

<b>Case Number:</b>	CM13-0041602		
<b>Date Assigned:</b>	12/20/2013	<b>Date of Injury:</b>	05/22/1999
<b>Decision Date:</b>	04/24/2014	<b>UR Denial Date:</b>	10/17/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/29/2013

### 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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in North Carolina. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 patient is a 66-year-old with a reported date of injury of 5/22/1999. The patient's diagnosis include myalgia and myositis NOS, chronic depressive personality disorder, chronic pain disorder, degenerative arthritis of the cervical spine, adjustment disorder with mixed anxiety and depression and pain disorder. The most recent progress reports from the primary treating physician noted the patient subjective findings of continued total body pain, chronic fatigue, problem sleeping, morning gel phenomenon, but the medications was helpful. The objective findings showed no new joint swelling with a normal neurologic examination and no rheumatoid arthritis deformities. The treatment plan consisted of continued medications plus pool therapy. On 10/15/2013 a request for certification for Soma, Provigil, Ativan, Lyrica, aquatic therapy sessions, Therapentin, Flurbiprofen and a urine test was made.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **PRESCRIPTION OF SOMA 350MG, #60: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines MUSCLE RELAXANTS Page(s): 63-65.

**Decision rationale:** The Chronic Pain Guidelines indicate that muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most low back pain cases, they show no benefit beyond non-steroidal anti-inflammatory drugs (NSAIDs) in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Carisoprodol (Soma) is not recommended for longer than a two to three (2 to 3) week period. The patient has been on long term use of this medication for over one (1) year. Based on the above guidelines, long term use of muscle relaxants are not recommended and thus this medication is not warranted for continued use.

**PRESCRIPTION OF PROVIGIL 100MG, #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES, PAIN (CHRONIC).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG), PROVIGIL.

**Decision rationale:** The Official Disability Guidelines indicate that Provigil is not recommended solely to counteract the sedation effects of narcotics until after first considering reducing excessive narcotic prescribing. Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and shift work sleep disorder. Patients should have a complete evaluation with a diagnosis made in accordance with the International Classification of Sleep Disorders or DSM diagnostic classification. This drug has been known to be misused and/or abused, particularly by patients that have a history of drug or stimulant abuse. Provigil is indicated for excessive sleepiness associated with narcolepsy, obstructive sleep apnea and shift work sleep disorder. This patient does complain subjectively of fatigue, but does not carry any of the before mentioned diagnosis. Therefore, the continued use of Provigil is not indicated.

**PRESCRIPTION OF ATIVAN 5MG, #60: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines BENZODIAZAPINES Page(s): 24. Decision based on Non-MTUS Citation THE OFFICIAL DISABILITY GUIDELINES (ODG), BENZODIAZAPINES.

**Decision rationale:** The Chronic Pain Guidelines indicate that benzodiazapines are not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction. Most guidelines limit use to four (4)

weeks. Benzodiazepines are a major cause of overdose, particularly as they act synergistically with other drugs such as opioids (mixed overdoses are often a cause of fatalities). Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly (3-14 day). The Official Disabilities Guidelines indicate that tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Tolerance to lethal effects does not occur and a maintenance dose may approach a lethal dose as the therapeutic index increases. The best prevention for substance use disorders due to benzodiazepines is careful prescribing. Adults who use hypnotics, including benzodiazepines such as temazepam, have a greater than 3-fold increased risk for early death, according to results of a large matched cohort survival analysis. The risks associated with hypnotics outweigh any benefits of hypnotics, according to the authors. In 2010, hypnotics may have been associated with 320,000 to 507,000 excess deaths in the U.S. alone. A dose-response effect was evident, with a hazard ratio of 3.60 for up to 18 pills per year, 4.43 for 18-132 pills per year, and 5.32 for over 132 pills per year. Benzodiazepines that are commonly prescribed include the following: alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, & triazolam. Benzodiazepines are not recommended as first-line medications by the Official Disability Guidelines. The criteria for use if provider & payor agree to prescribe anyway: 1) Indications for use should be provided at the time of initial prescription; and 2) Authorization after a one-month period should include the specific necessity for ongoing use as well as documentation of efficacy. This patient has been on long term Ativan for greater than one (1) year. There has been no specific documentation of ongoing necessity of the medication. Past requests have recommended weaning and appropriate amounts for weaning have been certified. The continued use of the medication at the requested amount is not warranted.

### **REQUEST FOR 36 AQUATIC THERAPY SESSIONS: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines  
AQUATIC THERAPY Page(s): 22.

**Decision rationale:** The Chronic Pain Guidelines indicate that aquatic therapy is recommended as an optional form of exercise therapy, where available, as an alternative to landbased physical therapy. Aquatic therapy (including swimming) can minimize the effects of gravity, so it is specifically recommended where reduced weight bearing is desirable, for example extreme obesity. Water exercise improved some components of health-related quality of life, balance, and stair climbing in females with fibromyalgia, but regular exercise and higher intensities may be required to preserve most of these gains. There is no clinical indication given in the progress notes that support aquatic therapy over physical therapy. There is no evidence of extreme obesity or the need for reduced weight bearing and thus aquatic therapy is not warranted.

### **RETROSPECTIVE PRESCRIPTION OF THERAPENTIN #150 DOS: 9/30/13: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES, PAIN (CHRONIC).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines ANTI-EPILEPSY DRUGS Page(s): 16-18.

**Decision rationale:** Therapentin is a combination of gabapentin and Theramine. Theramine is a blend of gamma-aminobutyric acid (GABA), chlorine bitartrate, L-arginine and L-serine. Gabapentin is an anti-epilepsy drug used for neuropathic pain. The Chronic Pain Guidelines recommend this medication for neuropathic pain (pain due to nerve damage). There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. The Official Disability Guidelines do not recommend Theramine or GABA. There is no evidence or clinical support to recommend this "co-pack" of Theramine and gabapentin over the solo use of gabapentin alone.

**RETROSPECTIVE PRESCRIPTION OF FLURBIPROFEN #1 DOS: 9/30/13: 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): 111-112.

**Decision rationale:** The Chronic Pain Guidelines indicate that for non-steroidal anti-inflammatory drugs (NSAIDs), the efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first two (2) weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for four to twelve (4 to 12) weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Indications for use include: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment, which is recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. For neuropathic pain, it is not recommended, because there is no evidence to support use. The FDA-approved agents include: Voltaren® Gel 1% (diclofenac), which is indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. The maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity).

and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. Non FDA-approved agents include: Ketoprofen, which is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Absorption of the drug depends on the base it is delivered in. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. Flurbiprofen is an NSAID cream. There is no specific discussion of this NSAID cream, but the patient also does not have specifically mentioned osteoarthritis of the elbow or knee or a joint amenable to topical NSAID use, therefore the use of this medication is not warranted.

**RETROSPECTIVE REQUEST FOR ONE URINE TEST, DOS: 9/30/13: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS Page(s): 74-96.

**Decision rationale:** The Chronic Pain Guidelines recommend frequent random urine toxicology screens to avoid misuse of opioids and in particular those at high risk of abuse. The patient had received a total of five (5) urine drug screens in the year 2013 per the progress notes. All of the previous urine drug screens had been negative. According to the latest progress note, there was no indication that the patient was on continued opioids and there was no clinical indications to suspect other red flags as defined by the guidelines, that would indicate potential abuse. For these reasons, the urine drug screen is not indicated.