

<b>Case Number:</b>	CM14-0172720		
<b>Date Assigned:</b>	12/12/2014	<b>Date of Injury:</b>	11/01/2000
<b>Decision Date:</b>	01/15/2015	<b>UR Denial Date:</b>	10/01/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/20/2014

### 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 Preventive Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Iowa. 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:

This is a 61 year old patient with date of injury of 11/01/2000. Medical records indicate the patient is undergoing treatment for lumbar radiculopathy, chronic pain syndrome, chronic pain related insomnia, myofascial syndrome, neuropathic pain, prescription narcotic dependence, chronic pain related depression and tension headaches. Subjective complaints include low back pain, left shoulder pain, right hip and leg pain, pain rated at 10/10 without medication and 6/10 with medication but reports her average pain over the weeks preceding visit was 8/10 with nausea and difficulty sleeping. Objective findings include vital signs within normal limits. Treatment has consisted of four pronged cane, Pristiq, Opana, Theramine, Prilosec, 5HTP, Fluriflex, Idrasil, Flector, Medrox, Sintralyne, Trazodone, Flexeril and Cidaflex. The utilization review determination was rendered on 10/01/2014 recommending non-certification of Urine Drug Screen, Kava Kava #90, Opana 40 MG #60 and Opana IR 10 MG #120.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Urine Drug Screen:** 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 and Substance abuse Page(s): 74-96, 108-109. Decision based on Non-MTUS Citation

University of Michigan Health System Guidelines for Clinical Care: Managing Chronic Non-terminal Pain, Including Prescribing Controlled Substances (May 2009), pg 32 Established Patients Using a Controlled Substance.

**Decision rationale:** MTUS states that use of urine drug screening for illegal drugs should be considered before therapeutic trial of opioids are initiated. Additionally, "Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion) would indicate need for urine drug screening. There is insufficient documentation provided to suggest issues of abuse, addiction, or poor pain control by the treating physician. University of Michigan Health System Guidelines for Clinical Care: Managing Chronic Non-terminal Pain, Including Prescribing Controlled Substances (May 2009) recommends for stable patients without red flags "twice yearly urine drug screening for all chronic non-malignant pain patients receiving opioids - once during January-June and another July-December". The patient has been on chronic opioid therapy and has taken multiple urine drug screens without any inconsistencies in the results. The treating physician has not indicated why a urine drug screen is necessary at this time and has provided no evidence of red flags. As such, the request for Urine Drug Screen is not medically necessary.

**Kava Kava #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Mental Illness and Stress (Acute and Chronic)

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Medical Food. <http://www.webmd.com/vitamins-supplements/ingredientmono-872-kava.aspx?activeingredientid=872&activeingredientname=kava>.

**Decision rationale:** MTUS is silent concerning Kava Kava. ODG states that a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation". ODG goes on to state "There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision". WebMD states "There are some BIG safety concerns about kava. Many cases of liver damage and even some deaths have been traced to kava use. As a result, kava has been banned from the market in

Switzerland, Germany, and Canada, and several other countries are considering similar action". The treating physician does not indicate any change in the patient anxiety or depression symptoms while taking this supplement. With the concerns for hepatic toxicity and the lack of changes in this patient's symptoms, the Prospective request for 1 prescription of Kava Kava #90 is not medically necessary.

**Opana 40 MG #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Acute and Chronic)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Lumbar & Thoracic (Acute & Chronic), Opioids & Pain, Opana.

**Decision rationale:** ODG does not recommend the use of opioids for low back "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "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 patient's decreased pain, increased level of function, or improved quality of life." ODG does not recommend the use of Opana specifically, guidelines state "Not recommended. See Opioids for general guidelines, as well as specific Oxymorphone (Opana) listing for more information and references. Due to issues of abuse and Black Box FDA warnings, Oxymorphone is recommended as second line therapy for long acting opioids. Oxymorphone products do not appear to have any clear benefit over other agents and have disadvantages related to dose timing (taking the IR formulation with food can lead to overdose), and potential for serious adverse events (when the ER formulation is combined with alcohol use a potentially fatal overdose may result). (Opana FDA labeling)" Medical documentation provided indicates that this medication has been previously weaned and noncertified for this patient. The treating physician has requested two separate prescriptions for Opana and combined they total 360 morphine equivalent dose (MED), far exceeding the guideline recommendations of 120 MED. As such the request for Opana 40 MG #60 is not medically necessary.

**Opana IR 10 MG #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 (ODG), Pain (Acute and Chronic)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Lumbar & Thoracic (Acute & Chronic), Opioids & Pain, Opana.

**Decision rationale:** ODG does not recommend the use of opioids for low back "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "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 patient's decreased pain, increased level of function, or improved quality of life." ODG does not recommend the use of Opana specifically, guidelines state "Not recommended. See Opioids for general guidelines, as well as specific Oxymorphone (Opana) listing for more information and references. Due to issues of abuse and Black Box FDA warnings, Oxymorphone is recommended as second line therapy for long acting opioids. Oxymorphone products do not appear to have any clear benefit over other agents and have disadvantages related to dose timing (taking the IR formulation with food can lead to overdose), and potential for serious adverse events (when the ER formulation is combined with alcohol use a potentially fatal overdose may result). (Opana FDA labeling)" Medical documentation provided indicates that this medication has been previously weaned and noncertified for this patient. The treating physician has requested two separate prescriptions for Opana and combined they total 360 morphine equivalent dose (MED), far exceeding the guideline recommendations of 120 MED. As such the request for Opana IR 10 MG #120 is not medically necessary.