MAXIMUS Federal Services

Case Number:	CM15-0181082		
Date Assigned:	09/22/2015	Date of Injury:	04/20/1992
Decision Date:	11/13/2015	UR Denial Date:	08/17/2015
Priority:	Standard	Application Received:	09/14/2015

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 51 year old female with an industrial injury dated 04-29-1990. Medical records indicate she is being treated for bilateral carpal tunnel syndrome status post multiple surgeries, chronic neuropathic pain at bilateral upper extremities, right rotator cuff tear status post-surgical repair and bilateral ulnar neuropathy. The progress record dated 07-21-2015 noted the injured worker presents with pain in right shoulder. The pain is rated as 9 out of 10 with medications and 5 out of 10 with medications. At the time of the visit the pain is documented as 7 out of 10. "She reports no change with the pain pattern." "Functionally, she is able to perform basic activities of daily living with pain management." Prior progress notes dated 04-27-2015, 05-26-2015 and 06-23-2015 document the pain ratings the same as recorded in the 07-21-2015 note. Physical examination dated 07-21-2015 is documented as revealing right shoulder tenderness and impingement signs. Her medications included Klonopin 1 mg tablet twice a day, Nucynta 100 mg one every 4 hours, Trazodone 50 mg tablet 1-3 at bedtime, Ultram 50 mg one twice a day and Dilaudid 4 mg one three times a day as needed. In the progress note dated 02-04-2015 (the earliest record available) the above medications are documented as the injured worker's medications. The injured worker was medically retired. The treatment plan included an injection of Toradol 60 mg for pain relief of shoulders, right shoulder injection and continue medications and topical cream. The treatment request is for the following treatments: Ultram 50 mg, QTY: 120; Trazodone 50 mg, QTY: 180; Retrospective review of Toradol 60 mg Injection, QTY: 1 (DOS: 07/21/15); Retrospective request for Klonopin 1 mg, QTY: 6; Nucynta 100 mg, QTY: 180; Flurbiprofen 20%, Cyclobenzaprine, Lidocaine 5%, QTY: 1. On 08-17-2015

utilization review issued the following determination: Ultram 50 mg, QTY: 120; Modified to Ultram 50 mg QTY: 22; Trazodone 50 mg, QTY: 180; Denied - Retrospective review of Toradol 60 mg Injection, QTY: 1 (DOS: 07/21/15); Denied, Retrospective request for Klonopin 1 mg, QTY: 6; Modified to Klonopin 1 mg QTY # 6; Nucynta 100 mg, QTY: 180; Denied, Flurbiprofen 20%, Cyclobenzaprine, Lidocaine 5%, QTY: 1, Denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective request for Klonopin 1mg, QTY: 6: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines.

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.

Nucynta 100mg, QTY: 180: 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 (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) Tapentadol (Nucynta).

Decision rationale: The request is for the medication Nucynta. This is categorized as a centrally acting opioid agonist. The ODG guidelines state the following regarding its use: Recommended only as second line therapy for patients who develop intolerable adverse effects with first line opioids. Three large RCTs concluded that tapentadol was efficacious and provided efficacy that was similar to oxycodone for the management of chronic osteoarthritis knee and low back pain,

with a superior gastrointestinal tolerability profile and fewer treatment discontinuations. (Afilalo, 2010) (Buynak, 2010) (Lange, 2010) Tapentadol is a centrally acting oral analgesic. It has two mechanisms of action, combining mu-opioid receptor agonism and norepinephrine reuptake inhibition. (Johnson, 2008) Nucynta (tapentadol) was made a Schedule II controlled substance. Nucynta may be abused by crushing, chewing, snorting or injecting the product. These practices pose a significant risk to the abuser that could result in overdose and death. (FDA, 2009) Nucynta has the same pain-relieving benefits of OxyIR, as well as the same risks that come with any opioid, but shows a significant improvement in gastrointestinal tolerability compared with oxycodone; if patients on OxyIR complain of constipation, nausea, and/or vomiting, Nucynta might be considered as a second-line choice. (Daniels, 2009) (Daniels2, 2009) (Hale, 2009) (Hartrick, 2009) (Stegmann, 2008) In one study, gastrointestinal adverse events led to discontinuation in 9% of the tapentadol group versus 22% of the oxycodone group. (Wild, 2010) This review questioned the opioid potency of tapentadol, and suggested that it affects pain modulation through inhibition of norepinephrine. (Prommer, 2010) But the manufacturer disagrees. (Nelson, 2011) In August 2011 FDA approved tapentadol extended release (Nucynta ER) for moderate to severe chronic pain. Nucynta was already approved for acute pain. (FDA, 2011) In this case, this medication is not indicated for use. There is a lack of documentation of failed first-line opiate therapy. There is also an excessive opiate load of over 120 MED. As such, it is not medically necessary for use.

Trazodone 50mg, QTY: 180: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Trazodone.

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 & Stress/Trazodone (Desyrel).

Decision rationale: The request is for the use of the medication trazodone. This is a medication in the category of a serotonin agonist and reuptake inhibitor and is used for depression. It also has anxiolytic and sedative hypnotic effects. The MTUS guidelines are silent regarding its use. The ODG guidelines state that this medication is indicated as an option for insomnia for patients with coexisting depression or anxiety. Its use as a first-line treatment for primary insomnia is not advised. Evidence for the off-label use of trazodone for treatment of insomnia is poor. The current recommendation is to use a combined pharmacologic and psychological and behavior treatment when primary insomnia is diagnosed. In this case, there is inadequate documentation of a psychiatric evaluation revealing comorbid factors, which would qualify the patient for use of trazodone as a first-line agent. As such, the request is not medically necessary.

Ultram 50mg, QTY: 120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

Decision rationale: Tramadol is a pain medication in the category of a centrally acting analgesic. They exhibit opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Centrally acting drugs are reported to be effective in managing neuropathic type pain although it is not recommended as first line therapy. The side effect profile is similar to opioids. For chronic back pain, it appears to be efficacious for short-term pain relief, but long term (>16 weeks) results are limited. It also did not appear to improve function. The use of tramadol for osteoarthritis is indicated for short-term use only (<3 months) with poor long-term benefit. In this case, the patient does not meet the qualifying criteria. This is secondary to the duration of use, with this medication being indicated on a short-term basis only. There is also an excess opiate load being prescribed at over 120 MED. As such, the request is not medically necessary.

Retrospective review of Toradol 60mg Injection, QTY: 1 (DOS: 07/21/15): Upheld

Claims Administrator guideline: Decision based on MTUS Neck and Upper Back Complaints 2004. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Ketorolac (Toradol, generic available).

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)/NSAIDs, specific drug list & adverse effects.

Decision rationale: The request is for the use of ketorolac intramuscular injection for pain relief. The MTUS guidelines are silent regarding this issue. The ODG guidelines state the following: Ketorolac (Toradol, generic available): 10 mg. [Boxed Warning]: The oral form is only recommended for short-term (up to 5 days) in management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation following IV or IM dosing, if necessary. This medication is not indicated for minor or chronic painful conditions. Increasing doses beyond a daily maximum dose of 40 mg will not provide better efficacy, and will increase the risk of serious side effects. The FDA boxed warning would relegate this drug to second-line use unless there were no safer alternatives. Dosing: Acute pain (transition from IV or IM) for adults < 65 years of age: 20mg PO followed by 10mg PO every 4 to 6 hours (max 40 mg/day). An oral formulation should not be given as an initial dose. (Toradol Package Insert) The FDA has approved a nasal formulation of ketorolac (Sprix) for short-term pain management. (FDA, 2010) As indicated above, this patient does not qualify for the use of ketorolac. This is secondary to the duration of use with the guidelines stating that it is not to be given for chronic painful conditions. As such, the request is not medically necessary.

Flurbiprofen 20%, Cyclobenzaprine, Lidocaine 5%, QTY: 1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients, which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the use of the topical muscle relaxant is not indicated for use for the patient's condition. The MTUS states the following regarding muscle relaxants used topically: "Baclofen: Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline-Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." As indicated above, due to inadequate clinical evidence of efficacy, the request is not medically necessary.