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| Case Number: | CM14-0005037 | | |
| Date Assigned: | 02/12/2014 | Date of Injury: | 01/24/2002 |
| Decision Date: | 07/11/2014 | UR Denial Date: | 01/07/2014 |
| Priority: | Standard | Application Received: | 01/14/2014 |

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 Internal 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:

Patient is a 50-year-old male who has submitted a claim for hypertension, diabetes, heart disease, obesity, sleep apnea, anxiety, depression, headaches, opiate-induced hypogonadism, GERD, reflex sympathetic dystrophy, chronic low back pain, and left ankle pain associated with an industrial injury date of January 24, 2002. Medical records from 2012 to 2014 were reviewed. Symptoms of gastrointestinal and emotional instability have improved. Patient was still losing weight. No adverse reactions were noted with medications. Patient denied chest pain, dyspnea, palpitations, dizziness, and syncope. Patient complained of constant total body pain at the neck, upper arms, low back, knees, and ankles. Patient experienced chronic fatigue, and sleeping difficulty. There was associated weakness, numbness and tingling sensation of feet, knees, and hands. There was mild improvement with intake of medications. Patient likewise complained of inguinal pain, left testicular pain, erectile dysfunction, with noted cloudy and foamy urine. Physical examination revealed a blood pressure range of 101/55 to 128/81 mmHg, pulse rate of 55 beats/min, O2 saturation of 97%, and weight of 244.5 pounds. Height and body mass index were not documented. Jugular venous distention was not evident. Cardiac exam revealed a regular rate and rhythm, without murmurs, gallops, or rubs. Edema, clubbing, and cyanosis were not seen. Abdominal exam, mentation and coordination were unremarkable. Bilateral SLR was positive. Tenderness, muscle spasm, and guarding were noted at the paralumbar muscles. Range of motion of both the cervical and lumbar spine was limited. PSA total was within normal limits, while testosterone was 233 ng/dL (normal range: 241 - 827 ng/dL) from 01/15/2013 laboratory test. Laboratory test from 08/06/2013 revealed trace ketones. Urinalysis result, dated November 26, 2013, revealed single organism less than 10,000 CFU per mL, organism that can be found at external genitalia. Urine was yellow, turbid, WBC of 6 to 10 per hpf, +3 glucose, and many / hpf bacteria. Urine drug screen, dated December 27, 2013, revealed consistent results with the

prescribed medications. Treatment to date has included right ankle surgery in 2002, bilateral carpal tunnel release in 2011, spinal cord stimulator, physical therapy, psychotherapy, and intake of medications such as Amlodipine, Invokana, Androgel, Celebrex, Januvia, Risperidone, Pantoprazole, Acetaminophen / Codeine, Atenolol, Benicar, Lyrica, Triamterene/HCTZ, Temazepam, Bupropion, Tizanidine, Metformin, and Carisoprodol. Utilization review from January 7, 2014 denied the requests for Amlodipine 5mg #30, Benicar 40mg #30, Triamterene/HCTZ 37.5/25mg #30, and Atenolol 50mg #45 because patient was prescribed with four different antihypertensive drugs; however, blood pressure was recorded as below normal. The requests for Invokana 300mg #30, Metformin hcl 1000mg #60, and Januvia 100mg #30 were denied because current blood glucose level was not documented. The request for Androgel 1.62% #2 was denied because testosterone deficiency related to the industrial injury was not evident. Celebrex 200mg #60 was denied because of its excessive dose and lack of medical indication. Risperidone 1mg #30 was denied because there was no evidence that patient has depression or psychoses resulting from the industrial injury. Pantoprazole 40mg #60 was denied because Celebrex was already prescribed and it is an alternative use for proton pump inhibitor. Acetaminophen/Codeine 300/60mg #90 was denied because guidelines recommend a maximum of 4000 mg of Acetaminophen daily and concurrent use of Tylenol/Codeine from two providers could potentially exceed that amount. Lyrica 150mg #90 was denied because patient is likewise on Gabapentin and there is no literature to support the use of pre-Gabalin and Gabapentin simultaneously. Temazepam 15mg #60 was denied because long-term use is not recommended. Bupropion 100mg #60 was denied because its medical indication was not documented. The requests for Tizanidine 2mg #60, and Carisoprodol 350mg #90 were denied because muscle spasm was not evident. Lastly, lab work - ua with reflex was non-certified because the urinary tract was not an accepted body part.

IMR ISSUES, DECISIONS AND RATIONALES

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

AMLODIPINE 5MG #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 (ODG).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation the JNC 8 Hypertension Guidelines, 2014 (<http://www.ajmc.com/publications/evidence-based-diabetes-management/2014/jan-feb2014/the-jnc-8-hypertension-guidelines-an-in-depth-guide/2>).

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, and the 2014 JNC 8 Hypertension Guidelines was used instead. It states that thiazide-type diuretics are the recommended initial therapy for most patients. Other alternatives include ACE inhibitors, ARBs, and calcium channel blockers (CCB). Triple therapy with thiazide, ACE inhibitors / ARBs, and CCB would precede the use of beta-blockers. In this case, patient is a known hypertensive with the following medications since 2012: Amlodipine, Olmesartan, Hydrochlorothiazide, and Atenolol. However, recent progress reports noted that

blood pressure range was measured at 101/55 to 128/81 mmHg; there was no management response concerning the documented low blood pressure. The medical necessity for Amlodipine was not established due to insufficient discussion concerning possible change of treatment regimen to prevent episodes of low BP. Therefore, the request for Amlodipine 5mg #30 is not medically necessary.

INVOKANA 300MG #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 (ODG).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation American Diabetes Association 2014 Guidelines for Type 2 Diabetes Medications (<http://www.ndei.org/ADA-2014-guidelines-type-2-diabetes-medications-.aspx>).

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, guidelines from American Diabetes Association 2014 was used instead. It states that Metformin is the preferred initial therapy. If non-insulin monotherapy at maximal tolerated dose does not achieve A1C target over three months, adding a second oral agent or GLP-1 receptor agonist may be given. Patient is a diagnosed case of diabetes mellitus and is on the following medications: Metformin (since 2012), Sitagliptin (Januvia) (since 2012), and Canagliflozin (Invokana) (since March 2013). However, the most recent laboratory test available is dated 08/06/2013, revealing trace ketones. Frequent monitoring of blood glucose is necessary to adjust current treatment regimen. The medical necessity for Invokana was not established due to insufficient information. Therefore, the request for Invokana 300mg #30 is not medically necessary.

ANDROGEL 1.52% #2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone Replacement For Hypogonadism (Related To Opioids).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone Replacement for Hypogonadism (related to opioids) Page(s): 110-111.

Decision rationale: Pages 110-111 of CA MTUS Chronic Pain Medical Treatment Guidelines state that testosterone replacement for Hypogonadism (related to opioids) is recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. In this case, patient has a known opiate-induced Hypogonadism and is on Androgel since 2012. Testosterone was measured at 233 ng/dl (normal range: 241 - 827 ng/dl) from 01/15/2013 laboratory test. Progress report from January 14, 2014 stated that non-certification of Androgel may lead to weakening of muscles and weight loss which may affect rehabilitation program. However, there are no available recent laboratory tests that may indicate

persistence of testosterone deficiency. The medical necessity for continuing Androgel therapy was not established. Therefore, the request for Androgel 1.62% #2 is not medically necessary.

CELEBREX 200MG #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Nsaids, Specific Drug List & Adverse Side Effects Page(s): 70.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.24.2, NSAIDS Page(s): 46.

Decision rationale: As stated on page 46 of the California MTUS Chronic Pain Medical Treatment guidelines, NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain and that there is no evidence of long-term effectiveness for pain or function. In this case, patient has been prescribed Celebrex since 2012. However, there was no documented relief of pain or functional improvement derived from its use. Moreover, long-term use is not recommended. Therefore, the request for Celebrex 200mg #60 is not medically necessary.

JANUVIA 100MG #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 (ODG).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation American Diabetes Association 2014 Guidelines for Type 2 Diabetes Medications (<http://www.ndei.org/ADA-2014-guidelines-type-2-diabetes-medications-.aspx>).

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, guidelines from American Diabetes Association 2014 was used instead. It states that Metformin is the preferred initial therapy. If non-insulin monotherapy at maximal tolerated dose does not achieve A1C target over three months, adding a second oral agent or GLP-1 receptor agonist may be given. Patient is a diagnosed case of diabetes mellitus and is on the following medications: Metformin (since 2012), Sitagliptin (Januvia) (since 2012), and Canagliflozin (Invokana) (since March 2013). However, the most recent laboratory test available is dated 08/06/2013, revealing trace ketones. Frequent monitoring of blood glucose is necessary to adjust current treatment regimen. The medical necessity for Januvia was not established due to insufficient information. Therefore, the request for Januvia 100mg #30 is not medically necessary.

RESPERIDONE 1MG #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants For Chronic Pain Page(s): 16.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (Odg) Pain Section, Anxiety Medications For Chronic Pain.

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG), Pain Section was used instead. ODG identifies that anxiety medications in chronic pain are recommended for diagnosing and controlling anxiety as an important part of chronic pain treatment. Risperidone (Risperdal), an antipsychotic, may be beneficial in treating PTSD. In this case, patient was noted to have anxiety and depression associated from chronic pain syndrome. He has been on Risperidone since 2012. However, there was no documented functional improvement with its use. The medical necessity was not established. Therefore, the request for Risperidone 1mg #30 is not medically necessary.

PANTOPRAZOLE 40MG #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Nsaids, Gi Symptoms & Cardiovascular Risk Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.24.2, NSAIDS, GI Symptoms, and Cardiovascular Risk Page(s): 68.

Decision rationale: As stated on page 68 of CA MTUS Chronic Pain Medical Treatment Guidelines, clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors: age > 65 years, history of peptic ulcer, GI bleeding or perforation; concurrent use of ASA, corticosteroids, or anticoagulant; or on high-dose/multiple NSAIDs. Patients with intermediate risk factors should be prescribed proton pump inhibitors (PPI). Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture. In this case, patient was noted to have GERD associated with multiple opioid and NSAID prescriptions. Patient has been on Pantoprazole since 2012. However, documentation concerning functional improvement derived from its use was not evident. Long-term use is likewise not advisable due to adverse effects. Therefore, the request for Pantoprazole 40mg #60 is not medically necessary.

ACETAMINOPHEN/CODEINE 300/60MG #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Specific Drug List Page(s): 92.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20-9792.26, Opioids Page(s): 78-81.

Decision rationale: As stated on page 78 of CA MTUS Chronic Pain Medical Treatment Guidelines, there are 4 A's for ongoing monitoring of opioid use: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant drug-

related behaviors. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. In this case, patient has been on this medication since 2012. However, the medical records do not clearly reflect continued analgesia, continued functional benefit, or a lack of adverse side effects. MTUS Guidelines require clear and concise documentation for ongoing management. Moreover, utilization review from February 14, 2014 partially certified the request for APAP/Codeine. Therefore, the request for Acetaminophen/Codeine 300/60mg #90 is not medically necessary.

ATENOLOL 50MG #45: 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).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation JNC 8 Hypertension Guidelines, 2014 (<http://www.ajmc.com/publications/evidence-based-diabetes-management/2014/jan-feb2014/the-jnc-8-hypertension-guidelines-an-in-depth-guide/2>).

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, and the 2014 JNC 8 Hypertension Guidelines was used instead. It states that thiazide-type diuretics are the recommended initial therapy for most patients. Other alternatives include ACE inhibitors, ARBs, and calcium channel blockers (CCB). Triple therapy with thiazide, ACE inhibitors / ARBs, and CCB would precede the use of beta-blockers. In this case, patient is a known hypertensive with the following medications since 2012: Amlodipine, Olmesartan, hydrochlorothiazide, and Atenolol. However, recent progress reports noted that blood pressure range was measured at 101/55 to 128/81 mmHg; there was no management response concerning the documented low blood pressure. The medical necessity for atenolol was not established due to insufficient discussion concerning possible change of treatment regimen to prevent episodes of low BP. Therefore, the request for Atenolol 50mg #45 is not medically necessary.

BENICAR 40MG #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 (ODG).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation JNC 8 Hypertension Guidelines, 2014 (<http://www.ajmc.com/publications/evidence-based-diabetes-management/2014/jan-feb2014/the-jnc-8-hypertension-guidelines-an-in-depth-guide/2>).

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, and the 2014 JNC 8 Hypertension Guidelines was used instead. It states

that thiazide-type diuretics are the recommended initial therapy for most patients. Other alternatives include ACE inhibitors, ARBs, and calcium channel blockers (CCB). Triple therapy with thiazide, ACE inhibitors / ARBs, and CCB would precede the use of beta-blockers. In this case, patient is a known hypertensive with the following medications since 2012: Amlodipine, Olmesartan, Hydrochlorothiazide, and Atenolol. However, recent progress reports noted that blood pressure range was measured at 101/55 to 128/81 mmHg; there was no management response concerning the documented low blood pressure. The medical necessity for Olmesartan (Benicar) was not established due to insufficient discussion concerning possible change of treatment regimen to prevent episodes of low BP. Therefore, the request for Benicar 40mg #30 is not medically necessary.

LYRICA 150MG #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs (AEDS) Page(s): 16.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.24.2., Anti-Epilepsy Drugs Page(s): 16-17.

Decision rationale: As stated on pages 16 - 17 of CA MTUS Chronic Pain Medical Treatment Guidelines, antidepressants, such as Pregabalin and Gabapentin, are recommended as a first line option for neuropathic pain, i.e., painful polyneuropathy. In this case, patient's manifestation of chronic low back pain radiating to lower extremities associated with numbness, is consistent with neuropathic pain. Patient has been on Lyrica since 2012; however, there is no documentation concerning pain relief and functional improvement derived from its use. Moreover, patient is likewise on Gabapentin; utilization review from February 14, 2014 certified the request for Gabapentin. There is no discussion concerning need to provide multiple antidepressants in this case. The medical necessity was not established. Therefore, the request for Lyrica 150mg #90 is not medically necessary.

TRIAMTERENE/HCTZ 37.5/25MG #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 (ODG).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation JNC 8 Hypertension Guidelines, 2014 (<http://www.ajmc.com/publications/evidence-based-diabetes-management/2014/jan-feb2014/the-jnc-8-hypertension-guidelines-an-in-depth-guide/2>).

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, and the 2014 JNC 8 Hypertension Guidelines was used instead. It states that thiazide-type diuretics are the recommended initial therapy for most patients. Other alternatives include ACE inhibitors, ARBs, and calcium channel blockers (CCB). Triple therapy with thiazide, ACE inhibitors / ARBs, and CCB would precede the use of beta-blockers. In this

case, patient is a known hypertensive with the following medications since 2012: Amlodipine, Olmesartan, Hydrochlorothiazide, and Atenolol. However, recent progress reports noted that blood pressure range was measured at 101/55 to 128/81 mmHg; there was no management response concerning the documented low blood pressure. The medical necessity for diuretic was not established due to insufficient discussion concerning possible change of treatment regimen to prevent episodes of low BP. Therefore, the request for Triamterene/HCTZ 37.5/25MG #30 is not medically necessary.

TEMAZEPAM 15MG #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 - 9792.26, Benzodiazepines Page(s): 24.

Decision rationale: As stated on page 24 of CA MTUS Chronic Pain Medical Treatment Guidelines, benzodiazepines are 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 sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. In this case, patient has been on Temazepam since 2012 for sleeping difficulty and anxiety. However, there is no documentation concerning functional improvement derived from its use. Moreover, long-term use is not recommended. The medical necessity was not been established. Therefore, the request for Temazepam 15mg #60 is not medically necessary.

BUPROPION 100MG #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants For Chronic Pain Page(s): 16.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 - 9792.26, Bupropion (Wellbutrin) Page(s): 16.

Decision rationale: As stated on page 16 of CA MTUS Chronic Pain Medical Treatment Guidelines, Bupropion (Wellbutrin) is a second-generation non-tricyclic antidepressant which is likewise effective in treating neuropathic pain. In this case, patient has anxiety disorder major depressive disorder, and neuropathic pain. He has been on Bupropion since 2012. However, medical records submitted and reviewed failed to indicate benefits derived from its use. There is no clear indication for continuing Bupropion at this time. Therefore, the request for Bupropion 100mg #60 is not medically necessary.

TIZANIDINE 2MG #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxant Page(s): 63.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.24.2, Muscle Relaxant Page(s): 63.

Decision rationale: According to page 63 of the CA MTUS Chronic Pain Medical Treatment Guidelines, non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. In this case, the patient has been on Tizanidine since 2012. However, there is no documentation concerning pain relief and functional improvement derived from its use. Recent physical examination still showed presence of muscle spasm at the paralumbar area. Long-term use is likewise not recommended. Therefore, the request for Tizanidine 2mg #60 Is not medically necessary.