

<b>Case Number:</b>	CM15-0116001		
<b>Date Assigned:</b>	06/24/2015	<b>Date of Injury:</b>	01/26/2007
<b>Decision Date:</b>	07/29/2015	<b>UR Denial Date:</b>	05/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/16/2015

### 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: Pennsylvania  
 Certification(s)/Specialty: Internal Medicine

### 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 69 year old male who sustained an industrial injury on 1/26/2007. He reported low back pain. The injured worker was diagnosed as having low back pain radicular with lumbar spinal stenosis and neurogenic claudication, congenital spinal stenosis. Treatment and evaluation to date has included oral medications, electrodiagnostic studies, magnetic resonance imaging of the lumbar spine (1/11/2008). He is retired. The request is for Flurbiprofen 20%; Gabapentin 10%; and Cyclobenzaprine 10%. On 4/22/2015, he reported that his symptoms remain the same from a previous visit. He rated his low back pain as 7-8/10, and indicated it radiated down both legs. Physical examination revealed an antalgic gait, difficulty in getting onto the examination table. He is moderately severely obese. He is noted to have a restricted low back range of motion. Negative findings for Waddell simulation were noted. The treatment plan noted he does not want surgery, and prefers medications. Topical creams were dispensed in the office to help with nerve pain, spasm, and inflammation. The provider noted plan to minimize any oral type of anti-inflammatories at this time due to the injured worker being diabetic. He is continued on oral Tramadol.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen 20% 150 cream (includes Flurbiprofen 30gm, Lidocaine 7.5gms, and Verapro base cr 112.5gms): Upheld**

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

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

**Decision rationale:** MTUS guidelines do not recommend any compounded product that contains at least one drug (or drug class) that is not recommended. Flurbiprofen is a non-steroidal anti-inflammatory agent (NSAID). Topical creams containing NSAIDs per MTUS may be recommended short term for osteoarthritis and tendinitis. Topical NSAIDs are not recommended for osteoarthritis of the spine, hip, or shoulder. This injured worker has lumbar spine pain. The site of application and directions for use were not specified. Note that topical flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. The MTUS guidelines indicate that Lidoderm is the only approved formulation of Lidocaine, and that no other commercially approved topical formulation of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The requested Flurbiprofen 20% (Flurbiprofen 30 gm, Lidocaine 7.5 gms in Versapro base) contains a formulation of Lidocaine that is not recommended per the MTUS guidelines. The physician has prescribed two creams containing topical lidocaine, which is duplicative and potentially toxic. As this compound contains two medications which are not recommended by the guidelines, the compound is not recommended. Therefore, the request for Flurbiprofen 20% 150 cream (includes Flurbiprofen 30gm, Lidocaine 7.5gms, and Verapro base cr 112.5gms) is not medically necessary.

**Gabapentin 10% 150gm cream (includes Gabapentin powder 15gms, Amitriptyline 7.5gms, Capsaicin 0.0375gms): Upheld**

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

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

**Decision rationale:** MTUS guidelines do not recommend any compounded product that contains at least one drug (or drug class) that is not recommended. The MTUS guidelines do not recommend Gabapentin as a topical analgesic. There is no peer-reviewed literature to support its use. MTUS guidelines indicate Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Amitriptyline is a tricyclic anti-depressant. The MTUS and ODG do not address amitriptyline in topical form. The requested Gabapentin 10% 150gm cream (includes Gabapentin powder 15gms, Amitriptyline 7.5gms, Capsaicin 0.0375gms) contains gabapentin, and a high dose of capsaicin, which are not recommended per the MTUS

guidelines. Therefore, the requested Gabapentin 10% 150gm cream (includes Gabapentin powder 15gms, Amitriptyline 7.5gms, Capsaicin 0.0375gms) is not medically necessary.

**Cyclobenzaprine 10% 150gm cream (includes Cyclobenzaprine powder 15gms, Lidocaine 3gms, Versapro base cr 132gms): Upheld**

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

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

**Decision rationale:** MTUS guidelines do not recommend any compounded product that contains at least one drug (or drug class) that is not recommended. Cyclobenzaprine is a muscle relaxant. The MTUS indicates there is no evidence for use of any muscle relaxant as a topical product. The MTUS guidelines indicate that Lidoderm is the only approved formulation of Lidocaine, and that no other commercially approved topical formulation of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The requested Cyclobenzaprine 10% (Cyclobenzaprine powder 15 gms/Lidocaine 3 gms in Versapro base) contains a formulation of Lidocaine that is not recommended per the MTUS guidelines. The physician has prescribed two creams containing topical lidocaine, which is duplicative and potentially toxic. As both of the ingredients in this compounded topical product are not recommended, the compound is not recommended. Therefore, the requested Cyclobenzaprine 10% 150gm cream (includes Cyclobenzaprine powder 15gms, Lidocaine 3gms, Versapro base cr 132gms) is not medically necessary.