

Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:
Nerve Graft with Radical Prostatectomy

Policy #: 370

Latest Review Date: April 2023

Category: Surgery

ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

- 1. Safe and effective;*
- 2. Not experimental or investigational*;*
- 3. Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - Furnished in a setting appropriate to the patient's medical needs and condition;*
 - Ordered and furnished by qualified personnel;*
 - One that meets, but does not exceed, the patient's medical need; and*
 - At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **unilateral or bilateral nerve graft** as a **non-covered benefit** and as **investigational** in individuals who have undergone **resection of one or both neurovascular bundles as part of a radical prostatectomy**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Nerve grafting at the time of radical prostatectomy, most commonly using the sural nerve, has been proposed to reduce the risk of 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 one neurovascular bundle.

There has been interest in sural nerve grafting to replace cavernous nerves resected at the time of prostatectomy. The sural nerve is considered expendable and has been used extensively 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 one 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.

KEY POINTS:

Most recently, the literature was reviewed through January 16, 2023.

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

The National Comprehensive Care Network (NCCN) on the treatment of prostate cancer (V.1.2023) states “Replacement of resected nerves with nerve grafts has not been shown to be beneficial,” for recovery of erectile function after radical prostatectomy.

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Genitofemoral Nerve Graft, Prostatectomy, Sural Nerve Graft, prostate cancer, bilateral nerve graft, unilateral nerve graft, radical prostatectomy, Avance[®], AxoGen

APPROVED BY GOVERNING BODIES:

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.

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).

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

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 64999 may be used to describe the nerve harvest and grafting component of the procedure.

64999	Unlisted procedure, nervous system
-------	------------------------------------

A nonspecific CPT code for nerve repair may be used:

64912	Nerve repair; with nerve allograft, each nerve, first strand (cable) (Effective 01/01/18)
64913	Nerve repair; with nerve allograft, each additional strand (List separately in addition to code for primary procedure) (Effective 01/01/18)

This procedure may be billed in conjunction with the radical prostatectomy CPT code range of 55840-55845.

REFERENCES:

1. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
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.
3. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. v2.2018. Available online at: www.nccn.org/professionals/physician_gls/PDF/prostate.pdf.
4. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 1.2020. Available online at: www.nccn.org/professionals/physician_gls/PDF/prostate.pdf.
5. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 2.2021. Available online at: www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.
6. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 3.2022. Available online at: www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.
7. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. v1.2023. Available online at: www.nccn.org/professionals/physician_gls/PDF/prostate.pdf.
8. Nerve grafting with an allograft during radical prostatectomy - Extended follow-up in a prospective randomized trial (NCT01770340). Sponsored by Kantonsspital Winterthur KSW (Switzerland). Last updated February 21, 2021. Available online at: clinicaltrials.gov.
9. 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.
10. 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.

11. Study of nerve reconstruction using AVANCE in subjects who undergo robotic assisted prostatectomy for treatment of prostate cancer (NCT00953277). Sponsored by AxoGen, Inc. Last updated May 21, 2015. Available online at: clinicaltrials.gov.

POLICY HISTORY:

Adopted for Blue Advantage, March 30, 2011

Available for comment April 4 – May 18, 2011

Medical Policy Group, October 2012

Medical Policy Group, December 2012

Medical Policy Group, December 2013

Medical Policy Group, January 2015

Medical Policy Group, April 2016

Medical Policy Group, April 2017

Medical Policy Group, December 2017

Medical Policy Group, April 2018

Medical Policy Group, April 2019

Medical Policy Group, April 2020

Medical Policy Group, April 2021

Medical Policy Group, April 2022

Medical Policy Group, April 2023

Medical Policy Group, November 2023: Archived effective 11/1/2023.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.