# Nerve Graft With Radical Prostatectomy

**Policy #** 00113
Original Effective Date: 06/05/2002
Current Effective Date: 06/14/2021

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

# Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers unilateral or bilateral nerve grafts in patients who have had resection of one or both neurovascular bundles as part of a radical prostatectomy to be **investigational.***

# Background/Overview

**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 patients. 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 the use of other nerves (eg, genitofemoral nerve) for grafting.

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# FDA or Other Governmental Regulatory Approval

**U.S. Food and Drug Administration (FDA)**

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/Source

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.

For individuals who have radical prostatectomy with resection of neurovascular bundles who receive nerve grafting, the evidence includes a randomized controlled trial, cohort studies, and case series. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. The randomized controlled trial 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 the effects of the technology on health outcomes.

# Supplemental Information

**Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 4 academic medical centers while this policy was under review in 2008; no input was received from physician specialty societies. Input from the 4 centers agreed that this procedure is considered investigational.

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**Practice Guidelines and Position Statements**
The National Comprehensive Cancer Network guidelines on the treatment of prostate cancer (v.1.2020) 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.

**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.

**Ongoing and Unpublished Clinical Trials**
A currently unpublished trial that might influence this review is shown in Table 1.

**Table 1. Summary of Key Trials**

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| *Ongoing* | | | |
| NCT01770340 | Nerve Grafting With an Allograft During Radical Prostatectomy - Extended Follow-up in a Prospective Randomized Trial | 30 | Jul 2020 |

NCT: national clinical trial.

# References


1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Nerve Graft in Association With Radical Prostatectomy", Policy 7.01.81, May 2020.
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):1135-1143. 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):212-216; 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):166-181. 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):2119-2124. 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
8. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 1.2020. https://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf.

# Policy History

Original Effective Date: 06/05/2002
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| | |
|---|---|
| 05/16/2002 | Medical Policy Committee review |
| 06/05/2002 | Managed Care Advisory Council approval |
| 06/24/2002 | Format revision. Coverage eligibility unchanged. |
| 06/01/2004 | Medical Director Review |
| 06/15/2004 | Medical Policy Committee review. Format revision. |
| 06/28/2004 | Managed Care Advisory Council approval |
| 08/02/2006 | Medical Director Review |
| 08/09/2006 | Medical Policy Committee approval. Format revisions, references and rationale/source updated. Coverage eligibility unchanged. |
| 06/13/2007 | Medical Director Review |
| 06/20/2007 | Medical Policy Committee approval. Policy updated with literature search. No change to policy statement. Sural removed from title. |

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|---|---|
| 06/04/2009 | Medical Director Review |
| 06/17/2009 | Medical Policy Committee approval. No change to coverage. |
| 06/03/2010 | Medical Policy Committee approval |
| 06/16/2010 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 06/02/2011 | Medical Policy Committee review |
| 06/15/2011 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 06/14/2012 | Medical Policy Committee review |
| 06/20/2012 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 06/06/2013 | Medical Policy Committee review |
| 06/25/2013 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 04/02/2015 | Medical Policy Committee review |
| 04/20/2015 | Medical Policy Implementation Committee approval. Updated rationale /source. Coverage eligibility unchanged. |
| 08/03/2015 | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed. |
| 04/07/2016 | Medical Policy Committee review |
| 04/20/2016 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes |
| 05/04/2017 | Medical Policy Committee review |
| 05/17/2017 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 05/03/2018 | Medical Policy Committee review |
| 05/16/2018 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 05/02/2019 | Medical Policy Committee review |
| 05/15/2019 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 05/07/2020 | Medical Policy Committee review |

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05/13/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/06/2021 Medical Policy Committee review
05/12/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 05/2022

# Coding

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

*The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

| Code Type | Code |
|---|---|
| CPT | 64912, 64913, 64999 |

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| | |
|---|---|
| HCPCS | No codes |
| ICD-10 Diagnosis | C61, D78.81, D78.89, E89.810-E89.811, E89.89, H59.011-H59.019, H59.032-H59.039, H59.091, H59.093, H59.099, H59.811-H59.819, H59.88, H95.811-H95.819, H95.88-H95.89, M96.89, N52.02-N52.03, N52.1, N52.2, N52.31-N52.39, N52.8, N52.9, N98.1-N98.8, Z90.721-Z90.722, Z90.79 |

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.