

Peripheral Nerve Injury Repair Using Synthetic Conduits or Processed Nerve Allografts

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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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Bioengineered Skin and Soft Tissue Substitutes is addressed separately in medical policy 00572.

Note: Microwave Tumor Ablation is addressed separately in medical policy 00569.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of processed nerve allografts (e.g., Avance nerve allograft) to be **eligible for coverage**** when **ALL** of the criteria are met:

- For the repair and closure of peripheral nerve gaps up to 70 mm; **AND**
- Direct primary repair is not feasible (see Note); **AND**
- Absence of active infection in a surgical field.

Note: Feasibility of direct repair may be limited in individuals with large nerve gaps, segmental nerve loss, or chronic and complex injuries.

Based on review of available data, the Company may consider the use of synthetic nerve conduits (e.g., NeuraGen synthetic conduit [Integra]) to be **eligible for coverage**** when **ALL** of the criteria are met:

- For the repair and closure of peripheral nerve gaps; **AND**
- Absence of active infection in a surgical field; **AND**
- No history of an allergic reaction or sensitivity to any component of the synthetic conduit (e.g., bovine, porcine, or chondroitin materials); **AND**
- For ANY of the following scenarios:
 - Repair of digital nerve injuries with gaps less than 15 mm; **OR**

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- Repair of digital nerve injuries with gaps 15-25 mm, where allograft nerve is not immediately available (e.g., in the context of urgent traumatic injuries); **OR**
- Repair of major nerves (any nerve aside from digital nerves) with small gaps not exceeding 6 mm, where allograft nerve is not available; **OR**
- In the context of conduit-assisted repair as a technique for tension-relief at the peripheral nerve repair site or major nerve with a gap not exceeding 6 mm.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers all other uses of processed nerve allografts and synthetic nerve conduits for individuals with peripheral nerve gaps to be **not medically necessary**.**

The use of processed nerve allografts and synthetic nerve conduits when patient selection criteria are not met is considered to be **not medically necessary**.**

Policy Guidelines

Feasibility of direct repair may be limited in individuals with large nerve gaps, segmental nerve loss, or chronic and complex injuries. While there are mixed data regarding comparability of autograft versus allograft repair, allograft repair offers the benefit of avoiding donor site morbidity. This is of particular importance where the primary consideration is the management or prevention of neuropathic pain. For larger sensory, motor, or mixed nerves, autograft repair should be considered the standard intervention except if there is insufficient donor material for autografting. The maximum available allograft length is 70 mm, and there is no data to support the technique of connecting allografts end-to-end.

For digital nerve injuries with gaps 15-25 mm, conduit repair yields acceptable sensory outcomes but is inferior to allograft repair. Therefore, conduit repair should only be used in such scenarios when allograft nerve is not immediately available (e.g. in the context of urgent traumatic injuries).

Nerve wraps are bioresorbable surgical implants designed to protect and support peripheral nerve healing following end-to-end repair with no gap (e.g., Axoguard®‡ Nerve Protector by AxoGen, indicated for the repair of peripheral nerve injuries where there is no gap, derived from porcine source). These devices provide a physical barrier that purports to reduce scar formation, reduce mechanical irritation, and promote a favorable environment for nerve regeneration. These materials are addressed in - Bioengineered Skin and Soft Tissue Substitutes (see Related Policies).

Contraindications

Both allograft and conduit repair are contraindicated in a surgical field with active infection. Synthetic conduits are contraindicated for individuals with a history of an allergic reaction or sensitivity to any component of the synthetic conduit (e.g., bovine, porcine, or chondroitin materials).

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Background/Overview

Peripheral Nerve Injury

Injuries to the peripheral nerves are common and occur in approximately 2.5% of trauma patients in the United States, with an average incidence of over 550,000 annually. Based on hospital ICD-9 coding, the most commonly injured peripheral nerves reported by hospitals were the upper extremity digital nerves, ulnar nerve, radial nerve, and the brachial plexus. Functional regeneration of injured nerves requires peripheral nerve surgery to allow axon regrowth and remyelination.

Conventional Treatment

Direct surgical repair (e.g. end-to-end coaptation or neurorrhaphy) is the standard of care for transected nerves when the gap distance permits tensionless suturing. However, when the size of the peripheral nerve gap precludes tensionless direct surgical repair, the standard of care is nerve autograft. Alternatives to autografting are being investigated to bridge nerve discontinuities to avoid complications from harvesting (e.g., pain or numbness) at the donor site as well as issues such as nerve fascicle mismatch and damage to the autograft from tissue handling.

Alternative Treatments

Allogenic nerve grafts are derived from human donors and are generally used to bridge gaps resulting from peripheral nerve injuries that are > 5 mm. Allogenic grafts are preferred for their potential to minimize donor site morbidity, as they eliminate the need for autografts. Allogenic grafts also address the challenge of obtaining a sufficient graft length as they are available in multiple lengths and diameters; this is particularly relevant in cases where the injury site is extensive. Before transplantation, allografts undergo processing to ensure immunological compatibility and reduce the risk of rejection, allowing for successful integration into the recipient's nervous system.

Synthetic nerve conduits are hollow tubular structures designed to bridge nerve gaps caused by injury or trauma, providing a supportive environment for the regrowth of damaged nerve fibers. They are available in various biocompatible materials, lengths, and diameters and are designed to degrade over time. The conduits serve as guidance channels for regenerating nerves, facilitating directional growth, and preventing scar tissue formation. Conduits are generally used for nerve gap repairs of <5 mm.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA) regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation, title 21, parts 1270 and 1271. Avance Nerve Grafts are subject to these regulations.

A number of processed nerve allografts and synthetic conduits have been approved through the FDA 510k process for individuals undergoing peripheral nerve repair (Table 1). This list includes products for which this reference medical policy did not find any published, peer-reviewed research that satisfied the PICO (Population, Intervention, Comparison, Outcome) criteria.

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Table 1. FDA 510K Approved Processed Nerve Allografts and Synthetic Conduits for Peripheral Nerve Repair

Product (manufacturer)	Year	510(k)	Product Code
NeuraGen nerve guide (Integra LifeSciences, Corp)	2001	<u>K011168</u>	JXI
Neuroflex collagen conduit (Stryker Orthopedics)	2014	<u>K131541</u>	JXI
Neurolac nerve guide (Polyganics BV)	2003	<u>K103081</u>	JXI
Neuromatrix (Stryker Orthopedics)	2001	<u>K012814</u>	JXI
Reaxon Plus Nerve Guide (Medovent, GmbH)	2018	<u>K180222</u>	JXI
Rebuilder nerve guidance conduit (CelestRay Biotech Company, LLC.)	2024	<u>K230794</u>	JXI

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Peripheral nerve injuries are common traumatic events for which the conventional treatment is the microsurgical repair for gaps <5 mm in length. Autologous grafting is used for repairing nerve gaps of greater length. Because autologous grafts must be harvested from the patient, there is a risk of donor site complications, and the overall success rate of autografting may be limited. Therapies such as processed nerve allografts and synthetic nerve conduits are being investigated to provide improved treatment alternatives.

Summary of Evidence

For individuals with peripheral nerve injury requiring repair and closure of the nerve gap who receive processed nerve allografts, the evidence includes 2 meta-analyses, 2 randomized controlled trials (RCTs) comparing allograft to collagen conduit repair with NeuraGen, and observational studies (1

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comparative case series, 1 retrospective cohort study, 1 case series, and 1 registry study). All studies, with the exception of 1 non-randomized controlled trial, used Avance allografts. The evidence base consisted primarily of peripheral nerve injuries to the fingers or upper extremities. Relevant outcomes were sensory and motor function changes, quality of life, and treatment-related morbidity. In 1 RCT that compared allograft to NeuraGen synthetic conduit, allograft patients had a greater return of protective sensation rate on the static 2-point discrimination (S2PD) score but did not differ on overall S2PD score or other outcome measures. The second RCT comparing allograft to NeuraGen found that S2PD favored the Avance allograft group at 1-year follow-up, but no differences were noted in moving 2-point discrimination (M2PD), Semmes Weinstein Monofilament (SWMF) test, or the Disability of the Arm and Shoulder (DASH) questionnaire. Limitations in the RCT evidence base included a lack of intention to treat (ITT) analysis, high loss to follow-up, lack of reporting power calculations, and insufficient follow-up duration. Three non-randomized comparative studies found no difference between NeuraGen (n=2) and direct surgical repair (n=2) in sensory or functional outcomes and complications compared to allograft. One meta-analysis found comparable pooled rates of S2PD and M2PD across assessed interventions, including allograft, autograft, artificial conduits, and direct surgical repair, but all estimates had extreme heterogeneity. Another meta-analysis found that meaningful recovery ($\geq$ S3 on the British Medical Research Council [BMRC] recovery grading system) was significantly higher in allograft and autografting than for synthetic conduits. Data from the ongoing Avance registry study suggested durability of outcomes and safety at more than 2 years of follow-up. There is an absence of comparison of Avance to autografting in the included literature, which is a significant limitation as this is the current standard of care for repairing peripheral nerve gap discontinuities larger than 5 mm. Additionally, substantial interventional, comparator, and outcome heterogeneity across the evidence base make it challenging to compare outcomes across studies reliably. Randomized comparisons of allograft to autograft with sufficient follow-up using validated outcome measures are needed to evaluate the relative risk-benefit of allografting. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with peripheral nerve injury requiring repair and closure of the nerve gap who receive synthetic nerve conduits, the evidence includes meta-analyses, RCTs, and observational studies. (2 comparing NeuraGen to allograft, 1 comparing Neurotube to autologous vein grafting, and 4 comparing conduit [1 Neurolac, 1 Polyhydroxybutyrate {PHB}, 1 polyglycolic acid {PGA}, and 1 silicone tube] to direct surgical repair), 1 non-randomized clinical trial, 1 comparative retrospective cohort study, 1 comparative case series, and 1 non-comparative case series. The evidence base consisted primarily of peripheral nerve injuries to the fingers or upper extremities. NeuraGen was evaluated in studies, and all other synthetic conduits were represented by a single study (Neuromatrix, Neuroflex, Neurotube, Neurolac, PHB conduit, PGA conduit, and collagen-filled conduit). In one RCT that compared Avance allograft to NeuraGen, allograft patients had a greater return of protective sensation rate on S2PD, but did not differ on overall S2PD score or other outcome measures. The second RCT comparing Avance allograft to NeuraGen found that S2PD favored the allograft group at 1-year follow-up, but no differences were noted in M2PD, SWMF test, or the DASH questionnaire. One RCT compared Neurotube conduit to an autologous vein conduit and found similar outcomes at a 2-year follow-up, but at 1-year analysis, the motor domain of the Rosen Model Instrument (RMI) favored the autologous treatment arm. Five other trials compared

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different types of conduits to direct surgical repair with generally equivalent outcomes; one RCT observed a significant difference in cold intolerance, which favored the synthetic conduit group, and another found that at short (<4 mm) and long nerve gaps (>8 mm) M2PD was better in the PGA conduit group than in direct surgical repair or autograft. Major limitations identified in the trial evidence base included an absence of participant blinding, lack of intention to treat analysis, high loss to follow-up, absence of power calculations, and short duration of follow-up. Three non-randomized comparative studies found no difference between synthetic conduits and Avance (n=2), direct surgical repair (n=1), or autograft (n=1) in sensory or functional outcomes as well as complications. A Cochrane review found that there is no clear benefit to patients treated with artificial nerve conduits or nerve wraps over direct surgical repair, and that complications may be greater for participants treated with synthetic nerve conduits or wraps. The overall evidence base was considered very uncertain, with few outcomes having more than 1 included study. One other meta-analysis found comparable pooled rates of S2PD and M2PD across assessed interventions, but all estimates had extreme heterogeneity. The third meta-analysis found that meaningful recovery ($\geq$ S3 on the BMRC recovery grading system) was significantly higher in allograft and autografting than for synthetic conduits. No guideline evidence was identified for synthetic nerve conduits for the treatment of peripheral nerve injuries. Many of the included trials have significant limitations, and the substantial heterogeneity in patient and intervention characteristics makes it challenging to compare outcomes reliably across studies. 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 Institute for Health and Care Excellence (NICE)

In 2017, NICE published guidance on processed nerve allografting to repair peripheral nerve discontinuities. The evidence base evaluated by NICE included the RCT by Means et al (2016) and the non-randomized trial by He et al (2013), which are discussed in this medical reference policy. NICE also evaluated two other smaller case series, which were not included in our evidence review due to the availability of higher-quality evidence. The following were among the recommendations issued:

- Current evidence on the safety and efficacy of processed nerve allografts to repair peripheral nerve discontinuities is adequate to support the use of this procedure for digital nerves, provided that standard arrangements are in place for clinical governance, consent, and audit.
- The evidence on the safety of processed nerve allografts to repair peripheral nerve discontinuities in other sites raises no major safety concerns. However, current evidence on its efficacy in these sites is limited in quantity. Therefore, for indications other than

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digital nerve repair, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

- This procedure should only be done by surgeons with training and experience in peripheral nerve repair.
- Patient selection should take into consideration the site, type of nerve (motor, sensory, mixed), and the size of the defect.
- NICE encourages further research into processed nerve allografts to repair peripheral nerve discontinuities. This should include information on the type of nerve repaired, the anatomical site, the size of the defect, patient-reported outcome measures, functional outcomes, time to recovery, and long-term outcomes (12 months to 18 months).

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

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04865679 ^a	Tolerability and Feasibility Pilot Clinical Study of a Large-Diameter Nerve Cap for Protecting and Preserving Terminated Nerve Ends (REPOSE-XL SM) [‡]	15	Dec 2026
NCT01526681 ^a	Registry of Avance ^{®‡} Nerve Graft's Utilization and Recovery Outcomes Post Peripheral Nerve Reconstruction	5000	Dec 2025
<i>Unpublished</i>			
NCT05339594 ^a	REINVENT Registry (Registry of the Nerve Gap Repair From Integra)	17	Jun 2024 (terminated)
NCT05199155	Use of a Nerve Regeneration Conduit (NerVFIX ^{®‡}) in the Treatment of Nerve Section of the Wrist	15	Dec 2023 (terminated)
NCT05343143 ^a	NeuraGen 3D Pilot Study	10	July 2024 (terminated)

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NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Peripheral Nerve Injury Repair Using Synthetic Conduits or Processed Nerve Allografts

Policy # 00926

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05/01/2025 Medical Policy Committee review

05/13/2025 Medical Policy Implementation Committee approval. New policy.

05/07/2026 Medical Policy Committee review

05/13/2026 Medical Policy Implementation Committee approval. Added When Services Are Considered Not Medically Necessary section to the policy. Added “Based on review of available data, the Company considers all other uses of processed nerve allografts and synthetic nerve conduits for individuals with peripheral nerve gaps to be not medically necessary.” Added “The use of processed nerve allografts and synthetic nerve conduits when patient selection criteria are not met is considered to be not medically necessary.”

Next Scheduled Review Date: 05/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 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 Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue 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 Louisiana Blue 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 Louisiana Blue 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.

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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	64910, 64912, 64913, 64999
HCPCS	C9352, C9355
ICD-10 Diagnosis	All Related Diagnoses

*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 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.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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‡ 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.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.