

<b>Case Number:</b>	CM15-0133675		
<b>Date Assigned:</b>	07/21/2015	<b>Date of Injury:</b>	12/21/2001
<b>Decision Date:</b>	08/25/2015	<b>UR Denial Date:</b>	06/23/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/10/2015

### 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: Massachusetts

Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 49-year-old male with an industrial injury dated 12/21/2001. The injured worker's diagnoses include status post lumbar spine surgery, lumbar radiculopathy, right knee osteoarthritis, left knee sprain/strain and left knee chondromalacia patella. Treatment consisted of diagnostic studies, prescribed medications, and periodic follow up visits. In a progress note dated 04/13/2015, the injured worker reported constant low back pain radiating to the lower extremities with numbness and tingling and bilateral knee pain. The injured worker rated pain a 9/10. Objective findings revealed patellar grinding in the knees and full muscle strength at L5 and S1 bilaterally in the lower extremities. The treatment plan consisted of medication management, home exercise therapy and follow up appointment. The treating physician prescribed Norco 10/325mg #120, Percocet 10/325mg #120, Theramine #180 and Trepadone #120 now under review.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10/325mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids  
Page(s): 74-97.

**Decision rationale:** According to the MTUS Chronic Pain Medical Treatment Guidelines section on Opioids, On-Going Management, pages 74-97, (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: current pain; 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 injured worker'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 injured worker'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 injured workers 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 for documentation of the clinical use of these controlled drugs. (d) Home: To aid in pain and functioning assessment, the injured worker should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or injured worker treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to non-opioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Additionally, the MTUS states that continued use of opioids requires (a) the injured worker has returned to work, (b) the injured worker has improved functioning and pain. There is no current documentation of baseline pain, pain score with use of opioids, functional improvement on current regimen, side effects or review of potentially aberrant drug taking behaviors as outlined in the MTUS and as required for ongoing treatment. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**Percocet 10/325mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Percocet (Oxycodone & Acetaminophen).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids  
Page(s): 74-97.

**Decision rationale:** According to the MTUS Chronic Pain Medical Treatment Guidelines section on Opioids, On-Going Management, p 74-97, (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: current pain; 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 injured worker'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 injured worker'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 injured workers 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 for documentation of the clinical use of these controlled drugs. (d) Home: To aid in pain and functioning assessment, the injured worker should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or injured worker treatment with issues of abuse, addiction, or poor pain control.(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to non-opioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Additionally, the MTUS states that continued use of opioids requires (a) the injured worker has returned to work, (b) the injured worker has improved functioning and pain. There is no current documentation of baseline pain, pain score with use of opioids, functional improvement on current regimen, side effects or review of potentially aberrant drug taking behaviors as outlined in the MTUS and as required for ongoing treatment. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**Theramine #180:** 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 Chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Theramine.

**Decision rationale:** According to the official disability guidelines, Theramine is not recommended. Theramine is a medical food from Physician Therapeutics, Los Angeles, CA, that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma- aminobutyric acid (GABA), where it says there is no high quality peer-reviewed literature that suggests that GABA is indicated; Choline, where it says there is no known medical need for choline supplementation; L-Arginine, where it says this medication is not indicated in current references for pain or inflammation; & L-Serine, where it says there is no

indication for the use of this product. In this manufacturer study comparing Theramine to Naproxen; Theramine appeared to be effective in relieving back pain without causing any significant side effects. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**Trepadone #120:** 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 Chapter, Trepadone (2015).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Trepadone.

**Decision rationale:** According to the ODG, Trepadone is a medical food and is non-recommended. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.