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| Case Number: | CM15-0020778 | | |
| Date Assigned: | 02/10/2015 | Date of Injury: | 11/08/1993 |
| Decision Date: | 04/01/2015 | UR Denial Date: | 01/13/2015 |
| Priority: | Standard | Application Received: | 02/04/2015 |

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 74 year old male who sustained an industrial injury on November 8, 1993. He has reported low back pain and leg pain and has been diagnosed with lumbago and post laminectomy syndrome lumbar region. Treatment has included surgery, medications, physical therapy, and a TENS unit. Currently the injured worker has ongoing axial baseline pain in the low back but the right leg was getting worse to below the knee. There was numbness and tingling to the right lower extremity. The treatment plan included physical therapy, TENS unit, and a medication regime. On January 13, 2015 Utilization Review non certified Foresta or Androgel, Ambien 10 mg # 30, Dexilant 60 mg # 30, and Zorvolex 18 mg # 60 citing the MTUS and Official Disability Guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fortesta or Androgel (given hypogonadism): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA on Androgel website (<http://www.fda.gov/downloads/Drugs/DrugSafety/UCM255313.pdf>) Official disability guidelines ODG pain chapter re: testosterone.

Decision rationale: This patient presents with low back pain and right sided leg pain. The current request is for Fortesta or Androgel (given hypogonadism). The MTUS, ACOEM and ODG guidelines do not discuss AndroGel. Therefore an alternative resource was consulted. The FDA (<http://www.fda.gov/downloads/Drugs/DrugSafety/UCM255313.pdf>) has the following regarding AndroGel; "Androgel 1.62% is a prescription medicine that contains testosterone. 1.62% is used to treat adult males who have low or no testosterone. It is recommended that healthcare providers test patient's blood before they start and while they are taking Androgel 1.62%." ODG guidelines under its pain chapter has the following regarding testosterone, "recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels." According to progress report dated 12/22/14, the treating physician recommended checking testosterone levels to rule out Hypogonadism secondary to opioid therapy and chronic pain. Under treatment plan it stated "consider Fortesta or AndroGel, given Hypogonadism." In this case, while the treating physician has concerns for Hypogonadism and the patient is on long-term opioid use, there is no documentation of low levels of testosterone. ODG recommends testosterone replacement for patients taking high-dose long-term opioids with documented low testosterone levels. This request IS NOT medically necessary.

Ambien 10mg 1 by mouth at bedtime #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC, Mosby's Drug Consult.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines mental illness and stress chapter regarding Zolpidem/Ambien.

Decision rationale: This patient presents with low back pain and right sided leg pain. The current request is for Ambien 10mg 1 by mouth once a day #30. The ACOEM and MTUS Guidelines do not address Ambien; however, the ODG Guidelines under the mental illness and stress chapter regarding Zolpidem/Ambien states, "Zolpidem, Ambien generic available Ambien CR, is indicated for short-term treatment of insomnia with difficulty of onset (7-10 days)." The patient reports poor sleep quality due to pain, but "meds help with pain/sleep." In this case, review of the medical file indicates the patient has been utilizing Ambien as early as 9/3/14 and ODG only support short-term use of this medication. The requested Ambien IS NOT medically necessary.

Dexilant 60mg 1 by mouth once a day #30: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 69.

Decision rationale: This patient presents with low back pain and right sided leg pain. The current request is for Dexilant 60mg 1 by mouth once a day #30. The MTUS Guidelines, pages 68 and 69, states that PPI is recommended with precaution for patients at risk for gastrointestinal events: 1. Ages greater than 65. 2. History of peptic ulcer disease and GI bleeding or perforation. 3. Concurrent use of ASA or corticoid and/or anticoagulant. 4. High dose/multiple NSAID. Review of the medical file indicates that the patient's current medication regimen includes Ambien, Cymbalta, Norco, Oxycontin, Senokot, Zanaflex and Zorvolex. The patient has been utilizing Zorvolex an NSAID on a long term basis and the treating physician reports that the patient has GI issues. The use of Dexilant is appropriate in this case. This request IS medically necessary.

Zorvolex 18mg, 1 by mouth twice a day as needed #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-68. Decision based on Non-MTUS Citation Official disability guidelines Pain chapter, Diclofenac.

Decision rationale: This patient presents with low back pain and right sided leg pain. The current request is for Zorvolex 18mg, 1 by mouth twice a day as needed #60. MTUS guidelines page 67 and 68 recommend NSAIDs (non-steroidal anti-inflammatory drugs) as an option for short-term symptomatic relief. However, for Diclofenac, ODG guidelines provide a specific discussion stating, "Not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that Diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients as did rofecoxib (Vioxx), which was taken off the market. According to the authors, this is a significant issue and doctors should avoid Diclofenac because it increases the risk by about 40%." It goes onto state that there is substantial increase in stroke. According to progress report dated 10/29/14, the trial of Zorvolex "worked well." In this case, the progress reports do not discuss why this medication was initiated. ODG does not support this medication unless other NSAIDs have failed and the patient is a very low risk profile. None of the report indicate whether the patient has utilized other NSAIDs or not. The request IS NOT medically necessary.