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| Case Number: | CM14-0088550 | | |
| Date Assigned: | 07/23/2014 | Date of Injury: | 09/01/1998 |
| Decision Date: | 11/21/2014 | UR Denial Date: | 05/21/2014 |
| Priority: | Standard | Application Received: | 06/12/2014 |

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, has a subspecialty in Interventional Spine 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 patient is a 57 year old male with an injury date of 09/01/98. Based on the 04/14/14 progress report provided by [REDACTED], the patient complains of chronic back pain. He is scheduled for spinal cord stimulator trial on 05/29/14. Based on the 05/12/14 progress report by [REDACTED], the patient is having a Testopel Implant. Note for "Testopel Implant": Serum T 404 4 months after 12 tablets implanted, estradiol normal. Patient is on total temporary disability. Based on the 04/20/14 QME report, patient's current medications on 08/31/04 included Fentanyl patches and 10 Fentanyl pops a day, hydrosadine (sic). On 04/29/09, patient used morphine 4-5 tablets a day. On 08/31/09, authorization was requested for a complete restoration of the patient's dentition using dental implants, attributed to the patient's extended use of buccal fentanyl. On 04/06/10, following lumbar spine surgery with removal of implant, exploration of fusion, revision of spinal fusion, T11-S1, he was admitted for long spinal surgery, and taken to the ICU for psychosis. He was on IV Fentanyl and IV Dilaudid drip. On 04/23/10, it is reported patient is taking a significant amount of opioid medication, approximately double his prior dose. Long acting morphine tapering begun. 08/12/10 patient is having difficulty with morphine taper, so Ziprexa was prescribed. 03/07/11 patient is tolerating taper of morphine. 04/26/11 taper of morphine is continued and he will be transitioned to Suboxone. 02/06/12, patient reports less pain with increase in medications. 02/13/12, patient rates his pain at 7/10 and his medications include MSContin, Tizanidine, Lamictal, Depakote, Trazodone, Lexapro, Wellbutrin, Ambien, Penbtoprazole, Tamsulosin, Testosterone Pellet, Nitrostat, Lisinopril, Metoprolol, aspirin, Plavix, Usiniprel, Senna, Taulosin, Crestor, Vesicare, Olanzapine, Vita-D, Cialis, Divalproex, and Depakote. 04/16/12 MS ER is prescribed. 07/16/12 Trazodone dosage is increased. 11/15/12 patient reports severe pain after tapering opiates and

1) dropping to just MS Contin. 12/27/12 patient is on Suboxone. 04/04/13, patient went to ER for significant back pain and limitation of movement and was prescribed narcotic and injection of Dilaudid. Diagnosis 04/14/14 by [REDACTED]: failed back syndrome post multiple lumbar surgeries, Hx of Hypovitaminosis D. improved, history of paranoid ideation - resolved, opioid induced, hypogonadism under treatment, opioid induced hyperalgesia, atopic dermatitis - resolved, neuritic pain bilateral feet. CAD: myocardial infarction September 2005, s/p Anterior STEMI. s/p LAD stenting 2005, s/p Angio with 3 stent placement in RCA on 11/30/09, hypertension, uncontrolled, obesity with BMI of 36.9 - secondary to work injury, depression due to chronic pain, s/p detox at [REDACTED], diastolic CHF, sleep disturbances - chronic with episodic exacerbations. Assessment 05/12/14 by [REDACTED] - Hypogonadism- high cholesterol- neurogenic bladder NOS- hypertension- heart disease- impotence, organic- inhibited male orgasm Plan 05/12/14 by [REDACTED] - Testopel, 12 pellets, routine- implant hormone pellets, routine- future labs:- hematocrit, routine one time- testosterone, total, routine one time. The utilization review determination being challenged is dated 05/21/14. The rationale follows: 1) Hematocrit: "There was no clear detail provided in the available documentation/information as to why this laboratory study needs to be obtained and how this will be helpful in the overall treatment plan. There was also no mention of any particular medical instability or complication occurring medically with regard to the patient's blood issues/blood work to support the need for this particular testing as well. Therefore, this request is not medically reasonable or necessary." 2) Testosterone: "There was no clear detail provided as to why the testosterone levels need to be obtained at this point and how this will be helpful and no clear detail provided as to when the last testosterone levels were obtained, including the results, a. routine testing of testosterone levels is not supported in the guideline criteria. Therefore, this request is not medically reasonable or necessary." 3) PSA (Prostate-Specific Antigen Test): "There was no clear detail provided as to why this lab work is being requested and how this will be helpful in the overall treatment plan and there was also no documentation of any particular objective prostate problems occurring to support the need for this particular testing. Therefore, this request is not medically reasonable or necessary." 4) Testopel (12) Pellets 75mg each: "There was no clear detail provided in the available documentation/information as to why the patient requires the ongoing opioid treatment that is causing the hypogonadism problems and other side effects for the patient and why opioid weaning and discontinuation could not be done and what specific overall functional benefit has been achieved with the opioid treatment as opposed to functionality without the opioids. There was also no clear detail provided as to what the long-term plans are for the opioids and whether the opioid treatment is going to be done for the long-term or short-term and if opioid treatment is no longer continued, then there would be no further need for testosterone replacement and hypogonadism issues would resolve. Therefore, this request is not medically reasonable or necessary." [REDACTED] is the requesting provider, and he provided treatment reports from 11/28/12 - 05/12/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Hematocrit: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Institutes of Health

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: National Institutes of Health; Hematocrit

Decision rationale: The patient presents with chronic back pain and hypogonadism. The request is for Hematocrit. His diagnosis dated 04/14/14 includes failed back syndrome post multiple lumbar surgeries, opioid induced hypogonadism under treatment and opioid induced hyperalgesia. MTUS and ODG are silent regarding the request. Therefore, the National Institutes of Health was referenced, which state "Hematocrit is a blood test that measures the percentage of the volume of whole blood that is made up of red blood cells. This measurement depends on the number of red blood cells and the size of red blood cells. This test may be order if there are signs of: Anemia; Diet deficiency; Leukemia; and Other medical condition." Per progress report dated 05/12/14, treating physician plans hematocrit, routine one time, however he has not explained reason for the request. Though patient presents with obesity and hypovitaminosis D, there is no mention of anemia, diet deficiency, leukemia or other medical condition presented by patient that would warrant a hematocrit blood test. This request is not medically necessary.

Testosterone: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 110-111.

Decision rationale: The patient presents with chronic back pain and hypogonadism. The request is for Testosterone. His diagnosis dated 04/14/14 includes failed back syndrome post multiple lumbar surgeries, opioid induced hypogonadism under treatment and opioid induced hyperalgesia. Regarding, testosterone levels, MTUS states "Routine testing of testosterone levels in men taking opioids is not recommended; however, an endocrine evaluation and/or testosterone levels should be considered in men who are taking long term, high dose oral opioids or intrathecal opioids and who exhibit symptoms or sign of hypogonadism, such as gynecomastia." Based on the 04/20/14 QME report, patient's current medications on 08/31/04 included Fentanyl patches and 10 Fentanyl pops a day, hydrosadine (sic). On 04/29/09, patient used morphine 4-5 tablets a day. On 08/31/09, authorization was requested for a complete restoration of the patient's dentition using dental implants, attributed to the patient's extended use of buccal fentanyl. On 04/06/10, following lumbar spine surgery with removal of implant, exploration of fusion, revision of spinal fusion, T11-S1, he was admitted for long spinal surgery, and taken to the ICU

for psychosis. He was on IV Fentanyl and IV Dilaudid drip. On 04/23/10, it is reported patient is taking a significant amount of opioid medication, approximately double his prior dose. Long acting morphine tapering begun. 08/12/10 patient is having difficulty with morphine taper, so Ziprexa was prescribed. 03/07/11 patient is tolerating taper of morphine. 04/26/11 taper of morphine is continued and he will be transitioned to Suboxone. 02/06/12, patient reports less pain with increase in medications. 02/13/12, patient rates his pain at 7/10 and his medications include MS Contin, Tizanidine, Lamictal, Depakote, Trazodone, Lexapro, Wellbutrin, Ambien, Penbtoprazole, Tamsulosin, Testosterone Pellet, Nitrostat, Lisinopril, Metoprolol, aspirin, Plavix, Usiniprel, Senna, Taulosin, Crestor, Vesicare, Olanzapine, Vita-D, Cialis, Divalproex, and Depakote. 04/16/12 MS ER is prescribed. 07/16/12 Trazodone dosage is increased. 11/15/12 patient reports severe pain after tapering opiates and dropping to just MS Contin. 12/27/12 patient is on Suboxone. 04/04/13, patient went to ER for significant back pain and limitation of movement and was prescribed narcotic and injection of Dilaudid. Treating physician has documented that patient has been taking opioids long term and diagnosis dated 04/14/14 documents hypogonadism. The request is in line with MTUS indications. This request is medically necessary

PSA (Prostate-Specific Antigen Test): Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Institutes of Health

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: National Institutes of Health; PSA

Decision rationale: The patient presents with chronic back pain and hypogonadism. The request is for PSA (Prostate-Specific Antigen Test). His diagnosis dated 04/14/14 includes failed back syndrome post multiple lumbar surgeries, opioid induced hypogonadism under treatment and opioid induced hyperalgesia. MTUS and ODG are silent regarding this request. Therefore, National Institutes of Health was referenced, which state "PSA stands for prostate-specific antigen. It is a protein produced by prostate cells. This article discusses the blood test to measure the amount of PSA in a man's blood. Reasons for a PSA test: This test may be done to screen for prostate cancer; it is also used to follow patients after prostate cancer treatment to see if the cancer has come back; or if a healthcare provider feels the prostate gland is not normal during physical exam." Review of the literature shows that there is correlation between low testosterone level or hypogonadal men and prevalence of prostate cancer. (Urology 2006 Dec;68(6):1263-7) In review of reports, treating physician has not stated reason for requesting PSA test. However, given the patient's low testosterone level with replacement therapy, obtaining PSA level would appear reasonable given the risk for prostate potential issues. This request is medically necessary.

TESTOPEL (12) Pellets 75mg Each: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone Replacements for Hypogonadism (related to opioids).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 110-111.

Decision rationale: The patient presents with chronic back pain and hypogonadism. The request is for Testopel (12) Pellets 75mg each. His diagnosis dated 04/14/14 includes failed back syndrome post multiple lumbar surgeries, opioid induced hypogonadism under treatment and opioid induced hyperalgesia. Regarding testosterone replacement for hypogonadism (related to opioids); MTUS states "Recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. Hypogonadism has been noted in patients receiving intrathecal opioids and long-term high dose opioids, Routine testing of testosterone levels in men taking opioids is not recommended; however, an endocrine evaluation and/or testosterone levels should be considered in men who are taking long term, high dose oral opioids or intrathecal opioids and who exhibit symptoms or signs of hypogonadism, such as gynecomastia."Based on the 04/20/14 QME report, patient's current medications on 08/31/04 included Fentanyl patches and 10 Fentanyl pops a day, hydrosadine (sic). On 04/29/09, patient used morphine 4-5 tablets a day. On 08/31/09, authorization was requested for a complete restoration of the patient's dentition using dental implants, attributed to the patient's extended use of buccal fentanyl. On 04/06/10, following lumbar spine surgery with removal of implant, exploration of fusion, revision of spinal fusion, T11-S1, he was admitted for long spinal surgery, and taken to the ICU for psychosis. He was on IV Fentanyl and IV Dilaudid drip. On 04/23/10, it is reported patient is taking a significant amount of opioid medication, approximately double his prior dose. Long acting morphine tapering begun. 08/12/10 patient is having difficulty with morphine taper, so Ziprexa was prescribed. 03/07/11 patient is tolerating taper of morphine. 04/26/11 taper of morphine is continued and he will be transitioned to Suboxone. 02/06/12, patient reports less pain with increase in medications. 02/13/12, patient rates his pain at 7/10 and his medications include MS Contin, Tizanidine, Lamictal, Dapacote, trazodone, Lexapro, Wellbutrin, Ambien, Penbtoprazole, Tamsulosin, Testosterone Pellet, Nitrostat, Lisinopril, Metoprolol, aspirin, Plavix, Usiniprel, Senna, Taulosin, Crestor, Vesicare, Olanzapine, Vita-D, Cialis, Divalproex, and Depakote. 04/16/12 MS ER is prescribed. 07/16/12 Trazodone dosage is increased. 11/15/12 patient reports severe pain after tapering opiates and dropping to just MS Contin. 12/27/12 patient is on Suboxone. 04/04/13, patient went to ER for significant back pain and limitation of movement and was prescribed narcotic and injection of Dilaudid. Treating physician has documented that patient has been taking opioids long term and diagnosis dated 04/14/14 documents hypogonadism. The request is in line with MTUS indications. This request is medically necessary.

