

Case Number:	CM14-0158956		
Date Assigned:	10/02/2014	Date of Injury:	06/08/1994
Decision Date:	11/06/2014	UR Denial Date:	09/20/2014
Priority:	Standard	Application Received:	09/29/2014

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 Family Medicine 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:

This 61-year old strawberry picker reported a low back injury after a fall at work on 6/7/1994. Her medical history is notable for diabetes, hypertension and hypothyroidism. Documented past treatment for her injury has included medications, back surgery, and epidural steroid injections. She has been scheduled for implantation of an intrathecal pain pump. The most recent progress note in the records from the primary treater is dated 9/9/14. According to the note, the patient has chronic severe low back pain that radiates to lower extremities. Average pain with medications is 10/10, with medications it is 7/10. The note states that the prescribed medications keep the patient functional, allow for increased mobility, and for tolerance of activities of daily living (ADLs) and home exercises. She is described as exercising three times per week, which consists of swinging and walking in water. She is in a wheel chair. Her work status is temporarily totally disabled. Diagnoses include post lumbar laminectomy syndrome, degenerative lumbosacral and cervical disc disease, thoracic and lumbosacral radiculitis, myalgia and myositis, peripheral neuropathy, and abdominal pain. She is on 32 different medications, of which only those for pain, muscle relaxation, or psychological diagnoses are listed here. These include Duragesic, Opana ER, Skelaxin, Lyrica, Flector patches, Voltaren, Vibryd, Cymbalta, Trazodone, Clonazepam, Wellbutrin, Ambien and Budeprion. The plan included prescribing Opana ER 40 mg, up to three per day, #90; and Duragesic 100mcg patches one every three days #10; and scheduling an intrathecal pump trial. There are 7 other monthly progress notes in the records, ranging from 2/25/14 to 8/12/14. At all these visits, the patient's dose and number dispensed of both Duragesic and Opana were exactly the same as on 9/9/14. All visit notes contained the statement that medications helped the patient's function, mobility, tolerance of ADLs and exercise (quoted above). Except for one early visit where the patient was using a walker, she was in a wheelchair. Her exercise level was consistently described as swinging and

walking in water three times per week, duration unspecified. She remained very obese throughout the 7 months (BMI over 35). Her pain levels did not significantly change over the seven-month period. She remained totally disabled. Virtually all of the notes contain a statement that the patient has been asked to taper her opioid medications as much as possible, but no tapering has occurred. There are two previous UR reports in the records in which Duragesic and Opana were non-certified or modified to allow for tapering.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 prescription of Opana ER 40 mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain, Opioids Dosing.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, Criteria for Use of Opioids, Opioids for neuropathic pain, and Opi.

Decision rationale: Opana ER is brand-name long-acting oxymorphone, which is an opioid analgesic. Per the first guideline cited above, medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. Per the second guideline, opioids should not be started without an evaluation of the patient's current status in terms of pain control and function. An attempt should be made to determine if the patient's pain is nociceptive or neuropathic. Red flags indicating that opioid use may not be helpful should be identified, as should risk factors for abuse. Specific goals should be set, and continued use of opioids should be contingent on meeting these goals. Opioids should be discontinued if there is no improvement in function or if there is a decrease in function. Per the third guideline, opioids are not recommended as first-line therapy for neuropathic pain. The response of neuropathic pain to drugs may depend on the cause of the pain. There are very limited numbers of studies that involve opioid treatment for chronic lumbar root pain. A recent study found that chronic radicular lumbar pain did not respond to opioids in doses that have been effective for painful diabetic neuropathy and postherpetic neuralgia. Patients taking opioids sometimes develop abnormal pain, a change in pain pattern, or persistence in pain at higher levels than expected, which are actually a result of taking opioids. This is called opioid hyperalgesia. According to the last MTUS guideline cited above, opioid hyperalgesia should be screened for, as it actually may require weaning off opioids rather than increasing doses. The clinical findings in this case do not demonstrate that any of the above criteria have been met. There is no documentation that Opana ER was introduced individually, with ongoing careful assessment of function. There is no documentation of evaluation of whether or not the patient's pain is nociceptive or neuropathic. No documented assessment was made of whether or not opioid use was likely to be helpful in this patient, or of her potential for abuse. No specific functional goals were set or followed. Most importantly, Opana ER was not discontinued when it became clear that it has not produced any functional improvement. This patient's level of function is documented as exactly the same from 2/24/14 to 9/9/14. Although her medications are described as helping her mobility and

function levels, she remains wheelchair-bound and totally disabled, and it is unlikely that this represents an improvement over her status without Opana. This is more than adequate evidence that this patient is not responding appropriately to this medication, and that it should be discontinued. Based on the evidence-based guidelines cited above and on the clinical findings in this case, Opana ER is not medically indicated for this patient. Opana ER is not medically necessary due to the lack of appropriate documentation prior to beginning it, on the failure to set and monitor functional goals, on the failure to monitor for opioid-induced hyperalgesia, and on the failure to discontinue it when it became clear that it has not produced any functional recovery.

1 prescription of Duragesic 100 mcg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, Criteria for Use of Opioids, Opioids for neuropathic pain, and Opi.

Decision rationale: Duragesic 100 mcg is a controlled-release patch form of Fentanyl, which is an opioid analgesic. Per the first guideline cited above, medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. Per the second guideline, opioids should not be started without an evaluation of the patient's current status in terms of pain control and function. An attempt should be made to determine in the patient's pain is nociceptive or neuropathic. Red flags indicating that opioid use may not be helpful should be identified, as should risk factors for abuse. Specific goals should be set, and continued use of opioids should be contingent on meeting these goals. Opioids should be discontinued if there is no improvement in function or if there is a decrease in function. Per the third guideline, opioids are not recommended as first-line therapy for neuropathic pain. The response of neuropathic pain to drugs may depend on the cause of the pain. There are very limited numbers of studies that involve opioid treatment for chronic lumbar root pain. A recent study found that chronic radicular lumbar pain did not respond to opioids in doses that have been effective for painful diabetic neuropathy and postherpetic neuralgia. Patients taking opioids sometimes develop abnormal pain, a change in pain pattern, or persistence in pain at higher levels than expected, which are actually a result of taking opioids. This is called opioid hyperalgesia. According to the last MTUS guideline cited above, opioid hyperalgesia should be screened for, as it actually may require weaning off opioids rather than increasing doses. The clinical findings in this case do not demonstrate that any of the above criteria have been met. There is no documentation that Duragesic was introduced individually, with ongoing careful assessment of function. There is no documentation of evaluation of whether or not the patient's pain is nociceptive or neuropathic. No documented assessment was made of whether or not opioid use was likely to be helpful in this patient, or of her potential for abuse. No specific functional goals were set or followed. Most importantly, Duragesic was not discontinued when it became clear that it has not produced any functional improvement. This patient's level of function is documented as exactly the same from 2/24/14 to 9/9/14. Although her medications are described as helping her mobility and function levels, she remains wheelchair-bound and totally disabled, and it is unlikely that this represents an improvement over her status without Duragesic. This is more than adequate evidence that this patient is not responding appropriately to this medication, and that it should be

discontinued. Based on the evidence-based guidelines cited above and on the clinical findings in this case, Duragesic is not medically indicated for this patient. Duragesic 100 mcg is not medically necessary due to the lack of appropriate documentation prior to beginning it, on the failure to set and monitor functional goals, on the failure to monitor for opioid-induced hyperalgesia, and on the failure to discontinue it when it became clear that it has not produced any functional recovery.