**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: Colorado
- 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 47 year old man sustained an industrial injury on 6/27/2013. The mechanism of injury is not detailed. Evaluations include cervical spine MRI dated 8/21/2013. Diagnoses include cervical radiculopathy, cervical facet pain, myofascial pain, and left shoulder pain. Treatment has included oral medications, radiofrequency facet neurolysis, and medical branch blocks. Physician notes on a PR-2 dated 3/11/2015 show complaints of persistent neck and left shoulder pain rated 4.10. Recommendations include Baclofen, Nabumatone, and follow up in five weeks. Patient also has existing request in place for Flexeril.

**IMR ISSUES, DECISIONS AND RATIONALES**

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

**Cyclobenzaprine 5 mg, sixty count:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 64 - 66.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 41-42, and 64.
**Decision rationale:** Cyclobenzaprine (Flexeril), and other antispasmodics are recommended for musculoskeletal pain associated with spasm, but only for a short course. It has been shown to help more than placebo with back pain and fibromyalgia, but has several side effects that limit its use. Furthermore, Cyclobenzaprine works best in the first 4 days of use, so short courses recommended, no more than 2-3 weeks. No quality consistent evidence exists to support chronic use of Cyclobenzaprine. The records supplied indicate patient has been taking Cyclobenzaprine greater than 3 months. The most current clinic note indicates patient taking Baclofen, so unclear if patient is even supposed to still be taking Cyclobenzaprine. Even if patient only takes the Cyclobenzaprine intermittently, its effectiveness diminishes so quickly, that its use after 3 months would yield little benefit relative to the risks of side effects, based on the evidence. As there is no support, per the guidelines, for long term use, the request for Cyclobenzaprine is not medically necessary.

**Baclofen 10 mg, thirty count:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 64 - 66.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 63-64.

**Decision rationale:** Per the Guidelines, muscle relaxers are recommended, as second line therapy for low back pain, primarily acute exacerbations of chronic issues. (Muscle relaxers are prescribed, however, for many musculoskeletal conditions) Some evidence suggests that muscle relaxers may help decrease pain and muscle spasm, and may increase mobility, but those effects are short lived. No benefit has been shown when muscle relaxers are added to non-steroidal anti-inflammatory drugs for pain. Appropriate effects of muscle relaxers diminish over time, and long term use with some can lead to dependence. Therefore, though these medications are commonly prescribed for a variety of conditions, they are not recommended as primary treatment for chronic painful musculoskeletal conditions. Of the muscle relaxers available, those with the least evidence to support their use include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou,2004) Baclofen is classified as an anti-spasticity drug, per the Guidelines, and works at the pre-synaptic and post-synaptic levels for GABA receptors. It is indicated to treat spasms and spasticity related to multiple sclerosis and spinal cord injuries, and has been used off label for paroxysmal neuropathy such as trigeminal neuralgia. Recommended dosing for Baclofen is 5mg 3 times per day, to titrate up as needed. Baclofen should not be abruptly discontinued due to possible hallucinations / seizures that may develop. For the patient of concern, the Baclofen is intended to be used for neck pain with related spasms. Per the records, the patient previously took Cyclobenzaprine as needed, but unclear if Cyclobenzaprine was stopped or Baclofen just to be added to regimen. There is no evidence to support the change from one muscle relaxer to another, or addition of second muscle relaxer because of lack of efficacy. Furthermore, patient does not have spasticity or spinal cord injury / multiple sclerosis, so Baclofen has little support for its use in this patient's condition. As patient has not had relief from previous extended use of muscle relaxer, including 2-4 weeks of Baclofen that patient purchased on his own, and as the Guidelines do not support the long term use of muscle relaxers regardless, the request for Baclofen is not medically necessary.
Nabumetone 750 mg, sixty count: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 67 - 73.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 67-68, 70, and 72.

Decision rationale: Per the Guidelines, non-steroidal anti-inflammatory drugs are recommended at the lowest effective dose for the shortest period needed, in moderate to severe pain from osteoarthritis, chronic low back pain, and exacerbations of chronic low back pain. However, acetaminophen may be considered as first line for those with significant gastrointestinal risk factors or cardiovascular / renal concerns, due to adverse effects that can occur with, non-steroidal anti-inflammatory drugs in regard to those systems. There is no evidence to suggest that one non-steroidal anti-inflammatory drug is better than another at relieving pain, though some have less documented gastrointestinal effects and others have possibly less cardiovascular effects, though these possible differences are disputed. There is no evidence-based information available that shows efficacy long term with non-steroidal anti-inflammatory drug treatment for pain and there are no known effects long term on overall function when using non-steroidal anti-inflammatory drug treatment. As above, a primary concern in choosing non-steroidal anti-inflammatory drugs instead of acetaminophen, would be risks for gastrointestinal events, which include: 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). If patient has risk factors for gastrointestinal event, then consider: 1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44) When considering non-steroidal anti-inflammatory drugs for chronic back pain, as an example, it is important to note that recent Cochrane reviews found no difference in pain levels when treated with non-steroidal anti-inflammatory drugs versus placebo, and no difference between treatment with non-steroidal anti-inflammatory drugs and acetaminophen. Furthermore, acetaminophen caused fewer side effects and adverse events than non-steroidal anti-inflammatory drugs or other pain relievers. (Roelofs-Cochrane, 2008) Per the records supplied for the patient of concern, there is no documentation of quantifiable measurement of functional improvement, and little evidence that the Nabumetone specifically has been useful in pain relief. Furthermore, there is no documentation in the records supplied that indicate patent has tried acetaminophen for pain in the past which would be first line therapy, and patient has been taking Nabumetone for longer than 3 months. Patient's extended use of Nabumetone exceeds recommended short course of use. With use exceeding recommended short course of non-steroidal anti-inflammatory drug and without evidence of use of acetaminophen first line, the Nabumetone is not medically necessary.