

<b>Case Number:</b>	CM14-0134444		
<b>Date Assigned:</b>	08/27/2014	<b>Date of Injury:</b>	10/05/2011
<b>Decision Date:</b>	09/25/2014	<b>UR Denial Date:</b>	08/06/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/20/2014

### 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 Anesthesiology, has a subspecialty in Pain Management and is licensed to practice in California. 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:

According to the records made available for review, this is a 43-year-old female with a 10/5/11 date of injury, status post L5-S1 discectomy, interbody fusion with fixation 1/27/07, and status post hardware removal 6/5/09. At the time (6/9/14) of request for authorization for Duragesic 25mcg/hr patch, Hydrocodone/Acetaminophen 10/325mg QTY 240, and Opana ER 20mg QTY 60, there is documentation of subjective (continued pain in neck described as aching and constant, shoulder pain located in both acromioclavicular joints, and pain 5/10 with medications) and objective (decreased cervical range of motion, tender at lumbar spine and facet joint, and decreased lumbar range of motion) findings, current diagnoses (cervical pain/cervicalgia, myofascial pain syndrome/fibromyalgia, and other affections of shoulder region, not elsewhere classified), and treatment to date (medications (including ongoing treatment with Lyrica, Miralax, Duragesic patch, Opana, Soma, Amrix, and hydrocodone/acetaminophen)). Regarding Duragesic 25mcg/hr patch, there is no documentation of pain that requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means, demonstrated opioid tolerance; no contraindications exist, and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Duragesic patch use to date. Regarding Hydrocodone/Acetaminophen 10/325mg QTY 240, there is no documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is being prescribed; there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Hydrocodone/Acetaminophen use to date. Regarding Opana ER 20mg QTY 60, there is no documentation that the prescriptions are from a single practitioner and are

taken as directed; the lowest possible dose is being prescribed; there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects, Opana used as second line therapy for long acting opioids, and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Opana use to date

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

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

**Duragesic 25mcg/hr patch:** 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic (fentanyl transdermal system) Page(s): 44. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Duragesic and Fentanyl.

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines identifies documentation of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means, as criteria necessary to support the medical necessity of Duragesic. MTUS Chronic Pain Medical Treatment Guidelines identifies that Duragesic is not recommended as first-line therapy. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. ODG identifies documentation that Duragesic is not for use in routine musculoskeletal pain. FDA identifies documentation of persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means; that the patient is already receiving opioid therapy, has demonstrated opioid tolerance, and requires a total daily dose at least equivalent to Duragesic 25 mcg/h; and no contraindications exist, as criteria necessary to support the medical necessity of Duragesic patch. Within the medical information available for review, there is documentation of diagnoses of cervical pain/cervicalgia, myofascial pain syndrome/fibromyalgia, and other affections of shoulder region, not elsewhere classified. In addition, there is documentation of persistent, moderate to severe chronic pain; that the patient is already receiving opioid therapy, and requires a total daily dose at least equivalent to Duragesic 25 mcg/h. However, there is no documentation of pain that requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means, demonstrated opioid tolerance; and no contraindications exist. In addition, given documentation of ongoing treatment with Duragesic patch, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Duragesic patch use to date. Therefore, based on guidelines and a review of the evidence, the request for Duragesic 25mcg/hr patch is not medically necessary.

**Hydrocodone/Acetaminophen 10/325mg QTY 240: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76,77,78,86,91.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-80.

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines necessitate documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is being prescribed; and there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects, as criteria necessary to support the medical necessity of opioids. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Within the medical information available for review, there is documentation of diagnoses of cervical pain/cervicalgia, myofascial pain syndrome/fibromyalgia, and other affections of shoulder region, not elsewhere classified. However, there is no documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is being prescribed; and there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. In addition, given documentation of ongoing treatment with Hydrocodone/Acetaminophen, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Hydrocodone/Acetaminophen use to date. Therefore, based on guidelines and a review of the evidence, the request for Hydrocodone/Acetaminophen 10/325mg QTY 240 is not medically necessary.

**Refill Hydrocodone/Acetaminophen 10/325mg QTY 240: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76,77,78,86,91.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-80.

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines necessitate documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is being prescribed; and there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects, as criteria necessary to support the medical necessity of opioids. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Within the medical information available for review, there is

documentation of diagnoses of cervical pain/cervicalgia, myofascial pain syndrome/fibromyalgia, and other affections of shoulder region, not elsewhere classified. However, there is no documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is being prescribed; and there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. In addition, given documentation of ongoing treatment with Hydrocodone/Acetaminophen, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Hydrocodone/Acetaminophen use to date. Therefore, based on guidelines and a review of the evidence, the request for Hydrocodone/Acetaminophen 10/325mg QTY 240 is not medically necessary.

**Refill Hydrocodone/Acetaminophen 10/325mg QTY 240: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76,77,78,86,91.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-80.

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines necessitate documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is being prescribed; and there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects, as criteria necessary to support the medical necessity of opioids. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Within the medical information available for review, there is documentation of diagnoses of cervical pain/cervicalgia, myofascial pain syndrome/fibromyalgia, and other affections of shoulder region, not elsewhere classified. However, there is no documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is being prescribed; and there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. In addition, given documentation of ongoing treatment with Hydrocodone/Acetaminophen, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Hydrocodone/Acetaminophen use to date. Therefore, based on guidelines and a review of the evidence, the request for Hydrocodone/Acetaminophen 10/325mg QTY 240 is not medically necessary.

**Opana ER 20mg QTY 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 (web Updated 7/10/14).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-80. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Oxymorphone (Opana).

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines necessitate documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is being prescribed; and there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects, as criteria necessary to support the medical necessity of opioids. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. ODG identifies Opana as second line therapy for long acting opioids. Within the medical information available for review, there is documentation of diagnoses of cervical pain/cervicalgia, myofascial pain syndrome/fibromyalgia, and other affections of shoulder region, not elsewhere classified. However, there is no documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is being prescribed; there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. In addition, there is no documentation of Opana used as second line therapy for long acting opioids. Furthermore, given documentation of ongoing treatment with Opana, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Opana use to date. Therefore, based on guidelines and a review of the evidence, the request for Opana ER 20mg QTY 60 is not medically necessary.