MAXIMUS Federal Services

Case Number:	CM14-0205247		
Date Assigned:	12/17/2014	Date of Injury:	11/23/2012
Decision Date:	02/12/2015	UR Denial Date:	11/20/2014
Priority:	Standard	Application Received:	12/08/2014

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 Rehab, has a subspecialty in Pain Medicine and is licensed to practice in 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:

The injured worker is a 55 year-old male with a date of injury of November 26, 2012. The patient's industrially related diagnoses include right upper extremity neuropraxia, cervicalgia, C/S spinal stenosis, s/p anterior fusion at C5-C6 and C6-C7 shoulder pain, and sprains and strains of shoulder and upper arm. Conservative treatments to date include physical therapy, chiropractic care, acupuncture, and medication use. Diagnostic work up includes a CT scan on 5/8/2014 that noted that there was no osseous union identified centrally. There is posterior osseous bridging at C6-C7. The cages are centrally placed and have incorporated into the adjacent endplate margins at L6-C7 and possibly C5-C6. The disputed issues are retrospective prescriptions (DOS 7/14/2014, 9/22/2014) and perspective prescriptions for Diclofenac Sodium / Baclofen / Gabapentin / Cyclobenzaprine / Bupivacaine / Lidocaine / Ethoxy and Versapro/Fluticasone. A utilization review determination on 11/20/2014 had non-certified these requests. The stated rationale for the denial was: "Regarding retrospective usage of Diclofenac Sodium / Baclofen / Gabapentin / Cyclobenzaprine / Bupivacaine / Lidocaine / Ethoxy and Diclofenac Sodium / Baclofen / Gabapentin / Cyclobenzaprine / Bupivacaine / Lidocaine / Ethoxy, and retrospective usage of Versapro/Fluticasone (DOS 7/14/14, 9/22/14) and prospective usage of Versapro/Fluticasone, Chronic Pain Medical Treatment Guidelines notes that topical analgesics are recommended as an option in certain circumstances. They are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neurotic pain when trials of antidepressants and anticonvulsants have failed. There is no evidence of use of any other muscle relaxant and anticonvulsant as a topical product. In this case, the claimant chronic neck pain with clinical deficits and limitations on exam. The claimant is using compounded pain creams and it is helping significantly with the surface pain. However, there is no evidence of objective functional

gains supporting the subjective improvement. Further, there is no documentation that oral pain medications are insufficient to alleviate pain symptoms. There is no clear evidence of failed trial of antidepressant and anticonvulsant therapy. Given this, and with lack of peer-reviewed literature to support use of topical analgesics, medical necessity is not established. denial is recommended.

IMR ISSUES, DECISIONS AND RATIONALES

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

RETROSPECTIVE: Diclofenac Sodium / Baclofen / Gabapentin / Cyclobenzaprine / Bupivacaine / Lidocaine / Ethoxy: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page(s): 111-113 OF 127.

Decision rationale: Regarding the request for retrospective compounded pain cream containing Diclofenac Sodium / Baclofen / Gabapentin / Cyclobenzaprine / Bupivacaine / Lidocaine / Ethoxy, Chronic Pain Medical Treatment Guidelines state that if one drug or drug class of a compounded formulation is not recommended, then the entire compounded formulation is not recommended. Regarding topical Baclofen and Cyclobenzaprine, guidelines state that topical muscle relaxants are not recommended as there is no peer-reviewed literature to support the use of topical baclofen or any other muscle relaxant as a topical product. Guidelines recommend the use of topical Lidocaine for localized peripheral pain after there has been evidence of a trial of the first line therapy such as tricyclic antidepressants, SNRIs, or antiepileptic drugs. Guidelines further stipulate that no commercially approved topical formulations of Lidocaine cream, lotion, or gel are indicated for neuropathic pain. Lastly, guidelines state that topical Gabapentin is not recommended. There is no peer-reviewed literature to support use. Given these guidelines, the retrospective prescription for Diclofenac Sodium / Baclofen / Gabapentin / Cyclobenzaprine / Bupivacaine / Lidocaine / Ethoxy pain cream is not medically necessary.

RETROSPECTIVE: Versapro/Fluticasone (Date of Service: 7/14/14, 9/22/14): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page(s): 111-113 OF 127. Decision based on Non-MTUS Citation Physician Desk Reference.

Decision rationale: Regarding request for the compounded formulation of Versapro/Fluticasone, Chronic Pain Medical Treatment Guidelines state that if one drug or drug class of a compounded formulation is not recommended, then the entire compounded formulation is not recommended. Regarding topical fluticasone, CA MTUS is silent regarding this issue. Therefore, the Physician

Desk Reference (PDR) was consulted which states that fluticasone cream is a topical corticosteroid that is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses and relief of the inflammatory and pruritic manifestations of atopic dermatitis. However, a search of the CA MTUS, ACOEM, ODG, National Library of Medicine, National Guideline Clearinghouse, and other online resources failed to reveal support for its use in the management of neck pain or the injured worker's other medical diagnoses. Within the medical records available for review, there was no documentation of any subjective dermatological complaints of itching, skin inflammation, irritation, or swelling, and no objective findings noted on dermatological physical examination consistent with skin conditions for which a corticosteroid cream would be indicated. Furthermore, there was no documentation identifying the medical necessity of this request. In the absence of such documentation, the retrospective prescription for Versapro/Fluticasone (Date of Service: 7/14/14, 9/22/14) is not medically necessary.

Diclofenac Sodium / Baclofen / Gabapentin / Cyclobenzaprine / Bupivacaine / Lidocaine / Ethoxy: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page(s): 111-113 OF 127.

Decision rationale: Regarding the request for the compounded pain cream containing Diclofenac Sodium / Baclofen / Gabapentin / Cyclobenzaprine / Bupivacaine / Lidocaine / Ethoxy, Chronic Pain Medical Treatment Guidelines state that if one drug or drug class of a compounded formulation is not recommended, then the entire compounded formulation is not recommended. Regarding topical Baclofen and Cyclobenzaprine, guidelines state that topical muscle relaxants are not recommended as there is no peer-reviewed literature to support the use of topical baclofen or any other muscle relaxant as a topical product. Guidelines recommend the use of topical Lidocaine for localized peripheral pain after there has been evidence of a trial of the first line therapy such as tricyclic antidepressants, SNRIs, or antiepileptic drugs. Guidelines further stipulate that no commercially approved topical formulations of Lidocaine cream, lotion, or gel are indicated for neuropathic pain. Lastly, guidelines state that topical Gabapentin is not recommended. There is no peer-reviewed literature to support use. Given these guidelines, the requested Diclofenac Sodium / Baclofen / Gabapentin / Cyclobenzaprine / Bupivacaine / Lidocaine / Ethoxy pain cream is not medically necessary.

Versapro/Fluticasone: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page(s): 111-113 OF 127. Decision based on Non-MTUS Citation Physician Desk Reference.

Decision rationale: Regarding the request for the compounded formulation of Versapro/Fluticasone, Chronic Pain Medical Treatment Guidelines state that if one drug or drug class of a compounded formulation is not recommended, then the entire compounded formulation is not recommended. Regarding topical fluticasone, CA MTUS is silent regarding this issue. Therefore, the Physician Desk Reference (PDR) was consulted which states that fluticasone cream is a topical corticosteroid that is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses and relief of the inflammatory and pruritic manifestations of atopic dermatitis. However, a search of the CA MTUS, ACOEM, ODG, National Library of Medicine, National Guideline Clearinghouse, and other online resources failed to reveal support for its use in the management of neck pain or the injured worker's other medical diagnoses. Within the medical records available for review, there was no documentation of any subjective dermatological complaints of itching, skin inflammation, irritation, or swelling, and no objective findings noted on dermatological physical examination consistent with skin conditions for which a corticosteroid cream would be indicated. Furthermore, there is no documentation identifying the medical necessity of this request. In the absence of such documentation, the currently requested Versapro/Fluticasone is not medically necessary.