MAXIMUS Federal Services

Case Number:	CM15-0104191		
Date Assigned:	06/12/2015	Date of Injury:	03/13/2014
Decision Date:	09/25/2015	UR Denial Date:	05/16/2015
Priority:	Standard	Application Received:	06/01/2015

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: California
Certification(s)/Specialty: Emergency Medicine

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 a 39-year-old male, who sustained an industrial injury on 03/13/2014. On provider visit dated 05/07/2015 the injured worker has reported experiencing withdrawal symptoms from medication, and reported of using marijuana to help with symptoms. The diagnoses have included insomnia, low back pain, lumbar radiculopathy, degenerative of lumbosacral intervertebral disc, anxiety disorder and lumbosacral spondylosis without myelopathy. The injured worker was noted to be discharge from practice due to noncompliance of controlled substances and marijuana usage. Treatment to date has included medication and laboratory studies. The provider requested Benadryl 25mg, Gabapentin 300mg, Gabapentin 600mg, Lidoderm patch, Clonidine HCL, Diazepam, Xanax, Diphenhydramine 35mg, Promethazine 25mg and Methocarbamol 750mg.

IMR ISSUES, DECISIONS AND RATIONALES

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

Benadryl 25mg #28: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness and Stress, Diphenhydramine (Benadryl).

Decision rationale: The request is for the use of Benadryl (Diphenhydramine) medication. The ODG guidelines advise the following regarding its use: Not recommended. See Insomnia treatment, where sedating antihistamines are not recommended for long-term insomnia treatment. The AGS updated Beers criteria for inappropriate medication use includes Diphenhydramine. (AGS, 2012) Anti-cholinergic drugs, including Diphenhydramine, may increase the risk for dementia by 50% in older adults. There is an obvious dose-response relationship between anti-cholinergic drug use and risk of developing dementia, but chronic use, even at low doses, would be in the highest risk category. While there is awareness that these drugs may cause short-term drowsiness or confusion, which is included in the prescribing information, there is no mention of long-term effects on cognition, and generally awareness of this issue is very low, and both the public and doctors need to be encouraged to use alternative treatments where possible. (Gray, 2015) As stated above, the use of this medication is not indicated. This is secondary to poor clinical evidence regarding its safe and effective use. As such, the request is not medically necessary.

Gabapentin 300mg #90 with three refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-17 of 127.

Decision rationale: The request is for the use of a medication in the category of an anti-epileptic drug (AED). These medications are recommended for certain types of neuropathic pain. Most of the randomized clinical control trials involved include post-herpetic neuralgia and painful polyneuropathy such as in diabetes. There are few trials which have studied central pain or radiculopathy. The MTUS guidelines state that a good response to treatment is 50% reduction in pain. At least a 30% reduction in pain is required for ongoing use, and if this is not seen, this should trigger a change in therapy. Their also should be documentation of functional improvement and side effects incurred with use. Disease states which prompt use of these medications include post-herpetic neuralgia, spinal cord injury, chronic regional pain syndrome, lumbar spinal stenosis, post-operative pain, and central pain. There is inadequate evidence to support use in non-specific axial low back pain or myofascial pain. In this case, there is inadequate documentation of adequate pain reduction for continued use. The records also do not reveal functional improvement or screening measures as required. As such, the request is not medically necessary.

Gabapentin 600mg #30 with three refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-17 of 127.

Decision rationale: The request is for the use of a medication in the category of an anti-epileptic drug (AED). These medications are recommended for certain types of neuropathic pain. Most of the randomized clinical control trials involved include post-herpetic neuralgia and painful polyneuropathy such as in diabetes. There are few trials, which have studied central pain or radiculopathy. The MTUS guidelines state that a good response to treatment is 50% reduction in pain. At least a 30% reduction in pain is required for ongoing use, and if this is not seen, this should trigger a change in therapy. Their also should be documentation of functional improvement and side effects incurred with use. Disease states which prompt use of these medications include post-herpetic neuralgia, spinal cord injury, chronic regional pain syndrome, lumbar spinal stenosis, post-operative pain, and central pain. There is inadequate evidence to support use in non-specific axial low back pain or myofascial pain. In this case, there is inadequate documentation of adequate pain reduction for continued use. The records also do not reveal functional improvement or screening measures as required. As such, the request is not medically necessary.

Lidoderm patch 5% #60 with two refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 56-57 of 127.

Decision rationale: The request is for the use of a Lidoderm patch to aid in pain relief. The MTUS guidelines state that its use is indicated for post herpetic neuralgia after an initial trial of an anti-epileptic medication. Further research is needed to recommend use for chronic neuropathic disorders besides post-herpetic neuralgia. In this case, the patient does not have a diagnosis documented, which would justify the use of Lidoderm patches. As such, the request is not medically necessary.

Clonidine HCL 0.1mg #21: 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: Clonidine.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 34-35 of 127.

Decision rationale: The request is for the use of the medication Clonidine. This is a centrally acting medication commonly used as an anti-hypertensive recommended only after a short-term trial indicates pain relief in patients refractory to opioid monotherapy or opioids with local anesthetic. There is little evidence that this medication provides long-term pain relief (when used in combination with opioids approximately 80% of patients had < 24 months of pain relief) and no studies have investigated the neuromuscular, vascular or cardiovascular physiologic changes that can occur over long period of administration. Side effects include hypotension, and the medication should not be stopped abruptly due to the risk of rebound hypertension. The medication is FDA approved with an orphan drug intrathecal indication for cancer pain only. Clonidine is thought to act synergistically with opioids. Most studies on the use of this drug intrathecally for chronic non-malignant pain are limited to case reports. (Ackerman, 2003) Clonidine (Catapres) is a direct-acting adrenergic agonist prescribed historically as an anti-hypertensive agent, but it has found new uses, including treatment of some types of neuropathic

pain. Additional studies: One intermediate quality randomized controlled trial found that intrathecal Clonidine alone worked no better than placebo. It also found that Clonidine with morphine worked better than placebo or morphine or Clonidine alone. (Ackermann, 2003) (Hassenbusch2, 2002) (Martin, 2001) (Raphael, 2002) (Roberts, 2001) (Siddall, 2000) (Taricco, 2006) In this case, the use of this medication is not supported by the guidelines. This is secondary to poor clinical efficacy of long-term pain relief. As such, the request is not medically necessary.

Diazepam 5mg #21: 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.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 24 of 127.

Decision rationale: The request is for the use of a medication in the category of benzodiazepines. It is usually indicated to treat anxiety disorders but has been used short-term as a muscle relaxant. The MTUS guidelines state the following: Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) In this case, a medication in this class would not be advised for continued use due to the duration of therapy. As such, the request is not medically necessary. All benzodiazepine medications should be titrated down slowly to prevent an acute withdrawal syndrome.

Xanax 0. 5mg #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), Mental Illness and Stress.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 24 of 127.

Decision rationale: The request is for the use of a medication in the category of benzodiazepines. It is usually indicated to treat anxiety disorders but has been used short-term as a muscle relaxant. The MTUS guidelines state the following: Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) In this case, a medication in this class would not be advised for continued use due to the duration of therapy. As such, the request is not medically necessary. All benzodiazepine medications should be titrated down slowly to prevent an acute withdrawal syndrome.

Diphenhydramine 35mg #28: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness and Stress, Diphenhydramine (Benadryl).

Decision rationale: The request is for the use of Diphenhydramine medication. The ODG guidelines advise the following regarding its use: Not recommended. See Insomnia treatment, where sedating antihistamines are not recommended for long-term insomnia treatment. The AGS updated Beers criteria for inappropriate medication use includes Diphenhydramine. (AGS, 2012) Anti-cholinergic drugs, including Diphenhydramine, may increase the risk for dementia by 50% in older adults. There is an obvious dose-response relationship between anti-cholinergic drug use and risk of developing dementia, but chronic use, even at low doses, would be in the highest risk category. While there is awareness that these drugs may cause short-term drowsiness or confusion, which is included in the prescribing information, there is no mention of long-term effects on cognition, and generally awareness of this issue is very low, and both the public and doctors need to be encouraged to use alternative treatments where possible. (Gray, 2015) As stated above, the use of this medication is not indicated. This is secondary to poor clinical evidence regarding its safe and effective use. As such, the request is not medically necessary.

Promethazine 25mg #21: 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, Promethazine (2015).

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) Antiemetics (for opioid nausea).

Decision rationale: The request is for the use of the medication Clonidine. This is a centrally acting medication commonly used as an anti-hypertensive; Recommended only after a short-term trial indicates pain relief in patient's refractory to opioid monotherapy or opioids with local anesthetic. There is little evidence that this medication provides long-term pain relief (when used in combination with opioids approximately 80% of patients had < 24 months of pain relief) and no studies have investigated the neuromuscular, vascular or cardiovascular physiologic changes that can occur over long period of administration. Side effects include hypotension, and the medication should not be stopped abruptly due to the risk of rebound hypertension. The medication is FDA approved with an orphan drug intrathecal indication for cancer pain only. Clonidine is thought to act synergistically with opioids. Most studies on the use of this drug intrathecally for chronic non-malignant pain are limited to case reports. (Ackerman, 2003) Clonidine (Catapres) is a direct-acting adrenergic agonist prescribed historically as an antihypertensive agent, but it has found new uses, including treatment of some types of neuropathic pain. Additional studies: One intermediate quality randomized controlled trial found that intrathecal Clonidine alone worked no better than placebo. It also found that Clonidine with morphine worked better than placebo or morphine or Clonidine alone. (Ackermann, 2003) (Hassenbusch2, 2002) (Martin, 2001) (Raphael, 2002) (Roberts, 2001) (Siddall, 2000) (Taricco,

2006) In this case, the use of this medication is not supported by the guidelines. This is secondary to poor clinical efficacy of long-term pain relief. As such, the request is not medically necessary.

Methocarbamol 750mg #30 with three refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63.

Decision rationale: The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate qualifying evidence for use of a muscle relaxant, the request is not medically necessary. All muscle relaxant medications should be titrated down slowly to prevent an acute withdrawal syndrome.