

<b>Case Number:</b>	CM15-0092208		
<b>Date Assigned:</b>	05/18/2015	<b>Date of Injury:</b>	08/13/2012
<b>Decision Date:</b>	06/17/2015	<b>UR Denial Date:</b>	04/30/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/13/2015

### 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: Arizona, California  
 Certification(s)/Specialty: Family Practice

### 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 50 year old male with an industrial injury dated 8/13/2012. The injured worker's diagnoses include erectile dysfunction, hypogonadism and Peyronie's disease. Treatment consisted of penile duplex ultrasound, testosterone pellet therapy and periodic follow up visits. In a progress note dated 3/12/2015, the injured worker presented for follow up of Peyronie's disease. The treating physician reported that the injured worker has stippled plaque with some calcification and shadowing with palpable portion of the plaque appeared to have multiple collagen islands. The treating physician prescribed services for Xiaflex injection 0.9 mg twice per 28 days, refill x 3 now under review.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Xiaflex injection 0.9 mg twice per 28 days, refill x 3: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Physicians' Desk Reference, 2015.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Clinical efficacy of collagenase Clostridium histolyticum in the treatment of Peyronie's disease by subgroup: results from two large, double-

blind, randomized, placebo-controlled, phase III studies. Lipshultz LI, Goldstein I, Seftel AD, Kaufman GJ, Smith TM, Tursi JP, Burnett AL. *BJU Int.* 2015 Feb 24.

**Decision rationale:** According to the clinical records, the claimant has Peyronie's disease. Xiaflex or collagenase is a novel treatment shown to benefit such disorders. Interval between injections is 6 weeks. In this case, the request for injections was twice in a month - which exceeds the product labeling and is not medically necessary.