

<b>Case Number:</b>	CM15-0184728		
<b>Date Assigned:</b>	09/25/2015	<b>Date of Injury:</b>	05/17/2010
<b>Decision Date:</b>	11/02/2015	<b>UR Denial Date:</b>	08/19/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/21/2015

### 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: Massachusetts

Certification(s)/Specialty: Physical Medicine & Rehabilitation, Pain Management

### 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 40 year old female, who sustained an industrial injury on 5-17-2010. The injured worker is undergoing treatment for: status post major fall with loss of consciousness; left upper extremity and low back injury. On 3-24-15, she is reported as "this patient's history indicates a successful outcome from prior transdermal use". There is notation of transdermal creams reducing the use of oral analgesics and eliminating possible side effects. On 6-2-15, she indicated having difficulty with some of her personal hygiene activities, standing and walking. She reported left hand pain, cramping and tingling, difficulty gripping and grasping. Physical findings revealed positive Tinel and elbow flexion testing of the left cubital tunnel; decreased light touch sensation and weakness. On 7-2-15, she underwent functional capacity evaluation where it was determined she had difficulty with handling and fingering activities with the left hand. The records do not discuss her pain level, or efficacy of prescribed medications. The treatment and diagnostic testing to date has included: functional capacity evaluation (7-2-15), medications, urine drug screen (2-10-15) was positive for hydrocodone and hydromorphone; multiple left wrist surgeries and left elbow ulnar nerve transposition surgeries, electrodiagnostic studies (1-21-15). Medications have included: Ultram, Cyclobenzaprine, Omeprazole, Diclofenac. The records indicate she has been utilizing transdermal creams since at least March 2015, possibly longer. Current work status: reported as unchanged. The request for authorization is for: Flurbiprofen 20 percent, Baclofen 10 percent, Dexamethasone micro 0.2 percent, Hyaluronic acid 0.2 percent in cream base, 240 gram; and Amitriptyline 10 percent, Gabapentin 10 percent, Bupivacaine 5 percent, Hyaluronic Acid 0.2 percent in cream base, 240

grams. The UR dated 8-19-2015: non-certified the request for Flurbiprofen 20 percent, Baclofen 10 percent, Dexamethasone micro 0.2 percent, Hyaluronic acid 0.2 percent in cream base, 240 gram; and Amitriptyline 10 percent, Gabapentin 10 percent, Bupivacaine 5 percent, Hyaluronic Acid 0.2 percent in cream base, 240 grams.

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

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

**Topical compound HMPC2-Flurbiprofen 20%/Baclofen 10%/Dexamethasone Micro 0.2%/Hyaluronic acid 0.2% in cream base 240g: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Knee.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The claimant sustained a work injury in May 2010 when she fell from a haystack and is being treated for left upper extremity and low back pain. She underwent left ORIF of a comminuted distal radius fracture in May 2010, an ulnar nerve transposition on 01/21/11, hardware removal and extensor compartment tenosynovectomy on 11/07/11 complicated by infection, a left wrist fusion on 01/30/13, and a left carpal tunnel release with hardware removal on 09/23/14. When seen, she was in no acute distress. There was finger weakness with good range of motion that was unchanged. There was decreased left ulnar and median nerve sensation. Topical medications are being requested. Oral medications include cyclobenzaprine, pantoprazole, Tramadol ER, and sumatriptan. Compounded topical preparations of flurbiprofen are used off-label (non-FDA approved) and have not been shown to be superior to commercially available topical medications such as diclofenac. Baclofen is a muscle relaxant and there is no evidence for the use of any muscle relaxant as a topical product. Oral cyclobenzaprine are also being prescribed which is duplicative. Any compounded product that contains at least one drug or drug class that is not recommended is not recommended. By prescribing a compounded medication, in addition to increased risk of adverse side effects, it would be difficult or impossible to determine whether any derived benefit was due to a particular component. In this case, there are other single component topical treatments that could be considered. This medication is not considered medically necessary. Oral Gabapentin has been shown to be effective in the treatment of painful diabetic neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. Its use as a topical product is not recommended. Many agents are compounded as monotherapy or in combination for pain control such as opioids antidepressants, glutamate receptor antagonists, alpha-adrenergic receptor agonists, adenosine, cannabinoids, cholinergic receptor agonists, GABA agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor. There is little to no research to support the use of many these agents including amitriptyline. Any compounded product that contains at least one drug or drug class that is not recommended is not recommended. By prescribing a compounded medication, in addition to increased risk of adverse side effects, it would be difficult or impossible to determine whether any derived benefit was due to a particular component. In this case, there are other single component topical treatments with generic availability that could be considered. This medication is not considered medically necessary.

**Topical compound HNPC1-Amitriptyline 10%/Gabapentin 10%/Bupivacaine 5%/Hyaluronic acid 0.2% in cream base 240g: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Knee.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The claimant sustained a work injury in May 2010 when she fell from a haystack and is being treated for left upper extremity and low back pain. She underwent left ORIF of a comminuted distal radius fracture in May 2010, an ulnar nerve transposition on 01/21/11, hardware removal and extensor compartment tenosynovectomy on 11/07/11 complicated by infection, a left wrist fusion on 01/30/13, and a left carpal tunnel release with hardware removal on 09/23/14. When seen, she was in no acute distress. There was finger weakness with good range of motion that was unchanged. There was decreased left ulnar and median nerve sensation. Topical medications are being requested. Oral medications include cyclobenzaprine, pantoprazole, Tramadol ER, and sumatriptan. Compounded topical preparations of flurbiprofen are used off-label (non-FDA approved) and have not been shown to be superior to commercially available topical medications such as diclofenac. Baclofen is a muscle relaxant and there is no evidence for the use of any muscle relaxant as a topical product. Oral cyclobenzaprine are also being prescribed which is duplicative. Any compounded product that contains at least one drug or drug class that is not recommended is not recommended. By prescribing a compounded medication, in addition to increased risk of adverse side effects, it would be difficult or impossible to determine whether any derived benefit was due to a particular component. In this case, there are other single component topical treatments that could be considered. This medication is not considered medically necessary. Oral Gabapentin has been shown to be effective in the treatment of painful diabetic neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. Its use as a topical product is not recommended. Many agents are compounded as monotherapy or in combination for pain control such as opioids antidepressants, glutamate receptor antagonists, alpha-adrenergic receptor agonists, adenosine, cannabinoids, cholinergic receptor agonists, GABA agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor. There is little to no research to support the use of many these agents including amitriptyline. Any compounded product that contains at least one drug or drug class that is not recommended is not recommended. By prescribing a compounded medication, in addition to increased risk of adverse side effects, it would be difficult or impossible to determine whether any derived benefit was due to a particular component. In this case, there are other single component topical treatments with generic availability that could be considered. This medication is not considered medically necessary.