

## ***Nerve Graft with Radical Prostatectomy***

**Effective:** November 1, 2020

**Next Review:** July 2021

**Last Review:** September 2020

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

Nerve grafting is performed to replace cavernous nerves that have been resected during radical prostatectomy for prostate cancer.

### **MEDICAL POLICY CRITERIA**

Unilateral or bilateral nerve graft is considered **not medically necessary** in patients who have undergone resection of one or both neurovascular bundles as part of a radical prostatectomy.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

### **CROSS REFERENCES**

None

### **BACKGROUND**

Nerve grafting is performed to replace cavernous nerves that have been resected during radical prostatectomy for prostate cancer. The intent of this nerve grafting is to treat the erectile dysfunction that is a common problem when nerve sparing surgical techniques are

unsuccessful or cannot be accomplished due to the location or extent of the tumor. The sural nerve, the most common donor nerve, is considered expendable and has been used extensively in other nerve grafting procedures, such as brachial plexus and peripheral nerve injuries. A portion of the sural nerve is harvested from one leg and then anastomosed to the divided ends of the cavernous nerve. Other nerves, such as the genitofemoral nerve, have also been used. Grafting may be unilateral or bilateral.

## **REGULATORY STATUS**

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

## **EVIDENCE SUMMARY**

In order to isolate the specific therapeutic effects of sural nerve grafting and individual patient differences (clinical and demographic, known and unknown), well-designed randomized controlled trials (RCTs) that compare groups of patients undergoing radical prostatectomy with and without sural nerve grafting are necessary. Primary outcomes include differences in proportion of patients experiencing improvement in sexual dysfunction (as measured by a standardized assessment tool), and rates of adverse effects. Although informative, evidence from observational studies describing experiences of sural nerve grafted patients is of limited utility in establishing causal relationships; therefore, the focus of the literature appraisal below is on RCTs investigating sural nerve grafting for erectile dysfunction.

## **SYSTEMATIC REVIEWS**

There were no systematic reviews identified.

## **RANDOMIZED CONTROLLED TRIAL**

A sole RCT by Davis (2009) has been identified which compared unilateral nerve sparing radical prostatectomy with, versus without, unilateral sural nerve grafting.<sup>[1]</sup> The trial was discontinued before full enrollment was achieved because there was adequate data at interim analysis of 107 patients with two-year follow-up to determine that nerve grafting was not beneficial. At two-year follow-up, there was no significant difference in erectile or urinary function, quality of life, or time to potency between the two groups. The results of this trial warrant cautious interpretation. Patients were not blinded to their treatment group assignment; thus, the possibility of treatment bias cannot be ruled out.

## **NONRANDOMIZED STUDIES**

Trindade (2017) evaluated the long-term treatment of erectile dysfunction using penile reinnervation after a radical prostatectomy.<sup>[2]</sup> A group of 10 patients underwent penile reinnervation by bridging the femoral nerve to the dorsal nerve of the penis and the inner part of the corpus cavernosum with sural nerve grafts. Six out of 10 patients were able to achieve full penetration within an average of 13 months post reinnervation surgery. The authors noted that patients previously submitted to radiotherapy had a slower return of erectile function.

A cohort study by Kung (2015). included 38 patients who underwent nerve grafting after radical prostatectomy and a random sample of 53 control patients who had open prostatectomy without nerve grafting.<sup>[3]</sup> Control patients had unilateral or bilateral nerve sparing prostatectomy, or non-nerve sparing prostatectomy. Complete urinary incontinence, no erectile

capacity at baseline, and follow-up data less than 12 months were study exclusion criteria. Unilateral nerve grafting (n=29) and unilateral nerve sparing (n=10) patients did not differ significantly for various outcomes, including urinary continence, erections sufficient for sex, spontaneous erections, and use of erectile dysfunction medications. Bilateral nerve grafting (n=9) and bilateral non-nerve sparing (n=10) patients had similar outcomes ( $p>0.05$ ). This study lacked randomization and blinding, and subgroup analyses included small numbers of patients.

A cohort study published by Namiki (2007) included 113 patients: 19 had unilateral nerve sparing plus sural nerve graft, 60 patients had unilateral nerve sparing with no grafting, and 34 patients had bilateral nerve sparing surgery.<sup>[4]</sup> Function was assessed using validated questionnaires and, at two years, no difference in sexual function scores was found between the unilateral nerve graft and bilateral nerve sparing patients. At three years, similar percentages of patients in the unilateral nerve graft (25%) and bilateral nerve sparing (28%) groups considered their sexual function as fair or good. Urinary function returned to baseline continence in the unilateral nerve graft and bilateral nerve sparing groups at six months and in the unilateral nerve sparing group at 12 months. Baseline sexual function differed between groups, which could have biased study findings; the nerve grafted and bilateral nerve sparing patients reported higher baseline function than the unilateral nerve sparing group.

The remainder of the literature on nerve grafting in association with prostatectomy consists of case series data.<sup>[5-13]</sup> While these studies contribute to the body of knowledge by providing direction for future research, evidence from these studies is unreliable due to methodological limitations, such as non-random allocation of treatment and lack of appropriate comparison groups.

## PRACTICE GUIDELINE SUMMARY

### NATIONAL COMPREHENSIVE CANCER NETWORK

The National Comprehensive Cancer Network (NCCN) prostate cancer guideline (version 2.2020) states that “replacement of resected nerves has not been shown to be beneficial” for recovery of erectile function after radical prostatectomy.<sup>[14]</sup>

## SUMMARY

There is not enough research to show that nerve grafting improves health outcomes for patients who have undergone radical prostatectomy. No clinical guidelines based on research recommend nerve grafting for people who have undergone radical prostatectomy. Therefore, this technique is considered not medically necessary.

## REFERENCES

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## CODES

**NOTE:** There are no specific CPT codes describing nerve grafting of the cavernous nerves. The CPT codes describing nerve grafts specifically identify the anatomic site and do not include the cavernous nerves. Therefore, CPT code 64999 (unlisted procedure, nervous system) should be used to describe the nerve harvest and grafting component of the procedure. A non-specific CPT code for nerve repair, such as 64910, 64911, 64912, or 64913, may be used.

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<b>Codes</b>	<b>Number</b>	<b>Description</b>
CPT	64999	Unlisted procedure, nervous system
HCPCS	None	

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**Date of Origin:** April 2002