

<b>Case Number:</b>	CM14-0141677		
<b>Date Assigned:</b>	09/18/2014	<b>Date of Injury:</b>	03/06/2009
<b>Decision Date:</b>	11/13/2014	<b>UR Denial Date:</b>	08/22/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/02/2014

### **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 Family Medicine and is licensed to practice in North Carolina. 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 patient is a 60 year-old with a reported date of injury of 03/26/2009. The patient has the diagnoses of hypertension, gastritis, lumbosacral spine injury, cervical spine injury and bilateral knee injury. Past treatment modalities have included surgical intervention. Per the most recent progress report from the primary treating physician dated 04/29/2014 the patient had complaints of persistent knee pain but improvement in pain on pain medication and transdermal creams. The physical exam noted no abnormalities. Treatment plan recommendations included continuation of medications and transdermal creams.

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

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

**Retrospective Terocin Patches (#30, DOS 10/14/2013): Upheld**

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

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

**Decision rationale:** The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of

systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) 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. The requested medication is a combination of methyl salicylate, capsaicin, lidocaine hydrochloride and menthol. Some of these ingredients are not listed in the California MTUS as recommended agents to be used as topical analgesics. Therefore criteria as set forth in the California MTUS have not been met as outlined above and the request is not medically necessary.

**Retrospective Genicin Capsules(500mg, #90, DOS: 10/14/2013): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines, Proprietary Glucosamine.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines glucosamine Page(s): 50.

**Decision rationale:** Glucosamine (and Chondroitin Sulfate) Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). (Richy, 2003) (Ruane, 2002) (Towheed-Cochrane, 2001) (Braham, 2003) (Reginster, 2007) A randomized, doubleblind placebo controlled trial, with 212 patients, found that patients on placebo had progressive joint-space narrowing, but there was no significant joint-space loss in patients on glucosamine sulphate. (Reginster, 2001) Another RCT with 202 patients concluded that long-term treatment with glucosamine sulfate retarded the progression of knee osteoarthritis, possibly determining disease modification. (Pavelka, 2002) The Glucosamine Chondroitin Arthritis Intervention Trial (GAIT) funded by the National Institutes of Health concluded that glucosamine hydrochloride (GH) and chondroitin sulfate were not effective in reducing knee pain in the study group overall; however, these may be effective in combination for patients with moderate-to-severe knee pain. [Note: The GAIT investigators did not use glucosamine sulfate (GS).] (Distler, 2006) Exploratory analyses suggest that the combination of glucosamine and chondroitin sulfate may be effective in the subgroup of patients with moderate-to-severe knee pain. (Clegg, 2006) In a recent meta-analysis, the authors found that the apparent benefits of chondroitin were largely confined to studies of poor methodological quality, such as those with small patient numbers or ones with unclear concealment of allocation. When the analysis was limited to the three best-designed studies with the largest sample sizes (40% of all patients), chondroitin offered virtually no relief from joint pain. While not particularly effective, chondroitin use did not appear to be harmful either, according to a meta-analysis of 12 of the studies. (Reichenbach, 2007) Despite multiple controlled clinical trials of glucosamine in osteoarthritis (mainly of the knee),

controversy on efficacy related to symptomatic improvement continues. Differences in results originate from the differences in products, study design and study populations. Symptomatic efficacy described in multiple studies performed with glucosamine sulphate (GS) support continued consideration in the OA therapeutic armamentarium. Compelling evidence exists that GS may reduce the progression of knee osteoarthritis. Results obtained with GS may not be extrapolated to other salts (hydrochloride) or formulations (OTC or food supplements) in which no warranty exists about content, pharmacokinetics and pharmacodynamics of the tablets. (Reginster, 2007) [Note: DONA Glucosamine Sulfate is the original crystalline glucosamine sulfate (GS), which was first developed and marketed for human use by Rotta Research Laboratorium, funding some of the initial trials. Glucosamine hydrochloride (GH) is not proprietary, so it tends to be less expensive but there has also been less funding for quality studies.] Recent research: This RCT assessed radiographic outcomes in OA of the knee in patients being treated with glucosamine hydrochloride (note: GH not GS), chondroitin sulfate (CS), glucosamine plus CS, celecoxib, or placebo. Over 2 years, no treatment achieved the predefined clinically important difference from placebo in terms of joint space width (JSW) loss. The effect of the combination of glucosamine plus CS may be less active than the effect of each treatment singly. Kellgren/Lawrence (K/L) grade 2 knees may represent a more potentially responsive population. Treatment effects on K/L grade 2 knees (less severe OA), but not on K/L grade 3 knees (more severe), showed a trend toward improvement relative to the placebo group. This medication is indicated for the treatment of moderate arthritis pain, especially of the knee. The patient has the diagnoses of bilateral knee injury but there is no documentation of actual arthritis as the cause of the pain. Therefore the criteria for use of the medication as outlined above per the California MTUS have not been met and the request is not medically necessary.

**Retrospective Flurbi (NAP) Cream (#180, DOS: 10/14/2013): Upheld**

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

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

**Decision rationale:** The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) 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. The requested medication is a NSAID topical analgesic. NSAID topical analgesics are indicted per the California MTUS in the treatment of chronic pain. However the California MTUS only lists diclofenec and ketoprofen as accepted NSAID topical agents. Therefore the request is not certified, as this NSAID cream does not contain either one of these agents. Therefore this request is not medically necessary.

**Retrospective Gabacyclotram (#180, DOS: 10/14/2013): 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.

The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally 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 NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists,  $\frac{1}{2}$  adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists,  $\frac{1}{2}$  agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). 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. The requested medication is a combination of Gabapentin and cyclobenzaprine. Both of these ingredients are not listed in the California MTUS as recommended agents to be used as topical analgesics. Therefore criteria as set forth in the California MTUS have not been met as outlined above and the request is not medically necessary.

**Retrospective Laxacin Tablets(#100, DOS: 10/14/2013):** Overturned

**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 opioids Page(s): 77.

**Decision rationale:** The California chronic pain medical treatment guidelines section on opioids states:(a) Intermittent pain: Start with a short-acting opioid trying one medication at a time.(b) Continuous pain: extended-release opioids are recommended. Patients on this modality may require a dose of "rescue" opioids. The need for extra opioid can be a guide to determine the sustained release dose required.(c) Only change 1 drug at a time.(d) Prophylactic treatment of constipation should be initiatedThe Patient is currently on opioid therapy. The requested medication is sennosides/docusate sodium. It is used in the treatment of constipation. The California MTUS recommends prophylactic treatment of constipation is initiated when using opioids in the treatment of chronic pain. Therefore the request is certified.

**Retrospective Genicin Capsules(500mg, #90, DOS: 10/14/2013):** 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 glucosamine Page(s): 50.

**Decision rationale:** Glucosamine (and Chondroitin Sulfate)Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). (Richy, 2003) (Ruane, 2002) (Towheed-Cochrane, 2001) (Braham, 2003) (Reginster, 2007) A randomized, doubleblind

placebo controlled trial, with 212 patients, found that patients on placebo had progressive joint-space narrowing, but there was no significant joint-space loss in patients on glucosamine sulphate. (Reginster, 2001) Another RCT with 202 patients concluded that long-term treatment with glucosamine sulfate retarded the progression of knee osteoarthritis, possibly determining disease modification. (Pavelka, 2002) The Glucosamine Chondroitin Arthritis Intervention Trial (GAIT) funded by the National Institutes of Health concluded that glucosamine hydrochloride (GH) and chondroitin sulfate were not effective in reducing knee pain in the study group overall; however, these may be effective in combination for patients with moderate-to-severe knee pain. [Note: The GAIT investigators did not use glucosamine sulfate (GS).] (Distler, 2006) Exploratory analyses suggest that the combination of glucosamine and chondroitin sulfate may be effective in the subgroup of patients with moderate-to-severe knee pain. (Clegg, 2006) In a recent meta-analysis, the authors found that the apparent benefits of chondroitin were largely confined to studies of poor methodological quality, such as those with small patient numbers or ones with unclear concealment of allocation. When the analysis was limited to the three best-designed studies with the largest sample sizes (40% of all patients), chondroitin offered virtually no relief from joint pain. While not particularly effective, chondroitin use did not appear to be harmful either, according to a meta-analysis of 12 of the studies. (Reichenbach, 2007) Despite multiple controlled clinical trials of glucosamine in osteoarthritis (mainly of the knee), controversy on efficacy related to symptomatic improvement continues. Differences in results originate from the differences in products, study design and study populations. Symptomatic efficacy described in multiple studies performed with glucosamine sulphate (GS) support continued consideration in the OA therapeutic armamentarium. Compelling evidence exists that GS may reduce the progression of knee osteoarthritis. Results obtained with GS may not be extrapolated to other salts (hydrochloride) or formulations (OTC or food supplements) in which no warranty exists about content, pharmacokinetics and pharmacodynamics of the tablets. (Reginster, 2007) [Note: DONA Glucosamine Sulfate is the original crystalline glucosamine sulfate (GS), which was first developed and marketed for human use by Rotta Research Laboratorium, funding some of the initial trials. Glucosamine hydrochloride (GH) is not proprietary, so it tends to be less expensive but there has also been less funding for quality studies.] Recent research: This RCT assessed radiographic outcomes in OA of the knee in patients being treated with glucosamine hydrochloride (note: GH not GS), chondroitin sulfate (CS), glucosamine plus CS, celecoxib, or placebo. Over 2 years, no treatment achieved the predefined clinically important difference from placebo in terms of joint space width (JSW) loss. The effect of the combination of glucosamine plus CS may be less active than the effect of each treatment singly. Kellgren/Lawrence (K/L) grade 2 knees may represent a more potentially responsive population. Treatment effects on K/L grade 2 knees (less severe OA), but not on K/L grade 3 knees (more severe), showed a trend toward improvement relative to the placebo group. This medication is indicated for the treatment of moderate arthritis pain, especially of the knee. The patient has the diagnoses of bilateral knee injury but there is no documentation of actual arthritis as the cause of the pain. Therefore the criteria for use of the medication as outlined above per the California MTUS have not been met and the request is not medically necessary.

**Retrospective Laxacin Tablets (#100, DOS: 5/1/2014): Overturned**

**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 opioids  
Page(s): 77.

**Decision rationale:** (a) Intermittent pain: Start with a short-acting opioid trying one medication

at a time.(b) Continuous pain: extended-release opioids are recommended. Patients on this modality may require a dose of "rescue" opioids. The need for extra opioid can be a guide to determine the sustained release dose required.(c) Only change 1 drug at a time.(d) Prophylactic treatment of constipation should be initiatedThe Patient is currently on opioid therapy. The requested medication is sennosides/docusate sodium. It is used in the treatment of constipation. The California MTUS recommends prophylactic treatment of constipation be initiated when using opioids in the treatment of chronic pain. Therefore the request is certified.

**Retrospective Somnicin (#30, DOS: 5/1/2014): 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) insomnia treatment

**Decision rationale:** The California MTUS and the ACOEM do not specifically address the requested medication. The requested medication is a combination of magnesium oxide, melatonin, oxitriptan and tryptophan. The Official Disability Guidelines section on insomnia list several medications as treatment options including hypnotics, sedating antihistamines and certain antidepressants. Melatonin is also listed however the other components of this medication are not listed as accepted insomnia treatments. There is no indication of failure of these recommended first line treatment options. Therefore the request is not certified.

**Retrospective Terocin Patches (#30, DOS: 5/1/2014): Upheld**

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

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

**Decision rationale:** The California chronic pain medical treatment guidelines section on topical analgesics states:Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) 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. The requested medication is a combination of methyl salicylate, capsaicin, lidocaine hydrochloride and menthol. Some of these ingredients are not listed in the California MTUS as recommended agents to be used as topical analgesics. Therefore criteria as set forth in the California MTUS have not been met as outlined above and the request is not certified.

**Retrospective Terocin Lotion (#240, DOS: 5/1/2014): Upheld**

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

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

**Decision rationale:** The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) 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. The requested medication is a combination of methyl salicylate, capsaicin, lidocaine hydrochloride and menthol. Some of these ingredients are not listed in the California MTUS as recommended agents to be used as topical analgesics. Therefore criteria as set forth in the California MTUS have not been met as outlined above and the request is not certified.

**Retrospective Gabapentin (#180, DOS: 5/1/2014): 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.

**Decision rationale:** The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) 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. The requested medication is a combination of Gabapentin and cyclobenzaprine. Both of these ingredients are not listed in the California MTUS as recommended agents to be used as topical analgesics. Therefore criteria as set forth in the California MTUS have not been met as outlined above and the request is not certified.