

<b>Case Number:</b>	CM14-0144151		
<b>Date Assigned:</b>	09/12/2014	<b>Date of Injury:</b>	06/19/2012
<b>Decision Date:</b>	11/10/2014	<b>UR Denial Date:</b>	08/14/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/05/2014

### 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 Neurology, has a subspecialty in Neuromuscular Medicine and is licensed to practice in New Jersey. 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 43-year-old man who sustained a work-related injury on June 19, 2012. Subsequently, he developed low back pain radiating to the right lower extremity. MRI of the lumbar spine performed November 5, 2012 showed that at L4-5 there are small symmetric disc bulges and mild ligamentum flavum buckling without center. Electromyography (EMG)/Nerve Conduction Velocity (NCV) study performed on June 20, 2014 revealed evidence of mild chronic S1 radiculopathy bilaterally. The pain has improved temporarily by the TENS unit, hot and cold packs, lying down, massage, medication, and stretching. The pain limits his daily activity 75% of the time and affects his sleep. The patient had a lumbar transforaminal epidural steroid injection on May 15, 2014. He reported significant improvement with resolution of the tingling sensation in his lower back. He reported excellent relief for 4-5 days after the injection. According to a progress report dated June 27, 2014, the patient complained of low back pain and pain that radiated down his right lower extremity to the right buttock and the posterior aspect of his leg. He has tingling in the buttock region. He gets spasm and stiffness in his low back and occasionally the radiation of his pain causes soreness in his right foot. He rated his pain as 5-8/10. He reported an acute flare-up of his lumbar pain described as aching. The patient continued to attend physical therapy sessions for sciatica. His physical examination of the lumbar spine revealed tenderness with reduced range of motion. Reflexes are 2+ and symmetric with bilateral knee jerks and ankle jerks. Motor strength is 5/5 and symmetric with leg flexion and extension, hip flexion and foot dorsiflexion and plantar flexion. There is pain with hip flexion testing, right greater than left, leading to low back and buttock pain. Sensation was diminished in the right L5 and right S1 distributions. Straight leg raise was positive on the right at 25 with pain originating in his back, radiating into his buttock and down his right lower extremity to his foot. The patient was diagnosed with L4-5 and L5-S1 herniated disc, foraminal stenosis at L5-S1, and

degenerative disc disease at L4-5 and L5-S1. An evaluation report dated June 23, 2014 documented that the patient has been experiencing abdominal pain. On exam, abdominal tenderness was noted and the patient was diagnosed with Gastroesophageal reflux disease secondary to NSAID's. The provider requested authorization to use Hydro/Bit/Acet and Duexis.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Hydro/Bit/Acet 10/325mg x 30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 91, 78.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of opioids Page(s): 78-79.

**Decision rationale:** According to MTUS guidelines, Hydrocodone Bit/Acet 2.5/325mg is a synthetic opioid indicated for the pain management but not recommended as a first line oral analgesic. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules:<(a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.(b) The lowest possible dose should be prescribed to improve pain and function.(c) Office: Ongoing review and documentation of pain relief, functional status,appropriate medication use, and side effects. Pain assessment should include: currentpain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework>There is no clear evidence of objective and recent functional and pain improvement with previous use of opioids. There is no clear documentation of the efficacy/safety of previous use of opioids. Therefore, the prescription of Hydrocodone Bit/Acet 10/325mg is not medically necessary at this time.

**Duexis 800mg x 90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Ibuprofen (Motrin, Advil, generic available).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

**Decision rationale:** Duexis is a combination of Ibuprofen and Famotidine. There is no documentation that the patient have a history of GI disease and failed the prescription of Famotidine separately. There is no controlled studies supporting the superiority of Duexis to Ibuprofen an Famotidine prescribed seprately. According to MTUS guidelines, Famotidine is indicated when NSAID are used in patients with intermediate or high risk for gastrointestinal events . The risk for gastrointestinal events are: (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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. . There is no controlled studies supporting the superiority of Famotidine to Duexis for the treatment of GI ulcer. Therefore, Duexis 800mg prescription is not medically necessary.

**Compound cream Flurbiprofen 25%:** 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.

**Decision rationale:** According to MTUS, in Chronic Pain Medical Treatment guidelines section Topical Analgesics (page 111), topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Many agents are combined to other pain medications for pain control. That is limited research to support the use of many of these agents. Furthermore, according to MTUS guidelines, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. There is no documentation that all component of the prescribed topical analgesic is effective for the treatment of back pain. There is no clear evidence that the patient failed or was intolerant to first line oral pain medications. Therefore, Flurbiprofen 25%, cream is not medically necessary.