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Nerve Graft with Radical Prostatectomy

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Unilateral or bilateral nerve graft **is considered experimental, investigational, and/or unproven** in individuals who have had resection of one or both neurovascular bundles as part of a radical prostatectomy.

Policy Guidelines

There are no specific CPT codes describing sural 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) may be used to describe the nerve harvest and grafting component of the procedure. Alternatively, a nonspecific CPT code for nerve repair—64910 or 64913 may be used.

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.

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 individuals. Studies have reported results from bilateral and unilateral nerve grafts, the latter involving resection of 1 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 1 leg and then anastomosed to the divided ends of the cavernous nerve. Reports also indicate 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 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 the 21 CFR Part 1271 regulations for Human Cellular and Tissue-Based Products (HCT/P).

Rationale

Medical policies assess clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the

intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Nerve Grafting

Clinical Context and Therapy Purpose

Individuals with prostate cancer may undergo treatment with prostatectomy or prostate radiation therapy. 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 White individuals. 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.

The purpose of nerve grafting in individuals who have radical prostatectomy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this medical policy.

Populations

The relevant population of interest is individuals who have radical prostatectomy with resection of neurovascular bundles.

Interventions

The therapy being considered is nerve grafting in association with radical prostatectomy.

Comparators

The relevant comparator is prostatectomy without nerve grafting.

Outcomes

The outcomes of interest are functional outcomes, quality of life, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.

- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Randomized Controlled Trials

One RCT evaluating nerve grafting to reduce risk of erectile dysfunction has been published; findings were reported by Davis et al. (2009). (2) The trial included individuals aged 65 years or younger with normal self-reported baseline erectile function selected for a unilateral nerve sparing radical prostatectomy with preservation of 1 neurovascular bundle. All patients had unilateral neurovascular bundle removal, and individuals were randomized to receive or not to receive sural nerve grafting after removal. The primary outcome was potency 2 years postsurgery, defined as the ability to have intercourse with or without erectile dysfunction medication. All patients received the same early erectile dysfunction therapy, including medication and mechanical devices. The investigators sought to detect an absolute difference of 20% between groups (graft, 60% potency rate vs no graft, 40% potency rate). A sample of 200 men was originally planned to provide 80% power. However, after 107 men were randomized, a preplanned interim analysis of evaluable patients found similar potency rates between groups. The data monitoring committee stopped the trial based on its estimate of less than a 5% chance that additional recruitment would result in a significant difference between groups. End point data were available for 66 patients. Potency was achieved in 32 (71%) of 45 sural nerve graft patients and 14 (67%) of 21 control patients (p=0.78). Trialists concluded that unilateral sural nerve graft did not result in an absolute improvement of 20% between groups, but that a smaller effect could not be ruled out. A limitation of the trial was that it was unblinded, which could have impacted self-report of potency because individuals knew the procedure they received.

Observational Studies

The literature also includes 2 retrospective cohort studies and 3 case series. (3-7) The cohort studies are described below.

The cohort study by Kung et al. (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. (3) 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 between groups (p>.05) on 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>.05). This study lacked randomization and blinding, and subgroup analyses included small numbers of patients.

The second cohort study, published by Namiki et al. (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. (4) Function was assessed using validated questionnaires and, at 2 years, no difference in sexual function scores was found between the unilateral nerve graft and bilateral nerve-sparing patients. At 3 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 6 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.

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 (RCT), cohort studies, and case series. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. The RCT 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 that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN)

The NCCN guidelines on the treatment of prostate cancer (v.1.2025) states: “Replacement of resected nerves with nerve grafts has not been shown to be beneficial” for recovery of erectile function after radical prostatectomy.” (1)

Ongoing and Unpublished Clinical Trials

A currently unpublished trial that might influence this policy is listed in Table 1.

Table 1. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT01770340	Nerve Grafting With an Allograft During Radical Prostatectomy - Extended Follow-up in a Prospective Randomized Trial	30	Jul 2020 (terminated)

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	55840, 55842, 55845, 55899, 64910, 64911, 64912, 64913, 64999
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
02/01/2025	Document updated with literature review. Coverage unchanged. No new references added; reference 1 updated.
12/01/2023	Reviewed. No changes.
01/01/2023	Document updated with literature review. Coverage unchanged. No new references added; reference 1 updated.
07/01/2021	Reviewed. No changes.
09/15/2020	Document updated with literature review. Coverage unchanged. No new references added.
10/15/2019	Reviewed. No changes.
11/15/2018	Document updated with literature review. Coverage unchanged.
01/01/2018	Document updated with literature review. Coverage unchanged.
07/15/2017	Reviewed. No changes.
01/01/2017	Document updated with literature review. Coverage unchanged. Editorial change made as follows: “undergone” changed to “had” in the coverage statement. Title changed from “Nerve Graft in Association With Radical Prostatectomy”.
05/15/2015	Reviewed. No changes.
07/01/2014	Document updated with literature review, coverage unchanged. CPT/HCPCS code(s) updated.
10/15/2013	Document updated with literature review, coverage unchanged and entire rationale section revised. Codes updated.
09/01/2009	Revised/ updated entire document. Coverage remains experimental, investigational and unproven.
09/01/2007	Revised/updated entire document.
08/15/2003	New Medical document