BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.81 Nerve Graft with Radical Prostatectomy

Annual Effective Policy Date: July 1, 2024

Original Policy Date: June 2012

Related Policies:

None

Nerve Graft with Radical Prostatectomy

Description

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.

OBJECTIVE

The objective of this evidence review is to evaluate whether nerve grafting in conjunction with radical prostatectomy reduces erectile dysfunction.

POLICY STATEMENT

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

POLICY GUIDELINES

None

BENEFIT APPLICATION

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

Nerve grafting with radical prostatectomy is a specialized procedure that may require out-of-network referral. In some cases, the nerve-harvesting procedure may be performed by a plastic surgeon or a neurosurgeon; in other cases, a urologist may perform both the nerve-harvesting, graft, and radical prostatectomy.

Specific contractual exclusions regarding treatment of impotence may apply.

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 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).

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 (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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network

The National Comprehensive Cancer Network guidelines on the treatment of prostate cancer (v.4.2023) states: "Replacement of resected nerves with nerve grafts has not been shown to be beneficial" for recovery of erectile function after radical prostatectomy.[1,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

REFERENCES

1. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 4.2023. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 9, 2024.
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. May 2009; 55(5): 1135-43. PMID 18783876
3. 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
4. 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): 212-6; discussion 216. PMID 17499797
5. 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): 166-81. PMID 19686422
6. 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): 2119-24. PMID 24903070
7. 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

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy	
March 2013	Replace policy	Literature review update; No change in policy statement.
March 2014	Replace policy	Literature review updated adding reference 7. No change in policy statement.
March 2015	Replace policy	Literature review updated adding reference 7. No change in policy statement.
June 2017	Replace policy	Title changed to "Nerve Graft With Radical Prostatectomy.€š Policy updated with literature review through March 31, 2017; references 2 and 6 added. Policy statement unchanged.
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; no references added; reference 7 updated. Policy statement unchanged except "not medically necessary€š corrected to "investigational€š 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).
June 2019	Replace policy	Policy updated with literature review through February 5, 2019; no references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through January 31, 2020; no references added. Policy statement unchanged.
June 2021	Replace policy	Policy updated with literature review through January 11, 2021; no references added; NCCN reference updated. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through February 24, 2022; no references added. NCCN reference updated. The word "patients" was replaced with "individuals" in the Policy Statement per updated Document Standards, intent unchanged.
June 2023	Replace policy	Policy updated with literature review through January 16, 2023; no references added; NCCN reference updated. Policy statement unchanged.
June 2024	Replace policy	Policy updated with literature review through February 8, 2024; no references added; NCCN reference updated. Policy statement unchanged.