

(70181)

<b>Medical Benefit</b>		<b>Effective Date:</b> 05/01/06	<b>Next Review Date:</b> 03/21
<b>Preauthorization</b>	No	<b>Review Dates:</b> 03/07, 05/08, 05/09, 03/10, 03/11, 03/12, 03/13, 03/14, 03/15, 03/16, 03/17, 03/18, 03/19, 03/20	

***This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>Who have radical prostatectomy with resection of neurovascular bundles</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Nerve grafting</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Prostatectomy without nerve grafting</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Functional outcomes</li> <li>Quality of life</li> <li>Treatment-related morbidity</li> </ul>

### DESCRIPTION

Nerve grafting at the time of radical prostatectomy, most commonly using the sural nerve, has been proposed to reduce the risk of postoperative erectile dysfunction.

### SUMMARY OF EVIDENCE

For individuals who have radical prostatectomy with resection of neurovascular bundles who receive nerve grafting, the evidence includes a randomized controlled trial, cohort studies, and case series. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. The randomized controlled trial did not find that unilateral nerve grafting was associated with a statistically significant improvement in potency rates at two years postsurgery. Cohort studies also did not result in better outcomes with nerve grafting. The evidence is insufficient to determine the effects of the technology on health outcomes.

### POLICY

Unilateral or bilateral nerve graft is considered **investigational** in patients who have had resection of one or both neurovascular bundles as part of a radical prostatectomy.

## BACKGROUND

### ERECTILE DYSFUNCTION

Erectile dysfunction is a common problem after radical prostatectomy. In particular, spontaneous erections are usually absent in men whose prostate cancer required bilateral resection of the neurovascular bundles as part of the radical prostatectomy procedure.

#### Treatment

A variety of noninvasive treatments are available, including vacuum constriction devices and intracavernosal injection therapy. However, spontaneous erectile activity is preferred by patients. Studies have reported results from bilateral and unilateral nerve grafts, the latter involving resection of one neurovascular bundle.

There has been interest in sural nerve grafting to replace cavernous nerves resection during prostatectomy. The sural nerve is considered expendable and has been extensively used in other nerve grafting procedures, such as brachial plexus and peripheral nerve injuries. As applied to prostatectomy, a portion of the sural nerve is harvested from one leg and then anastomosed to the divided ends of the cavernous nerve. Reports also indicate the use of other nerves (e.g., genitofemoral nerve) for grafting.

## REGULATORY STATUS

A nerve graft with radical prostatectomy is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA).

Several nerve cuff products have been cleared for marketing by FDA through the 510(k) process. FDA product code: JXI. An example of a human tissue nerve graft product, the Avance® nerve graft (AxoGen), is regulated by FDA under 21 CFR, Part 1271 regulations for Human Cellular and Tissue-based Products (HCT/P).

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Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Davis JW, Chang DW, Chevray P, et al. Randomized phase II trial evaluation of erectile function after attempted unilateral cavernous nerve-sparing retropubic radical prostatectomy with versus without unilateral sural nerve grafting for clinically localized prostate cancer. *Eur Urol.* May 2009;55(5):1135-1143. PMID 18783876
2. Kung TA, Waljee JF, Curtin CM, et al. Interpositional nerve grafting of the prostatic plexus after radical prostatectomy. *Plast Reconstr Surg Glob Open.* Jul 2015;3(7):e452. PMID 26301141

3. Namiki S, Saito S, Nakagawa H, et al. Impact of unilateral sural nerve graft on recovery of potency and continence following radical prostatectomy: 3-year longitudinal study. *J Urol*. Jul 2007;178(1):212-216; discussion 216. PMID 17499797
4. Rabbani F, Ramasamy R, Patel MI, et al. Predictors of recovery of erectile function after unilateral cavernous nerve graft reconstruction at radical retropubic prostatectomy. *J Sex Med*. Jan 2010;7(1 Pt 1):166-181. PMID 19686422
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6. Souza Trindade JC, Viterbo F, Petean Trindade A, et al. Long-term follow-up of treatment of erectile dysfunction after radical prostatectomy using nerve grafts and end-to-side somatic-autonomic neurorraphy: a new technique. *BJU Int*. Jun 2017;119(6):948-954. PMID 28093890
7. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 2.2018. [https://www.nccn.org/professionals/physician\\_gls/PDF/prostate.pdf](https://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf). Accessed March 15, 2019.