MAXIMUS Federal Services

Case Number:	CM14-0157599		
Date Assigned:	09/30/2014	Date of Injury:	11/30/2010
Decision Date:	10/28/2014	UR Denial Date:	09/08/2014
Priority:	Standard	Application Received:	09/25/2014

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 Colorado. 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 52 year old female with date of injury 11/30/2010, continues care with treating physician for Lumbar radiculopathy and Failed Back Surgery Syndrome. Records reviewed included handwritten progress notes from treating physician, March 2014 - September 2014, and inpatient medication record from post-surgery in 2013. Per the first office note available, visit date 3/14/2014, patient was already taking Lyrica, Flexeril, and Oxycontin, with pain rated 9/10, dull and achy. Patient also complained of difficulty sleeping. Plan is unclear on the note other than refill of medications. Note from office visit 4/11/2014, indicates 2 additional medications, Dilaudid (Hydromorphone) and Ambien, that patient is taking and pain continues at 7/10, dull and achy with decreased reflexes and complaints of numbness in bilateral legs. Plan on that date indicated Psychiatric Evaluation and Spinal Cord Stimulator trial for 10 days. As of 5/9/2014 office visit, Cymbalta (Duloxetine) has been added to medication list, and pain is rated 8/10. Plan, per the notes, was refill of medications and follow up 1 month. As of 6/7/2014 office visit, treating physician documents physical findings and subjective complaints that are essentially unchanged, and indicates continued need for Psychiatric evaluation and Spinal cord stimulator in the plan. Medications were refilled again on this date. Per the note for 7/19/2014 office visit, patient continues to complain of 6-8/10 pain and treating physician increased Dilaudid (Hydromorphone) from 4mg dose to 8mg dose. Notes for 8/8/2014 and 9/13/2014 visits do not indicate any improvement in symptoms with pain rating 9/10, and indicate a new symptom of right hip pain. Retroactive review is requested for prescriptions for Dilaudid (Hydromorphone), Lyrica, Oxycontin, and Cymbalta (Duloxetine).

IMR ISSUES, DECISIONS AND RATIONALES

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

Hydromorphone 8mg, qty 90, dos 9/3/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 93.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 60,76,78-79,81,83,88,95.

Decision rationale: This patient has chronic pain related to failed back surgery syndrome and lumbar radiculopathy after injury in 2010. Per the guidelines, criteria for use of opioids includes questions that should be addressed when initiating / continuing opioids: 1) Are there reasonable alternatives to treatment, and have these been tried? 2) Is the patient likely to improve? Examples: Was there improvement on opioid treatment in the acute and sub-acute phases? Were there trials of other treatment, including non-opioid medications? The records supplied for review do not indicate that opioids have been successful for patient, ever. Patient rates pain at all visits almost exactly same, and then even worse at times, with no lasting improvement. Other than Acetaminophen in the post-operative period, no documentation of sustained use of other non-opioid therapies was provided. The patient has been on opioids for an unspecified time, but at least 6 months based on the records supplied. Per the guidelines, there is no evidence that long term opioid use (more than 16 weeks) provides long term improvement in function for chronic back pain, and opioid use is not generally recommended to start for treatment of lumbar root pain / radiculopathy. When opioids are prescribed for long-term use, ongoing monitoring is recommended by the guidelines to verify continued need and appropriate use. The 4 A's for Ongoing Monitoring are analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. The treating physician documented pain level each visit, which did not improve. He documented the absence of a single side effect (constipation) each visit, but he made no mention of functional changes or changes in activities of daily living, and he did not address whether or not any aberrant drug-taking behaviors were present / evaluated. The guidelines do specify that continuing opioids long term may be appropriate if patient has returned to work and/or if pain and function have improved. The records supplied for review do not indicate if patient is working and as mentioned above, do not indicate functional status. Furthermore, pain has not improved on the opioids. Reasons to discontinue opioid therapy, per the guidelines, include development of hyperalgesia and/or failure to improve pain and/or function. (Chronic opiate use can sometimes result in a change in patient response to opioids, causing abnormal increase in pain. In these cases, opioids can actually increase rather than decrease sensitivity to noxious stimuli. Sometimes the weaning of opioid medication then is more appropriate than increased dosing.(Chang, 2007) Patient's pain, which never improved significantly on opioids per the notes supplied, actually was worse at 9/10 at the 2 visits after Hydromorphone was increased to 8mg, suggesting hyperalgesia. Given the possible hyperalgesia and failure to improve with opioids regardless, continued long term opioid use and request for higher dose Hydromorphone are not medically necessary.

Lyrica 75mg, qty. 120, dos 9/3/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Specific Anti-epilepsy Drugs Page(s): 19-20.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 76-17,and 19-20.

Decision rationale: Per the guidelines, no randomized controlled trials exist to recommend Lyrica, or other anti-epileptic drugs, for treatment of radiculopathy. When Lyrica is used for pain relief, "good" response can be defined as a 50% reduction in pain and a "moderate" response as a 30% reduction in pain. If patient does not achieve at least 30% improvement in pain, then changes should be considered: Switch to different first line agent or use Lyrica in combination with other agents. If therapy with Lyrica is initiated, the pain level, functional improvement or lack thereof and side effects should be followed and documented. Lyrica is FDA-approved for diabetic neuropathy and post-herpetic neuralgia. and is first-line treatment for both. Lyrica is also the first FDA-approved treatment for fibromyalgia. (ICSI,2007) (Tassone, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Crofford, 2005) (Stacey, 2008). As Lyrica has no indication for or evidence to support its use in radiculopathy, and no evidence that it has improved pain or function for this patient, Lyrica is not medically necessary.

Oxycontin 40mg, qty. 90, dos 8/20/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 92.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s):) 60, 76, 78-79, 81, 83, 88.

Decision rationale: This patient has chronic pain related to failed back surgery syndrome and lumbar radiculopathy after injury in 2010. The records supplied for review do not indicate that opioids have been helpful for patient. Patient rates pain at all visits almost exactly the same, and then even worse at times, with no lasting improvement. Patient has tried Acetaminophen, documented on post-operative records in 2013, but has not tried any other non-opioid therapies, at least not any documented. The patient has been on opioids for an unspecified time, but at least 6 months based on the records supplied. Per the guidelines, there is no evidence that long term opioid use (more than 16 weeks) provides long term improvement in function for chronic back pain, and opioid use is not generally recommended to start for treatment of lumbar root pain / radiculopathy. When opioids are prescribed for long-term use, ongoing monitoring is recommended by the guidelines to verify continued need and appropriate use. The recommended 4 A's for Ongoing Monitoring are analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. The treating physician documented pain level each visit, which did not improve. He documented the absence of a single side effect (constipation) each visit, but he made no mention of functional changes or changes in activities of daily living, and he did not address whether or not any aberrant drug-taking behaviors were present / evaluated. The guidelines do specify that continuing opioids long term may be appropriate if patient has returned to work and/or if pain and function have improved. The records supplied for review do not indicate if patient is working and as mentioned above, do not indicate functional status.

Furthermore, pain has not improved on the opioids. Reasons to discontinue opioid therapy, per the guidelines, include development of hyperalgesia and/or failure to improve pain and/or function. Given patient failure to improve with opioids, lack of adequate documentation of functional status, and lack of adequate monitoring of opioid use, continued long term opioid use and request for Oxycontin is not medically necessary.

Lyrica 75mg, qty. 60, dos 8/20/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Specific Anti-epilepsy Drugs Page(s): 19-20.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 16-17 and 19-20.

Decision rationale: The rationale for the decision on this request is the same as the rationale for previous request for Lyrica. Per the guidelines, no randomized controlled trials exist to recommend Lyrica, or other anti-epileptic drugs, for treatment of radiculopathy. When Lyrica is used, a "good" response can be defined as a 50% reduction in pain and a "moderate" response as a 30% reduction in pain. If patient does not achieve at least 30% improvement in pain, then changes should be considered including switch to alternate first line agent or use in combination with other agents. If therapy with Lyrica is initiated, the pain level, functional improvement or lack thereof and side effects should be followed and documented. Lyrica is FDA-approved for diabetic neuropathy and post-herpetic neuralgia. and is first-line treatment for both. Lyrica is also the first FDA-approved treatment for fibromyalgia. (ICSI,2007) (Tassone, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Crofford, 2005) (Stacey, 2008). As Lyrica has no indication for and no evidence to support its use in radiculopathy, and no evidence that it has improved pain or function for this patient, Lyrica is not medically necessary.

Hydromorphone 4mg, qty 90, dos 8/20/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 93.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 60, 76, 78-79, 81, 83, 88.

Decision rationale: Rationale is much the same for 4mg Hydromorphone as it was for 8mg Hydromorphone above.Patient has chronic pain related to failed back surgery syndrome and lumbar radiculopathy after injury in 2010. The records supplied for review do not indicate that opioids have been helpful for patient. Patient rates pain at all visits almost exactly same, and then even worse at times, with no lasting improvement. Patient has tried Acetaminophen, documented on post-operative records in 2013, but has not tried any other non-opioid therapies, at least not any documented.The patient has been on opioids for an unspecified time, but at least 6 months based on the records supplied. Per the guidelines, there is no evidence that long term opioid use (more than 16 weeks) provides long term improvement in function for chronic back pain, and opioid use is not generally recommended to start for treatment of lumbar root pain /

radiculopathy.When opioids are prescribed for long-term use, ongoing monitoring is recommended by the guidelines to verify continued need and appropriate use. The 4 A's for Ongoing Monitoring are analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. The treating physician documented pain level each visit, which did not improve. He documented the absence of a single side effect (constipation) each visit, but he made no mention of functional changes or changes in activities of daily living, and he did not address whether or not any aberrant drug-taking behaviors were present / evaluated. The guidelines do specify that continuing opioids long term may be appropriate if patient has returned to work and/or if pain and function have improved. The records supplied for review do not indicate if patient is working and as mentioned above, do not indicate functional status. Furthermore, pain has not improved on the opioids. Reasons to discontinue opioid therapy, per the guidelines, include development of hyperalgesia and/or failure to improve pain and/or function. Given patient failure to improve with opioids regardless, continued long term opioid use and request for Hydromorphone is not medically necessary.

Duloxetine 60mg, qty. 30, dos 8/20/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Specific Antidepressants Page(s): 15-16.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 14-16 and 43-44.

Decision rationale: While Duloxetine can be used off label for chronic pain and radiculopathy, no high quality evidence supports use of Duloxetine in lumbar radiculopathy treatment. It is recommended as an option in first-line treatment of neuropathic pain. Per the guidelines, Duloxetine(Cymbalta) is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRIs). It has FDA approval for treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy, and has been found to be effective for treating fibromyalgia in women with and without depression, 60 mg once or twice daily. (Arnold, 2005). Furthermore, improvement in symptoms with Duloxetine generally is noted within 1 week of starting the medications. Maximum recommended dosing for off label use for chronic pain is Duloxetine 60mg daily. Patient has been taking Duloxetine at the recommended dose for at least 3 months at time of the request for refill approval. Per the records provided, no improvement in pain has been noted since patient started Duloxetine, and patient is taking it for an off label indication with no evidence to support use for radiculopathy, so the request to continue Duloxetine is not medically necessary.