MAXIMUS Federal Services

| Case Number: | CM14-0196955 | | |
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| Date Assigned: | 12/05/2014 | Date of Injury: | 05/04/2012 |
| Decision Date: | 01/16/2015 | UR Denial Date: | 10/31/2014 |
| Priority: | Standard | Application Received: | 11/24/2014 |

## 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 New York. 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 claimant is a 41-years /old male who sustained an industrial injury on 05/04/2012. The mechanism of injury occurred when he was going down a steep hill and became stuck in the mud injuring his left knee. His diagnoses include left knee internal derangement: status post left knee arthroscopy in 9/13 with residual ankylosis, left lower extremity complex regional pain syndrome, lumbar discogenic pain, history of left leg deep venous thrombosis with questionable pulmonary embolus. He continues to complain of left knee and low back pain. On physical exam his gait is left guarded and antalgic. There is left leg atrophy, hyperalgesia and moderate to severe weakness of the left leg. Treatment has included medical therapy with opiates and epidural steroid injection therapy. The treating provider has requested Cialis 20mg # 10.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Cialis 20mg #10:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA Guideline

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medscape Internal Medicine 2013- Erectile Dysfunction

**Decision rationale:** Tadalafil is PDE5 inhibitor marketed in pill form for treating erectile dysfunction (ED) under the name Cialis, and under the name Adcirca for the treatment of pulmonary arterial hypertension. The PDE5 inhibitors are the recommended first-line treatment for ED. However, their use is not recommended in men who have recent history of stroke or myocardial infarction (within the last 6-8 weeks), or who have significantly low blood pressure, uncontrolled high blood pressure, unstable angina, severe cardiac failure, severe liver impairment or end-stage kidney disease requiring dialysis. Prescribers should consult the prescribing information of the individual PDE5 inhibitors. Although the PDE5 inhibitors show the same mechanism of action, these drugs have some pharmacological differences that translate into differing clinical effects. The PDE5 inhibitors show marked differences in their duration of effect. According to the prescribing information, the duration of effect with Sildenafil and Vardenafil is approximately 4-5 however; consistent with its half-life of 17.5 h, Tadalafil's duration of effect is up to 36 h. This broad window of responsiveness allows patients with ED more freedom to choose when they participate in sexual intercourse. Although several comparative trials are currently being undertaken, results of published head-to-head comparative trials of different PDE5 inhibitors are lacking. Therefore, caution must be used when comparing results as studies have used different designs, enrolled different patient populations (e.g. exclusion of patients who failed to respond to sildenafil) and utilized different efficacy measures, all of which may impact on treatment outcomes. However, all three PDE5 inhibitors have been clearly shown to be effective in the general population of men with ED. There is no accepted urologic industrial injury in this case. There is no information available in the documentation to explain why Cialis is necessary on an industrial basis. There is no documentation of any details regarding the claimant's erectile dysfunction or any relation to prescribed medications. Medical necessity for the requested item has not been established. The requested item is not medically necessary.