

Case Number:	CM15-0143857		
Date Assigned:	08/04/2015	Date of Injury:	05/29/1992
Decision Date:	09/22/2015	UR Denial Date:	07/06/2015
Priority:	Standard	Application Received:	07/24/2015

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: Physical Medicine & Rehabilitation

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 60-year-old male, who sustained an industrial injury on 05-29-1992. He has reported injury to the neck, upper back, and psyche. The diagnoses have included cervical radiculopathy; cervical degenerative disc disease; cervical myofascial pain syndrome; failed neck surgery syndrome; occipital neuralgia; depressive disorder; and chronic pain. Treatment to date has included medications, diagnostics, moist heat, physical therapy, home exercise program, intrathecal pump placement, and surgical intervention. Medications have included Oxycontin, Roxicodone, Clonazepam, Morphine Sulfate solution injectable, Prozac, Wellbutrin XL, Zanaflex, Senokot, and Zantac. A progress note from the treating physician, dated 06-24-2015, documented a follow-up visit with the injured worker. Currently, the injured worker complains of neck pain; arm pain; headaches; the pain is sharp, electrical-shooting, and burning; today, the pain is rated at 3 out of 10 on the pain scale; on a bad day, the pain is rated at 8-9 out of 10 on the pain scale; pain is aggravated by heat, cold, activity, sitting, and standing; and pain is alleviated by cold, activity, rest, lying down, sitting, standing, walking, and medications. Objective findings included no acute distress; cervical spine range of motion is decreased; diffuse tenderness and spasm of the lumbar-sacral spine; decreased range of motion of the lumbar spine; pain with range of motion; and gait is antalgic. The treatment plan has included the request for tox screen; Oxycontin 80 mg #168; Roxicodone 30 mg #112; Zanaflex 4 mg #120; pump refills and maintenance x 6; and pump reprograms x 6.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tox screen: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug Testing Page(s): 43.

Decision rationale: The patient presents on 05/26/15 with upper back and cervical spine pain rated 3/10 at best, 8/10 at worst. The patient's date of injury is 05/29/92. Patient is status post intrathecal pump placement at a date unspecified. The request is for Tox screen. The RFA is dated 06/02/15. Physical examination dated 05/26/15 reveals diffuse tenderness to palpation of the lumbar paraspinal region, decreased lumbar and cervical range of motion. The patient is currently prescribed Oxycontin, Roxicodone, Clonazepam, Morphine Sulfate, Prozac, Wellbutrin, Senokot, and Zantac. Patient is currently classified as permanent and stationary. MTUS Chronic Pain Medical Treatment Guidelines, Page 43 has the following under Drug Testing: "Recommended as an option, using a urine drug screen to assess for the use or the presence of illegal drugs. For more information, see Opioids, criteria for use: (2) Steps to Take Before a Therapeutic Trial of Opioids & (4) On-Going Management; Opioids, differentiation: dependence & addiction; Opioids, screening for risk of addiction (tests); & Opioids, steps to avoid misuse/addiction. "While MTUS Guidelines do not specifically address how frequent UDS should be considered for various risks of opiate users, ODG Pain Chapter, under Urine Drug Testing has the following: Patients at "moderate risk" for addiction/aberrant behavior are recommended for point-of-contact screening 2 to 3 times a year with confirmatory testing for inappropriate or unexplained results. Patients at "high risk" of adverse outcomes may require testing as often as once per month. Patients at "low risk" of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. In regard to the urine drug screen, the provider has exceeded guideline recommendations. While MTUS does not set a specific frequency for urine drug screening, ODG specifies that patients who are considered low risk only require urine drug screening at 6 month interval from narcotic initiation, and on a yearly basis thereafter. There is no discussion as to whether this patient is considered at risk for drug abuse/diversion. This patient underwent urine drug screening per progress note dated 03/11/15 with consistent findings. Without a rationale as to why this patient requires more frequent urine drug screening, or a discussion of suspected non-compliance or diversion, the requested urine drug screen cannot be substantiated. The request is not medically necessary.

Oxycontin 80 mg #168: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Criteria for use of Opioids Page(s): 60, 61, 76-78, 88, 89.

Decision rationale: The patient presents on 05/26/15 with upper back and cervical spine pain rated 3/10 at best, 8/10 at worst. The patient's date of injury is 05/29/92. Patient is status post intrathecal pump placement at a date unspecified. The request is for Oxycontin 80MG #168. The RFA is dated 06/02/15. Physical examination dated 05/26/15 reveals diffuse tenderness to palpation of the lumbar paraspinal region, decreased lumbar and cervical range of motion. The patient is currently prescribed Oxycontin, Roxicodone, Clonazepam, Morphine Sulfate, Prozac,

Wellbutrin, Senokot, and Zantac. Patient is currently classified as permanent and stationary. Regarding chronic opiate use, MTUS guidelines page and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4A's analgesia, ADLs, adverse side effects, and adverse behavior, as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS p77 states, "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." In regard to the continuation of Oxycontin for the management of this patient's chronic pain, the requesting physician has not provided adequate documentation of medication efficacy. Most recent progress note, dated 05/26/15 does not include documentation of analgesia via a validated scale or any activity-specific functional improvements. Per progress note dated 05/26/15 has the following statement: "Is the pain always the same" YES. This statement casts doubt upon the efficacy of this patient's medications. A consistent urine drug screening was provided, dated 06/25/15, and the provider does note a lack of inconsistent/aberrant behaviors. MTUS guidelines require documentation of analgesia via a validated scale attributed to medications, activity-specific functional improvements, consistent urine drug screening, and a stated lack of aberrant behavior. In this case, the latter 2 criteria have been satisfied, however, without evidence of analgesia or functional improvement continuation of this medication cannot be substantiated. Owing to a lack of complete 4A's documentation, the request is not medically necessary and the patient should be slowly weaned off of this medication.

Roxicodone 30mg #112: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Criteria for use of Opioids Page(s): 60, 61, 76-78, 88,89.

Decision rationale: The patient presents on 05/26/15 with upper back and cervical spine pain rated 3/10 at best, 8/10 at worst. The patient's date of injury is 05/29/92. Patient is status post intrathecal pump placement at a date unspecified. The request is for Roxicodone 30MG #112. The RFA is dated 06/02/15. Physical examination dated 05/26/15 reveals diffuse tenderness to palpation of the lumbar paraspinal region, decreased lumbar and cervical range of motion. The patient is currently prescribed Oxycontin, Roxicodone, Clonazepam, Morphine Sulfate, Prozac, Wellbutrin, Senokot, and Zantac. Patient is currently classified as permanent and stationary. Regarding chronic opiate use, MTUS guidelines page and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4A's analgesia, ADLs, adverse side effects, and adverse behavior, as well as 'pain assessment' or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS p77 states, "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." In regard to the continuation of Roxicodone for the management of this patient's chronic pain, the requesting physician has not provided adequate documentation of medication efficacy. Most recent progress note, dated 05/26/15 does not include documentation of analgesia via a validated scale or any activity-specific functional improvements. Per progress note dated 05/26/15 has the following statement: "Is the pain always the same" YES. This statement casts doubt upon the

efficacy of this patient's medications. A consistent urine drug screening was provided, dated 06/25/15, and the provider does note a lack of inconsistent/aberrant behaviors. MTUS guidelines require documentation of analgesia via a validated scale attributed to medications, activity-specific functional improvements, consistent urine drug screening, and a stated lack of aberrant behavior. In this case, the latter 2 criteria have been satisfied, however, without evidence of analgesia or functional improvement continuation of this medication cannot be substantiated. Owing to a lack of complete 4A's documentation, the request is not medically necessary and the patient should be slowly weaned off of this medication.

Zanaflex 4mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tizanidine Page(s): 66.

Decision rationale: The patient presents on 05/26/15 with upper back and cervical spine pain rated 3/10 at best, 8/10 at worst. The patient's date of injury is 05/29/92. Patient is status post intrathecal pump placement at a date unspecified. The request is for Zanaflex 4MG #120. The RFA is dated 06/02/15. Physical examination dated 05/26/15 reveals diffuse tenderness to palpation of the lumbar paraspinal region, decreased lumbar and cervical range of motion. The patient is currently prescribed Oxycontin, Roxicodone, Clonazepam, Morphine Sulfate, Prozac, Wellbutrin, Senokot, and Zantac. Patient is currently classified as permanent and stationary. MTUS Chronic Pain Medical Treatment Guidelines for Muscle Relaxants for pain, pg 66 states the following regarding Tizanidine: 'Tizanidine is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. One study -conducted only in females demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. ' MTUS pg 60 also states, 'A record of pain and function with the medication should be recorded,' when medications are used for chronic pain. ' In regard to the continuation of Zanaflex, the requesting physician has not provided adequate documentation of medication efficacy. This patient has been taking this medication since at least 03/31/15. Most recent progress note, dated 05/26/15 has the following regarding medication efficacy: 'Alleviating factors: Cold, Heat, Rest, Medications.' Such vague documentation of efficacy does not satisfy MTUS requirements, which require a statement confirming that any particular medication is improving function or reducing pain, when such medications are prescribed for chronic pain. Listing 'medications' among alleviating factors does not constitute satisfactory documentation of medication efficacy. Without such documentation, continuation of this medication cannot be substantiated. The request is not medically necessary.

Pump refills and maintenance X6: Overturned

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, under Implantable Drug Delivery Systems: Refills.

Decision rationale: The patient presents on 05/26/15 with upper back and cervical spine pain rated 3/10 at best, 8/10 at worst. The patient's date of injury is 05/29/92. Patient is status post intrathecal pump placement at a date unspecified. The request is for pump refills and maintenance x6. The RFA is dated 06/02/15. Physical examination dated 05/26/15 reveals diffuse tenderness to palpation of the lumbar paraspinal region, decreased lumbar and cervical range of motion. The patient is currently prescribed Oxycontin, Roxicodone, Clonazepam, Morphine Sulfate, Prozac, Wellbutrin, Senokot, and Zantac. Patient is currently classified as permanent and stationary. MTUS and ACOEM Guidelines do not discuss intrathecal drug delivery systems or periodic refills. However, ODG Guidelines has the following in the Pain chapter, under Implantable Drug Delivery Systems: Refills: IDDSs dispense drugs according to instructions programmed by the clinician to deliver a specific amount of drug per day or to deliver varying regimens based on flexible programming options, and the pump may need to be refilled at regular intervals. The time between refills will vary based on pump reservoir size, drug concentration, dose, and flow rate. A programming session, which may occur along with or independent of a refill session, allows the clinician to adjust the patient's prescription as well as record or recall important information about the prescription. According to the FDA, the manufacturer's manuals should be consulted for specific instructions and precautions for initial filling, refilling and programming. For most pumps, the maximum dose that can be delivered between refills is 1000mg. If refills are usually administered after 16 to 17 mL have been infused, and most pumps are 18-20mL, the minimum time between each visit is 42 days if the daily dose rate is 20 mg/day. Given that a refill visit presents a good opportunity for monitoring, this panel suggested that the concentration be adjusted to allow refill visits a minimum of every 4 to 6 weeks, and maximum of every 2-3 months. In regard to the prospective refills and maintenance of this patient's intrathecal pump, the request is appropriate. Official disability guidelines do not set forth a specific number of refills, as dosing varies between patient's and reservoir size varies among different models of implantable drug deliver systems. However, six return visits for the purpose of ensuring proper functioning of the unit and refills of the medication reservoir is a reasonable and appropriate measure. Therefore, the request is medically necessary.

Pump reprograms x 6: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, under Implantable Drug Delivery Systems.

Decision rationale: The patient presents on 05/26/15 with upper back and cervical spine pain rated 3/10 at best, 8/10 at worst. The patient's date of injury is 05/29/92. Patient is status post intrathecal pump placement at a date unspecified. The request is for pump reprograms x6. The RFA is dated 06/02/15. Physical examination dated 05/26/15 reveals diffuse tenderness to palpation of the lumbar paraspinal region, decreased lumbar and cervical range of motion. The patient is currently prescribed Oxycontin, Roxicodone, Clonazepam, Morphine Sulfate, Prozac, Wellbutrin, Senokot, and Zantac. Patient is currently classified as permanent and stationary. MTUS and ACOEM Guidelines do not discuss intrathecal drug delivery system reprogramming. However, ODG Guidelines has the following in the Pain chapter, under Implantable Drug Delivery Systems: Refills: IDDSs dispense drugs according to instructions programmed by the clinician to deliver a specific amount of drug per day or to deliver varying regimens based on flexible programming options, and the pump may need to be refilled at regular intervals. The time between refills will vary based on pump reservoir size, drug concentration, dose, and flow rate. A programming session, which may occur along with or independent of a refill session, allows the clinician to adjust the patient's prescription as well as record or recall important information about the prescription. According to the FDA, the manufacturer's manuals should be consulted for specific instructions and precautions for initial filling, refilling and programming. For most pumps, the maximum dose that can be delivered between refills is 1000mg. If refills are usually administered after 16 to 17 mL have been infused, and most pumps are 18-20mL, the minimum time between each visit is 42 days if the daily dose rate is 20 mg/day. Given that a refill visit presents a good opportunity for monitoring, this panel suggested that the concentration be adjusted to allow refill visits a minimum of every 4 to 6 weeks, and maximum of every 2-3 months. In regard to the prospective request for reprogramming of this patient's intrathecal pump, the treater has not provided a reason for the request. While the provider is justified in programming/reprogramming the implanted unit to achieve better analgesia, it is unclear how simply adjusting the pump can be classified as separately billable service, as it does not require any invasive techniques. Guidelines indicate that such reprogramming should take place during refill visits. Without a rationale provided as to why such reprogramming is routinely required, or cannot be carried out as part of this patient's regular follow-up visits for refills, the medical necessity of the request as written cannot be substantiated. The request is not medically necessary.