

Case Number:	CM15-0015569		
Date Assigned:	02/03/2015	Date of Injury:	09/11/2011
Decision Date:	03/23/2015	UR Denial Date:	01/15/2015
Priority:	Standard	Application Received:	01/27/2015

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: Ohio, North Carolina, Virginia
 Certification(s)/Specialty: Family Practice

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This 33 year old female sustained an industrial injury on 9/11/11, with subsequent ongoing back pain. Magnetic resonance imaging showed L4-S1 degenerative disc disease, T9-10 disc protrusion and facet arthropathy. Previous treatment included transcutaneous electrical nerve stimulator unit, physical therapy, medications, medial branch block and bilateral lumbar radiofrequency neurotomy. In a PR-2 dated 1/6/15, the injured worker complained of constant upper, mid and low back pain, rated 9/10 on the visual analog scale, associated with bilateral leg pain. Physical exam was remarkable for diffuse tenderness to palpation in bilateral spine paraspinal muscles. Current diagnoses included chronic pain disorder, chronic upper back pain T9-10, chronic low back pain L4-S1, degenerative disc disease and overweight. The treatment plan included continuing medications (Percocet, Gralise, Zipson and topical compound creams), continue smoke cessation, home exercise program and lumbar brace. On 1/15/15, Utilization Review noncertified a request for Zipsor 25 mg, sixty count with three refills, Gralise 600 mg, ninety count with three refills, Compound: Flurbiprofen 20% and Lidocaine 5%, and Compound: Cyclobenzaprine 10% and Lidocaine 5% citing CA MTUS Chronic Pain Medical Treatment Guidelines. As a result of the UR denial, an IMR was filed with the Division of Workers Comp.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zipsor 25 mg, sixty count with three refills: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG formulary

Decision rationale: The medical record reveals that the NSAIDS naproxen, ibuprofen, and Relafen were ineffective. Diclofenac(Zipsor) is not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients as did rofecoxib (Vioxx), which was taken off the market. According to the authors, this is a significant issue and doctors should avoid diclofenac because it increases the risk by about 40%. For a patient who has a 5% to 10% risk of having a heart attack, that is a significant increase in absolute risk, particularly if there are other drugs that don't seem to have that risk. For people at very low risk, it may be an option. In this instance, there is no history of failure with generic diclofenac although no form of diclofenac is approved on the ODG formulary. A 30 day supply of generic diclofenac costs [REDACTED] and a 30 day supply of Zipsor costs [REDACTED]. Because there is no documentation of a failure on generic diclofenac, Zipsor 25 mg, sixty count with three refills is not medically necessary.

Gralise 600 mg, ninety count with three refills: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG formulary

Decision rationale: Gralise is a long acting form of gabapentin that costs [REDACTED] per month and is listed as an "N" drug on the ODG formulary. Gabapentin costs [REDACTED] and is a "Y" drug on the ODG formulary. The medical record does not demonstrate a failure with generic gabapentin. Therefore, Gralise 600 mg, ninety count with three refills is not medically necessary.

Compound: Flurbiprofen 20% and Lidocaine 5%: 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: Compounds containing any ingredient that is not recommended is not recommended in its entirety. Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI

anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In this instance, the formulation contains lidocaine in non-patch form or so it appears from the request. This form of lidocaine is not recommended per the guidelines cited. Therefore, Flurbiprofen 20% and Lidocaine 5% is not medically necessary.

Compound: Cyclobenzaprine 10% and Lidocaine 5%: 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: Compounds containing any ingredient that is not recommended is not recommended in its entirety. Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. Additionally the use of topical muscle relaxants like cyclobenzaprine is not recommended. In this instance, the formulation contains lidocaine in non-patch form or so it appears from the request. This form of lidocaine is not recommended per the guidelines cited. The formulation also contains a topical muscle relaxant. Therefore, Cyclobenzaprine 10% and Lidocaine 5% is not medically necessary.