



American Urological Association

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August 5, 2014

Dear Medical Director,

It has come to the attention of the American Urological Association that your insurance carrier may not cover Xiaflex (collagenase clostridium histolyticum) for the treatment of Peyronie's disease and, therefore, is not reimbursed. This non-surgical treatment is not considered experimental or investigational.

On December 6, 2013, the United States Food and Drug Administration granted Auxilium approval for the use of Xiaflex for the treatment of Peyronie's disease.

Peyronie's disease is caused by scar tissue, called plaque, which forms along the length of the penis in the corpora cavernosa. This plaque is not visible, and depending on the severity of the condition, this condition can cause penile curvature with erection. The curvature can make intercourse difficult and/or painful for the patient and his partner.

There are no specific Current Procedural Terminology (CPT)[®] codes for this treatment. The treatment is performed on three separate encounters. The first two visits include the injection of the drug and the third visit includes the manipulation to break up the plaque in the penis.

In addition, this drug is only available through a FDA restricted program under a Risk Evaluation and Mitigation Strategy (REMS) because of the risks of adverse reactions. Physicians who are using this treatment must be trained in the administration of this drug.

The American Urological Association has developed Recommendations for Coding for Xiaflex and that document is attached for your review on appeal.

The AUA requests that you reconsider your determination and reverse the denial of Xiaflex (J0775) and CPT codes for the appropriate reporting of this treatment.

Headquarters

Michael T. Sheppard, CPA, CAE
Executive Director

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American Urological Association

Attached are the AUA's recommendations for reporting Xiaflex for reimbursement. We have educated our members through articles and information posted on the AUA's website. We ask that you reconsider your coverage and reimbursement of Xiaflex as a new non-surgical medical option for the treatment of Peyronie's disease.

In the case of an appeal by a physician, all correspondence should be directed to the medical office requesting the review of the denied claim.

If you have any other questions about this request for coverage and reimbursement, please contact Stephanie N. Stinchcomb, Senior Manager of Reimbursement & Regulation at 866-746-4282, extension 3786.

Thank you very much for your consideration.

Sincerely,

David Penson, M.D., MPH
Chair, AUA Health Policy Council

Ronald P. Kaufman, M.D.
Chair, AUA Coding and Reimbursement Committee

Jeffrey A. Dann, M.D.
AUA Advisor to AMA Current Procedural Terminology (CPT) Editorial Panel

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