

## FEP 7.01.81 Nerve Graft With Radical Prostatectomy

**Effective Date:** July 15, 2018

**Related Policies:** None

### Nerve Graft With Radical Prostatectomy

#### 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.

#### FDA 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 the 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 the FDA under 21 CFR, Part 1271 regulations for Human Cellular and Tissue-based Products (HCT/P).

#### POLICY STATEMENT

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.

#### BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

#### RATIONALE

#### 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 2 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.

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### SUPPLEMENTAL INFORMATION

#### Practice Guidelines and Position Statements

The National Comprehensive Cancer Network guidelines on the treatment of prostate cancer (v.2.2018) states: "Replacement of resected nerves with nerve grafts has not been shown to be beneficial" for recovery of erectile function after radical prostatectomy.<sup>7</sup>

#### U.S. Preventive Services Task Force Recommendations

Not applicable.

#### Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

### REFERENCES

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
5. Siddiqui KM, Billia M, Mazzola CR, et al. Three-year outcomes of recovery of erectile function after open radical prostatectomy with sural nerve grafting. *J Sex Med.* Aug 2014;11(8):2119-2124. PMID 24903070
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 neurotaphy: 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 12, 2018.

### POLICY HISTORY

Date	Action	Description
June 2012	New Policy	
March 2013	Update Policy	Literature review update; No change in policy statement.
March 2014	Update Policy	Literature review updated adding reference 7. No change in policy statement.
March 2015	Update Policy	Literature review updated adding reference 7. No change in policy statement.
June 2017	Update Policy	Title changed to "Nerve Graft With Radical Prostatectomy." Policy updated with literature review through March 31, 2017; references 2 and 6 added. Policy statement unchanged.
June 2018	Update Policy	Policy updated with literature review through February 5, 2018; no references added; reference 7 updated. Policy statement unchanged except "not medically necessary" corrected to "investigational" since 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).

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