Regence

Medical Policy Manual Surgery, Policy No. 117

Nerve Graft with Radical Prostatectomy

Effective: September 1, 2023

Next Review: July 2024
Last Review: July 2023

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

Patients with prostate cancer may undergo treatment with prostatectomy or prostate radiation therapy. Nerve grafting is performed to replace cavernous nerves that have been resected

during radical prostatectomy in individuals with 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.Several studies have reported racial disparities among individuals with low-risk prostate cancer.[1] African American individuals enrolled in active surveillance programs have been shown to have a higher risk of disease progression than individuals who identified as white. For African American individuals in the low-to-intermediate risk categories, there have been reports of increased risk of biochemical recurrence after treatment. While reasons for clinical disparities in this population are still being investigated, studies suggest that disparities in prostate cancer health outcomes can be minimized when health care access is equal.

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 individuals 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 individuals 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.[2] The trial was discontinued before full enrollment was achieved because there was adequate data at interim analysis of 107 individuals 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. Individuals 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.[3] A group of 10 individuals 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 individuals were able to achieve full penetration within an average of 13 months post reinnervation surgery. The authors noted that individuals previously submitted to radiotherapy had a slower return of erectile function.

A cohort study by Kung (2015) included 38 individuals who underwent nerve grafting after radical prostatectomy and a random sample of 53 control individuals who had open prostatectomy without nerve grafting.[4] Control individuals 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) individuals 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) individuals had similar outcomes ($p>0.05$). This study lacked randomization and blinding, and subgroup analyses included small numbers of individuals.

A cohort study published by Namiki (2007) included 113 individuals: 19 had unilateral nerve sparing plus sural nerve graft, 60 individuals had unilateral nerve sparing with no grafting, and 34 individuals had bilateral nerve sparing surgery.[5] 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 individuals. At three years, similar percentages of individuals 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 individuals 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.[6-14] 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 3.2022) states that “replacement of resected nerves has not been shown to be beneficial” for recovery of erectile function after radical prostatectomy.[1]

SUMMARY

There is not enough research to show that nerve grafting improves health outcomes for individuals 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

1. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology™. Prostate Cancer. v.2.2023. [cited 07/24/2023]. 'Available from:' http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.
2. 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.* 2009;55(5):1135-43. PMID: 18783876
3. 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 international.* 2017;119(6):948-54. PMID: 28093890
4. Kung TA, Waljee JF, Curtin CM, et al. Interpositional Nerve Grafting of the Prostatic Plexus after Radical Prostatectomy. *Plastic and reconstructive surgery Global open.* 2015;3(7):e452. PMID: 26301141
5. 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.* 2007;178(1):212-6; discussion 16. PMID: 17499797
6. Kim ED, Nath R, Slawin KM, et al. Bilateral nerve grafting during radical retropubic prostatectomy: extended follow-up. *Urology.* 2001;58(6):983-7. PMID: 11744473
7. Canto EI, Nath RK, Slawin KM. Cavermap-assisted sural nerve interposition graft during radical prostatectomy. *Urol Clin North Am.* 2001;28(4):839-48. PMID: 11791500
8. Singh H, Karakiewicz P, Shariat SF, et al. Impact of unilateral interposition sural nerve grafting on recovery of urinary function after radical prostatectomy. *Urology.* 2004;63(6):1122-7. PMID: 15183964
9. Secin FP, Koppie TM, Scardino PT, et al. Bilateral cavernous nerve interposition grafting during radical retropubic prostatectomy: Memorial Sloan-Kettering Cancer Center experience. *J Urol.* 2007;177(2):664-8. PMID: 17222654
10. Sim HG, Kliot M, Lange PH, et al. Two-year outcome of unilateral sural nerve interposition graft after radical prostatectomy. *Urology.* 2006;68(6):1290-4. PMID: 17141842
11. Nelson BA, Chang SS, Cookson MS, et al. Morbidity and efficacy of genitofemoral nerve grafts with radical retropubic prostatectomy. *Urology.* 2006;67(4):789-92. PMID: 16584763
12. Zorn KC, Bernstein AJ, Gofrit ON, et al. Long-term functional and oncological outcomes of patients undergoing sural nerve interposition grafting during robot-assisted laparoscopic radical prostatectomy. *J Endourol.* 2008;22(5):1005-12. PMID: 18419333
13. 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.* 2010;7(1 Pt 1):166-81. PMID: 19686422
14. 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.* 2014. PMID: 24903070

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.

Codes	Number	Description
CPT	64999	Unlisted procedure, nervous system
HCPCS	None	

Date of Origin: *April 2002*