

<b>Case Number:</b>	CM15-0201197		
<b>Date Assigned:</b>	10/20/2015	<b>Date of Injury:</b>	08/13/2014
<b>Decision Date:</b>	12/28/2015	<b>UR Denial Date:</b>	09/21/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/13/2015

### 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: Arizona, Michigan

Certification(s)/Specialty: Preventive Medicine, Occupational 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 49 year old male who sustained an industrial injury 08-31-14. A review of the medical records reveals the injured worker is undergoing treatment for lumbar radiculopathy. Medical records (09-02-15) reveal the injured worker complains of low back pain rated at 8/10. The physical exam (09-02-15) reveals decreased range of motion of the lumbar spine, as well as tenderness to palpation of the bilateral sacroiliac joints and lumbar paravertebral muscle. Muscle spasms of the bilateral gluteus and lumbar paravertebral muscles are present. Prior treatments are not addressed. The original utilization review (09-18-15) non certified the request for Protonix 20mg #60, Voltaren 100mg #60, Zolpidem 10mg #30, Percocet 10/325 #60, and topical compounds Flurbiprofen 20%-Baclofen 10%-Dexamethasone 0.2%-Hyaluronic Acid 0.2% and Amitriptyline 10%-Gabapentin 10%-Bupivacaine 5%-Hyaluronic Acid 0.2%. There is not additional documentation so there is no way to know how long the injured worker has been on Percocet or Zolpidem. There is not documentation of gastrointestinal disease or symptoms.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retro, Protonix 20mg #60, DOS: 9/2/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria 1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID low-dose ASA). Per the ODG, PPI's are "Recommended for patients at risk for gastrointestinal events. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole had been recommended before prescription Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)" A review of the injured workers medical records did not reveal past or current gastrointestinal complaints that would indicate that the injured worker is at risk for a gastrointestinal event, therefore the request for Retro, Protonix 20mg #60, DOS: 9/2/15 is not medically necessary.

**Retro, Voltaren 100mg #60 DOS: 9/2/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**Decision rationale:** Per the MTUS, NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-

term effectiveness for pain or function. A review of the injured workers medical records however do not reveal documentation of pain and functional improvement with the use of this medication, without this information continued use is not supported, therefore the request for Retro, Voltaren 100mg #60 DOS: 9/2/15 is not medically necessary.

**Retro, Zolpidem 10mg #30 DOS: 9/2/15: 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:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Zolpidem (Ambien).

**Decision rationale:** The MTUS did not specifically address the use of Ambien, therefore other guidelines were consulted. Per the ODG, Zolpidem is a prescription short-acting non-benzodiazepine hypnotic, which is recommended for short-term (7-10 days) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term, however given the risks there is no clear indication for the continued use of this medication in the injured worker, the risks outweigh the benefits and the continued use of Zolpidem is not medically necessary.

**Retro, Flurbiprofen 20%/ Baclofen 10%/ Dexamethasone 0.2%/ Hyaluronic acid 0.2% 240gm DOS: 9/2/15: Upheld**

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

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

**Decision rationale:** Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. There is no peer-reviewed literature to support the use of topical baclofen. A review of the injured workers medical records that are available to me does not show a trial of recommended first line agents that have failed and there are no extenuating circumstances that would warrant deviating from the guidelines, therefore the request for Retro, Flurbiprofen 20%/ Baclofen 10%/ Dexamethasone 0.2%/ Hyaluronic acid 0.2% 240gm DOS: 9/2/15 is not medically necessary.

**Retro, Amitriptyline HCl 10%/ Gabapentin 10%/ Bupivacaine Hcl 5%/ Hyaluronic acid 0.2% 240gm DOS: 9/2/15: Upheld**

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

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

**Decision rationale:** Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. There is no peer-reviewed literature to support the use of Gabapentin. This compounded product is not supported by the guidelines. A review of the injured workers medical records that are available to me also does not show a trial of recommended first line agents that have failed, therefore the request for Retro, Amitriptyline HCl 10%/ Gabapentin 10%/ Bupivacaine Hcl 5%/ Hyaluronic acid 0.2% 240gm DOS: 9/2/15 is not medically necessary.

**Retro Percocet 10/325mg #60, DOS: 9/2/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

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

**Decision rationale:** Per the MTUS, opioids should be discontinued if there is no overall improvement in function, unless there are extenuating circumstances, Opioids should be continued if the patient has returned to work or has improved functioning and pain. Ongoing management actions should include prescriptions from a single practitioner, taken as directed and all prescriptions from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. Documentation should follow the 4 A's of analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. Long term users of opioids should be regularly reassessed. In the maintenance phase the dose should not be lowered if it is working. Also, patients who receive opioid therapy may sometimes develop unexpected changes in their response to opioids, which includes development of abnormal pain, change in pain pattern, persistence of pain at higher levels than expected when this happens opioids can actually increase rather than decrease sensitivity to noxious stimuli. It is important to note that a decrease in opioid efficacy should not always be treated by increasing the dose or adding other opioids, but may actually require weaning. A review of the injured workers medical records that are available does not reveal any documentation of pain or functional improvement with the use of percocet, ongoing management actions as required by the guidelines were also not discussed,

without this information medical necessity for continued use is not supported, therefore the request for Retro Percocet 10/325mg #60, DOS: 9/2/15 is not medically necessary.