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Concerning: Transprostatic Implant appeal letter February 2015

February 2015

Dear Medical Director,

Many scientific studies document that sexual health is an integral part of good overall health and that sexual dysfunction compromises overall health and life satisfaction. The importance of sexual health in enhancing quality of life is an unchallenged and intuitive concept to men and women everywhere.

The Sexual Medicine Society of North America (SMSNA) is North America's leading professional society, which is concerned with the medical aspects of sexual health and sexual dysfunction. Among the patients for whom our members care, the sexual side effects of treatment for benign enlargement of the prostate gland are a common problem. Benign enlargement of the prostate gland (also called benign prostatic hyperplasia or BPH) is a condition which affects most older men. Until recently, virtually all treatments for this common condition have been associated with risks of erectile dysfunction and/or ejaculatory dysfunction. Pharmacologic therapy for BPH provides modest improvement in urinary function but up to 30% of patients discontinue treatment because of insufficient improvement in urinary symptoms and/or bothersome side effects, including sexual dysfunction. Surgical therapy for BPH provides better levels of improvement in urinary function but also higher levels of sexual dysfunction. Studies on surgical therapy for BPH show that 3 to 14% of men suffer from erectile dysfunction and 30 to 80% suffer from ejaculatory dysfunction after treatment.

A new method for treatment of BPH, the cystourethrosopic insertion of permanent adjustable transprostatic implants (also known as the Urolift® prostatic urethral lift procedure), has been approved by the FDA. This new procedure has the key advantage of avoiding the risks of erectile and ejaculatory dysfunction while still providing excellent improvement in urinary function. In two key publications,^{1,2} the incidence of erectile and ejaculatory dysfunction after adjustable transprostatic implants was zero. The absence of sexual side effects of this therapy makes adjustable transprostatic implants a very attractive option for the treatment of BPH in all sexually active men. Some urologists believe it is the treatment of choice for sexually active men with BPH.

It has come to the attention of the SMSNA that your organization considers the Urolift® prostatic urethral lift procedure to be investigational and/or experimental in the treatment of BPH, thereby making this procedure ineligible



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for reimbursement. It is difficult for us to understand how an FDA approved procedure could be considered investigational or experimental. The SMSNA does not consider this FDA-approved procedure to be investigational or experimental. We believe that the Urolift® prostatic procedure is a standard option for the treatment of BPH and that it should be recognized as an appropriate therapeutic tool, which is being used by many urologists. We request that you reconsider your position on this procedure, which has excellent clinical results and which has the distinct advantage compared to other treatments for BPH of preserving normal sexual function.

Sincerely,

Lawrence S. Hakim
SMSNA President

Ira D. Sharlip
Legislative Affairs Committee Chair

1. Woo HH, et.al. Preservation of sexual function with the prostatic urethral lift: a novel treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. J Sex Med 2012;9:568-575
2. Roehrborn CG, et. al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: the L.I.F.T. Study. J Urol 2013;190:2161-2167