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| Case Number: | CM14-0153935 | | |
| Date Assigned: | 09/23/2014 | Date of Injury: | 08/07/2011 |
| Decision Date: | 10/24/2014 | UR Denial Date: | 08/25/2014 |
| Priority: | Standard | Application Received: | 09/22/2014 |

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 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 is a 50-year-old male who reported an industrial injury to the back on 8/7/2011, over three (3) years ago, attributed to the performance of his usual and customary job tasks. The patient continues to complain of persistent low back pain along with pain to the bilateral shoulders. The patient was noted to be taking tramadol; Valium; topical FluriFlex; and topical TG hot compounded analgesic. The objective findings on examination included midline tenderness and tenderness of the lumbar paraspinal musculature; decreased range of motion of the lumbar spine; DTRs and motor strength were documented as normal; sciatic nerve compression test was negative; prior treatment included the requested medications along with surgical intervention and acupuncture. The patient reported some improvement in symptoms with the previously provided acupuncture. The patient is documented to have received at least six prior sessions of acupuncture.

IMR ISSUES, DECISIONS AND RATIONALES

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

8 ACPUNCTURE FOR LUMBAR SPINE:

Claims Administrator guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

Decision rationale: The request for 2x4 additional sessions of acupuncture directed to the back was not supported with objective evidence of functional improvement with the previous certified sessions of acupuncture. There was no sustained functional improvement documented from the previous course of acupuncture provided for the effects of the industrial injury. There is no demonstrated medical necessity for eight (8) additional sessions of acupuncture. There was no provided conservative care by the requesting physician prior to the request for acupuncture after it was noted that the patient had received at least six (6) sessions of physical therapy without a demonstrated reduction in the medication prescribed or an increase in function. The treating physician requested acupuncture sessions to the back based on persistent chronic pain due to the reported industrial injury and muscle pain not controlled with medications and home exercises. The request is not consistent with the recommendations of the CA Medical Treatment Utilization Schedule for the continued treatment with acupuncture. The patient was noted to have received the CA MTUs recommended number of sessions of acupuncture over a 1-2 month period of treatment. There is no documented sustained functional improvement. The current request is for maintenance treatment. The patient is not demonstrated to be participating in a self-directed home exercise program for conditioning and strengthening. There is no demonstrated functional improvement on a PR-2 by the acupuncturist. There is no documented reduction of medications attributed to the use of acupuncture. The recent clinical documentation demonstrates that the patient has made no improvement to the cited body parts with the provided conservative treatment for the diagnoses of sprain/strain. Acupuncture is not recommended as a first line treatment and is authorized only in conjunction with a documented self-directed home exercise program. There is no documentation that the patient has failed conventional treatment. There was no rationale supporting the use of additional acupuncture directed to the back. The use of acupuncture is not demonstrated to be medically necessary. There is no objective evidence to support the continued treatment with acupuncture directed to the cited diagnoses. An initial short course of treatment to demonstrate functional improvement through the use of acupuncture is recommended for the treatment of chronic pain issues, acute pain, and muscle spasms. A clinical trial of four (4) sessions of acupuncture is consistent with the CA Medical Treatment Utilization Schedule; the ACOEM Guidelines and the Official Disability Guidelines for treatment of the back. The continuation of acupuncture treatment would be appropriately considered based on the documentation of the efficacy of the four (4) sessions of trial acupuncture with objective evidence of functional improvement. Functional improvement evidenced by the decreased use of medications, decreased necessity of physical therapy modalities, or objectively quantifiable improvement in examination findings and level of function would support the medical necessity of 8-12 sessions over 4-6 weeks. There is no demonstrated medical necessity for the requested additional eight (8) sessions of acupuncture; therefore this request is not medically necessary.

ULTRAM 50 MG Qty 90: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-48, Chronic Pain Treatment Guidelines Opioids for chronic pain Page(s): 80-82. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter chronic pain medications; opioids

Decision rationale: Evidence-based guidelines recommend short-term use of opioids for the management of chronic nonmalignant moderate to severe pain. Long-term use is not

recommended for nonmalignant pain due to addiction, dependency, intolerance, abuse, misuse and/or side effects. Ongoing opioid management criteria are required for long-term use with evidence of reduce pain and improve function as compared to baseline measurements or a return to work. The prescription for Tramadol 50 mg #90 for short acting pain relief is being prescribed as an opioid analgesic for the treatment of chronic pain. There is no objective evidence provided to support the continued prescription of opioid analgesics for chronic pain with no objective findings on examination. There is no documented functional improvement from this opioid analgesic and the prescribed Tramadol should be discontinued. The ACOEM Guidelines and CA MTUS do not recommend opioids for chronic pain. The chronic use of Tramadol is not recommended by the CA MTUS, the ACOEM Guidelines, or the Official Disability Guidelines for the long-term treatment of chronic pain only as a treatment of last resort for intractable pain. The provider has provided no objective evidence to support the medical necessity of continued Tramadol for chronic pain. The ACOEM Guidelines updated chapter on chronic pain states, "Opiates for the treatment of mechanical and compressive etiologies: rarely beneficial. Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (70 days). This leads to a concern about confounding issues; such as, tolerance, opioid-induced hyperalgesia, long-range adverse effects, such as, hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect." ACOEM guidelines state that opioids appear to be no more effective than safer analgesics for managing most musculoskeletal symptoms; they should be used only if needed for severe pain and only for a short time. The long-term use of opioid medications may be considered in the treatment of chronic musculoskeletal pain, if: The patient has signed an appropriate pain contract; Functional expectations have been agreed to by the clinician and the patient; Pain medications will be provided by one physician only; The patient agrees to use only those medications recommended or agreed to by the clinician. ACOEM also notes, "Pain medications are typically not useful in the subacute and chronic phases and have been shown to be the most important factor impeding recovery of function." The prescription of opiates on a continued long-term basis is inconsistent with the CA MTUS and the Official Disability Guidelines recommendations for the use of opiate medications for the treatment of chronic pain. There is objective evidence that supports the use of opioid analgesics in the treatment of this patient over the use of NSAIDs for the treatment of chronic pain. The current prescription of opioid analgesics is consistent with evidence-based guidelines based on intractable pain. The prescription of Tramadol 50 mg #90 as prescribed to the patient is not medically necessary.

2 VALIUM 10 MG: Upheld

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

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-
- medications for chronic pain; benzodiazepines

Decision rationale: The prescription of Valium/Diazepam 10 mg #2 prior to a MRI for the treatment of anxiety is inconsistent with the recommendations of the CA MTUS, ACOEM Guidelines, and the Official Disability Guidelines. The use of Valium is associated with abuse,

dependence; significant side effects related to the psychotropic properties of the medication and is not recommended by the CA MTUS. The prescription of Valium for sleep or anxiety is not recommended due to the potential for abuse and the long half-life of the medication. Alternative medications are readily available for insomnia. The treatment of insomnia is not documented by the provider. No over the counter or other remedies were prescribed prior to prescribing a benzodiazepine. There is no documented alternative treatment with diet and exercise or evaluation of sleep hygiene. The prescription of Diazepam/Valium for this patient is not recommended due to the potential for abuse and the 24-hour half-life of the medication. Alternative medications are readily available. There is no clinical documentation with objective findings on examination to support the medical necessity of Diazepam. There is no provided evidence that the patient has received benefit or demonstrated functional improvement with Diazepam. There is no demonstrated medical necessity for the prescribed Valium/Diazepam 10 mg #2 for use while undergoing a MRI study.

FLURIFLEX (Unspecified): Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines anti-inflammatory medications, topical analgesics Page(s): 112-113, 22, 67-68.

Decision rationale: The prescription for FluriFlex topical creams is not medically necessary for the treatment of the patient for pain relief for the orthopedic diagnoses of the patient. There is no demonstrated medical necessity for more than OTC medications and topical available OTC. The prescribed topical creams are not medically necessary over numerous sports creams available OTC. There is no Orthopedic clinical documentation submitted to demonstrate the use of the topical creams for appropriate diagnoses or for the recommended limited periods of time. It is not clear that the topical compounded medications are medically necessary in addition to prescribed oral medications. There is no provided subjective/objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the ODG, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. The use of topical NSAIDS is documented to have efficacy for only 2-4 weeks subsequent to injury and thereafter is not demonstrated to be as effective as oral NSAIDs. There is less ability to control serum levels and dosing with the topicals. The patient is not demonstrated to have any GI issue at all with NSAIDS. The use of a topical NSAID is only demonstrated to be effective for a short-term basis and is not medically necessary. The prescription of topical compounded medications in addition to the prescribed oral medications is not medically necessary. The request for the topical compounded analgesic FluriFlex topical creams is not medically necessary for the treatment of the patient for the treatment of chronic pain. The use of the topical creams does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of creams on areas that are not precise. The volume applied and the times per day that the creams are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of creams to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are

more effective than generic oral medications. The prescription is accompanied with a state of medical necessity by the vendor which states that "compounded medications are not absorbed by the stomach so they do not cause any of the dangerous side effects that may be experienced by taking medications orally (ie damage to the liver and kidneys)." In fact, medications that are transdermal or oral enter the blood stream and are ultimately broken down in the liver or kidneys. The breakdown of the prescribed topical medication still occurs in the kidneys and liver. "Compounded medications are absorbed through the skin so less medication enters the blood stream. The benefit of this is that there is reduced chance of building tolerance to drugs thereby curbing any potential addiction to medication." There is no objective evidence to support this contention and high serum levels can be achieved through transdermal applications. The serum levels can be similar and have the same propensity towards tolerance. "Compounds have fewer possibilities of drug interactions because less of the medication enters the blood stream" is not supported with objective evidence. The ability to interact with other medications in the blood stream is the same whether the route of absorption is oral or transdermal. "Compounds provide faster relief than medications taken orally. With compound medications you get fast pain relief to the affected area within a matter of minutes of application" is also not supported with objective evidence. The use of FluriFlex topical creams is not supported by the applicable ODG guidelines as cited below. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be appropriate. There is no documented objective evidence that the patient requires both the oral medications and the topical compounded medication for the treatment of the industrial injury. The prescription for FluriFlex topical creams is not medically necessary for the treatment of the patient's pain complaints. The prescription of FluriFlex topical creams is not recommended by the CA MTUS and the Official Disability Guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or appropriate - noting the specific comment, "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder." The objective findings in the clinical documentation provided do not support the continued prescription of for the treatment of chronic back pain. Therefore this request is not medically necessary.

TGHOT compound (unspecified): Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, 128. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--topical analgesics; topical analgesics compounded

Decision rationale: The prescription for TGHOT topical creams is not medically necessary for the treatment of the patient for pain relief for the orthopedic diagnoses of the patient. There is no demonstrated medical necessity for more than OTC medications and topical available OTC. The prescribed topical creams are not medically necessary over numerous sports creams available OTC. There is no Orthopedic clinical documentation submitted to demonstrate the use of the topical creams for appropriate diagnoses or for the recommended limited periods of time. It is not clear that the topical compounded medications are medically necessary in addition to prescribed oral medications. There is no provided subjective/objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the ODG, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. The use of topical

NSAIDS is documented to have efficacy for only 2-4 weeks subsequent to injury and thereafter is not demonstrated to be as effective as oral NSAIDs. There is less ability to control serum levels and dosing with the topicals. The patient is not demonstrated to have any GI issue at all with NSAIDs. The use of a topical NSAID is only demonstrated to be effective for a short-term basis and is not medically necessary. The prescription of topical compounded medications in addition to the prescribed oral medications is not medically necessary. The request for the topical compounded analgesic TGHot topical creams is not medically necessary for the treatment of the patient for the treatment of chronic pain. The use of the topical creams does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of creams on areas that are not precise. The volume applied and the times per day that the creams are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of creams to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The prescription is accompanied with a state of medical necessity by the vendor which states that "compounded medications are not absorbed by the stomach so they do not cause any of the dangerous side effects that may be experienced by taking medications orally (ie damage to the liver and kidneys)." In fact, medications that are transdermal or oral enter the blood stream and are ultimately broken down in the liver or kidneys. The breakdown of the prescribed topical medication still occurs in the kidneys and liver. "Compounded medications are absorbed through the skin so less medication enters the blood stream. The benefit of this is that there is reduced chance of building tolerance to drugs thereby curbing any potential addiction to medication." There is no objective evidence to support this contention and high serum levels can be achieved through transdermal applications. The serum levels can be similar and have the same propensity towards tolerance. "Compounds have fewer possibilities of drug interactions because less of the medication enters the blood stream" is not supported with objective evidence. The ability to interact with other medications in the blood stream is the same whether the route of absorption is oral or transdermal. "Compounds provide faster relief than medications taken orally. With compound medications you get fast pain relief to the affected area within a matter of minutes of application" is also not supported with objective evidence. The use of TGHot topical creams is not supported by the applicable ODG guidelines as cited below. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be appropriate. There is no documented objective evidence that the patient requires both the oral medications and the topical compounded medication for the treatment of the industrial injury. The prescription for TGHot topical creams is not medically necessary for the treatment of the patient's pain complaints. The prescription of TGHot topical creams is not recommended by the CA MTUS and the Official Disability Guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or appropriate - noting the specific comment, "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder." The objective findings in the clinical documentation provided do not support the continued prescription of for the treatment of chronic back pain. Therefore this request is not medically necessary.