary.

**Flurbiprofen 20%, Trama 20%, QTY: 210 dispensed 8/11/2014: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Topical Analgesics.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the topical analgesic compound requested is Flurbiprofen 20%/Tramadol 20%. Tramadol is not FDA approved for a topical application. In addition, there are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). It is evident from the records that the patient is able to use oral medications and there is no rationale provided for the use of a topical analgesic compound. Medical necessity for the requested topical analgesic has not been established. The retrospective request for this topical analgesic treatment of Flurbiprofen 20/Tramadol 20 is not medically necessary.

**Amitr 10% Dextr10%, Gabap 10% QTY: 210 dispensed 3/24/2014: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Topical Analgesics.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for

example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, Amitr 10%, Dextr 10%, Gabap 10% is the topical analgesic compound requested. Gabapentin is not recommended as a topical agent per CA MTUS Guidelines. There is no peer-reviewed literature to support its use. It is evident from the records that the patient is able to use oral medications and there is no rationale provided for the use of a topical analgesic compound. Medical necessity for the requested topical analgesic has not been established. The retrospective request for this topical analgesic compound is not medically necessary.

**Amitr 10%, Dextr 10%, Gabap 10% QTY: 210 dispensed 4/24/2014: Upheld**

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

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

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, Amitr 10%, Dextr 10%, Gabap 10% is the topical analgesic compound requested. Gabapentin is not recommended as a topical agent per CA MTUS Guidelines. There is no peer-reviewed literature to support its use. It is evident from the records that the patient is able to use oral medications and there is no rationale provided for the use of a topical analgesic compound. Medical necessity for the requested topical analgesic has not been established. The retrospective request for this topical analgesic compound is not medically necessary.

**Amitr10% Dextr 10%, Gabap 10% QTY 210 dispensed 5/26/2014: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Topical Analgesics.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages

that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, Amitr 10%, Dextr 10%, Gabap 10% is the topical analgesic compound requested. Gabapentin is not recommended as a topical agent per CA MTUS Guidelines. There is no peer-reviewed literature to support its use. It is evident from the records that the patient is able to use oral medications and there is no rationale provided for the use of a topical analgesic compound. Medical necessity for the requested topical analgesic has not been established. The retrospective request for this topical analgesic compound is not medically necessary.

**Amitr 10%, Dextr 10%, Gabap10% QTY: 210 dispensed 6/26/2014: 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:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, Amitr 10%, Dextr 10%, Gabap 10% is the topical analgesic compound requested. Gabapentin is not recommended as a topical agent per CA MTUS Guidelines. There is no peer-reviewed literature to support its use. It is evident from the records that the patient is able to use oral medications and there is no rationale provided for the use of a topical analgesic compound. Medical necessity for the requested topical analgesic has not been established. The retrospective request for this topical analgesic compound is not medically necessary.

**Amitr 10%, Dextr 10%, Gabap 10% QTY: 210 dispensed 8/11/2014: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Topical Analgesics.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and

anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, Amitr 10%, Dextr 10%, Gabap 10% is the topical analgesic compound requested. Gabapentin is not recommended as a topical agent per CA MTUS Guidelines. There is no peer-reviewed literature to support its use. It is evident from the records that the patient is able to use oral medications and there is no rationale provided for the use of a topical analgesic compound. Medical necessity for the requested topical analgesic has not been established. The retrospective request for this topical analgesic compound is not medically necessary.