MAXIMUS Federal Services

Case Number:	CM14-0051479		
Date Assigned:	08/08/2014	Date of Injury:	07/21/2012
Decision Date:	10/14/2014	UR Denial Date:	04/07/2014
Priority:	Standard	Application Received:	04/18/2014

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 Physical Medicine and Rehabilitation and is licensed to practice in Nevada. 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 61-year-old male with a 7/21/12 date of injury. The mechanism of injury was not noted. According to a progress report dated 3/18/14, the patient was status post three-level posterior lumbar interbody fusion on 10/2/13. He complained of burning pain in the neck and back which he rated at 7/10. He stated that he had been attending physical therapy which is helping. Objective findings: tenderness in the paraspinous musculature of the lumbar region, midline tenderness noted in the lumbar region, significant spasms noted over the thoracolumbar junction area, sensation testing with a pinwheel is slightly abnormal, restricted ROM of lumbar spine. Diagnostic impression: left knee arthropathy with degenerative arthrosis; L3-4, L4-5, and L5-S1 lumbar fusion on 10/2/13.Treatment to date: medication management, activity modification, surgery, physical therapy.A UR decision dated 4/7/14 denied the requests for Sentra PM, Fluriflex cream, TG Hot Cream, Hydrocodone/APAP 10/325 mg, Cyclobenzaprine, and Zolpidem. Regarding Hydrocodone/APAP 10/325 mg, the patient is currently 6 months out from fusion surgery and should be at a point that he can be weaned off opioids. Ongoing use of chronic opioids is not supported in the current clinical setting. Regarding cyclobenzaprine, documentation does not identify significant functional/vocational benefit with the use of muscle relaxants. Regarding Zolpidem, prolonged use may result in further functional impairment, increased pain levels and levels of depression. The most recent urine drug screen tested negative for Ambien. Regarding Fluriflex cream and TG Hot cream, the requested formulations contain agents that are not recommended by CA MTUS guidelines. The documentation does not indicated that the patient has failed the gamut of readily available oral agents in the antidepressant, antiepileptic, or NSAID class to support the medical necessity of topical agents. Regarding Sentra PM, the documentation does not describe a dietary deficiency in this compound that would support medical necessity of dietary supplementation.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra PM #60 2 bottles for 2 months 2 cap 30 minutes before bed: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation X Official Disability Guidelines (ODG) Pain Chapter X Other Medical Treatment Guideline or Medical Evidence: http://nutrientpharmacology.com/PDFs/monographs/sentraPM-monograph.pdf

Decision rationale: CA MTUS does not address medical foods. However, the FDA states that specific requirements for the safety or appropriate use of medical foods have not yet been established. According to an online search, Sentra PM is a medical food intended for use in management of sleep disorders associated with depression. Sentra PM is a proprietary blend of neurotransmitter precursors (choline bitartrate, glutamate, and 5-hydroxytryptophan); polyphenolic antioxidants (hawthorn berry, cocoa); an amino acid uptake stimulator (gingko biloba); activators of amino acid utilization (acetyl-L-carnitine, glutamate, cocoa powder); and an adenosine antagonist (cocoa powder). Sentra PM contains choline and acetylcarnitine. Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. There is no documentation that the patient has a choline deficiency. The documentation does not describe a dietary deficiency in this compound that would support medical necessity of dietary supplementation. In addition, there is no documentation that the issue of proper sleep hygiene has been addressed. A specific rationale identifying why Sentra PM would be required in this patient despite lack of guidelines support was not identified. Therefore, the request for Sentra PM was not medically necessary.

Fluriflex Cream 180gm Apply 2x daily: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

Decision rationale: An online search has revealed that Fluriflex ointment/cream is a combination of Flurbiprofen/Cyclobenzaprine 15/10%. CA MTUS Chronic Pain Medical Treatment Guidelines state that ketoprofen, lidocaine (in creams, lotion or gels), capsaicin in a 0.0375% formulation, baclofen and other muscle relaxants, and gabapentin and other antiepilepsy drugs are not recommended for topical applications. In addition, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. This compound contains topical cyclobenzaprine and Flurbiprofen, which are not

currently supported by MTUS and ODG guidelines. A specific rationale identifying why Fluriflex cream would be required in this patient despite lack of guideline support was not provided. Therefore, the request for Fluriflex Cream 180gm Apply 2x daily was not medically necessary.

TG Hot Cream 180gm apply 2x daily: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter

Decision rationale: An online search has revealed that TG Hot is a topical analgesic containing Tramadol/Gabapentin/Menthol/Camphor/Capsaicin 8/10/2/.05%. CA MTUS Chronic Pain Medical Treatment Guidelines state that ketoprofen, lidocaine (in creams, lotion or gels), capsaicin in a 0.0375% formulation, baclofen and other muscle relaxants, and gabapentin and other antiepilepsy drugs are not recommended for topical applications. In addition, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Guidelines do not support the use of tramadol, gabapentin, or capsaicin in a 0.0375% or higher topical formulation. A specific rationale identifying why TG Hot cream would be required in this patient despite lack of guideline support was not provided. Therefore, the request for TG Hot Cream 180gm apply 2x daily was not medically necessary.

Hydrocodone APAP 10/325mg 1po q6-8h prn, #60: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78-81.

Decision rationale: CA MTUS Chronic Pain Medical Treatment Guidelines do not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest possible dose; and unless there is ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. According to a progress report dated 3/18/14, the provider stated that Norco has been effective because it allows the patient to perform some activities of daily living and is helping provide relief with the patient's moderate to severe pain. A urine drug screen was not provided for review, however, in a 1/28/14 progress report, the provider refers to one recently taken, and does not describe any inconsistencies. Guidelines support the use of opioids where there is documentation of pain relief and improvement in activities of daily living. Therefore, the request for Hydrocodone APAP 10/325mg 1po q6-8h prn, #60 was medically necessary.

Cyclobenzaprine 7.5mg 1po q12h prn #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants. Decision based on Non-MTUS Citation Official Disability Guidelines

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41-42.

Decision rationale: According to page 41 of the CA MTUS Chronic Pain Medical Treatment Guidelines, Cyclobenzaprine is recommended as an option, using a short course of therapy. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief. There is also a post-op use. The addition of cyclobenzaprine to other agents is not recommended. According to the reports reviewed, the patient has been utilizing cyclobenzaprine since at least 1/28/14, if not earlier. Guidelines do not support the long-term use of cyclobenzaprine. In addition, there is no documentation of an acute exacerbation of the patient's pain. Therefore, the request for Cyclobenzaprine 7.5mg 1po q12h prn #60 was not medically necessary.

Zolpidem 10mg 1po qhs #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines - Stress and mental illness chapter

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 - Ambien X Other Medical Treatment Guideline or Medical Evidence: FDA (Ambien)

Decision rationale: CA MTUS does not address this issue. ODG and the FDA state that Ambien is approved for the short-term (usually two to six weeks) treatment of insomnia. Additionally, pain specialists rarely, if ever, recommend Ambien for long-term use. According to the reports reviewed, the patient has been utilizing Ambien since at least 1/28/14, if not earlier. Guidelines do not support the long-term use of Ambien. In addition, there is no documentation that the provider has addressed proper sleep hygiene techniques with the patient. Therefore, the request for Zolpidem 10mg 1po qhs #30 was not medically necessary.