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MEDICAL POLICY – 7.01.584

Nerve Repair for Peripheral Nerve Injuries Using Synthetic Conduits or Allografts

Effective Date:	Jan. 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	Dec. 23, 2024	None
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

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Introduction

Peripheral nerves are the nerves that connect the brain and spinal cord to the rest of the body. Peripheral nerve injuries are common and are usually caused by traumatic injury. The most common sites of peripheral nerve injuries are in the arms and hands. These injuries can limit the functioning and recovery of the affected area. The standard treatment for peripheral nerve injuries is surgery performed with a microscope and small specialized instruments. When there are small gaps between cut nerves, nerve endings can be reconnected with sutures. When there are large nerve gaps and direct repair is not possible, autologous nerve grafting is performed. This is where a nerve is taken from somewhere else on the body and grafted at the site of injury to form a bridge between the two injured nerve ends. Alternative treatments to the standard direct suture repair or autologous grafting are being explored, but at this time they are currently considered unproven (investigational).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Synthetic conduits or allografts examples: • **Avancenerve graft** • **Axoguard nerve connector** • **Axoguard nerve protector** • **NeuraGen nerve guide** • **NeuraWrap nerve protector** • **Neuroflex collagen conduit** • **NeuroMatrixcollagen conduit** • **NeuroMend collagen wrap**	**Synthetic conduits and nerve allografts are considered investigational for the repair or closure of nerve gaps from peripheral nerve injuries**

Coding

Code	Description
CPT	
64910	Nerve repair; with synthetic conduit or vein allograft (e.g., nerve tube), each nerve
64912	Nerve repair; with nerve allograft, each nerve, first strand (cable)
64913	Nerve repair; with nerve allograft, each additional strand (List separately in addition to code for primary procedure)
64999	Unlisted procedure, nervous system
HCPCS	
C9352	Microporous collagen implantable tube (NeuraGen Nerve Guide), per cm length
C9353	Microporous collagen implantable slit tube (NeuraWrap Nerve Protector), per cm length
C9355	Collagen nerve cuff (NeuroMatrix), per 0.5 cm length

Code	Description
C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 cm length

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

Avance Nerve Graft: Is a processed human peripheral nerve tissue proposed for the surgical repair of peripheral nerve discontinuities to support nerve regeneration.

AxoGuard Nerve Connector: Is a porcine submucosa extracellular matrix proposed for the approximation and repair of severed peripheral nerves with less than a 5 mm gap allowing for a natural healing process where an individual's own cells incorporate into the extracellular matrix to form and remodel a tissue similar to the connective tissue surrounding the nerve.

AxoGuard Nerve Protector: Is a porcine submucosa extracellular matrix surgical implant proposed for the separation and protection of injured nerves where there is no gap preventing the attachment of soft tissue as the individual's own cells incorporate with the extracellular matrix to remodel and form a separating tissue layer to aid in the prevention of nerve entrapment during the healing process. It can be used to protect injured nerves up to 40 mm.

NeuraGen Nerve Guide: Is a resorbable bovine, type 1 collagen based tubular implant for the repair of peripheral nerve discontinuities. It is proposed as an interface between the nerve and surrounding tissue serving as a conduit for axonal growth across a nerve gap of 3 cm or less.

NeuraWrap Nerve Protector: Is a resorbable bovine, type 1 collagen implant that provides an encasement for injured peripheral nerves. It is proposed to serve as an interface between the nerve and surrounding tissue. It can be used to wrap nerves from 3 mm to 10 mm in diameter.

Neuroflex Collagen Conduit: Is a resorbable, flexible type 1 collagen-based tubular matrix with corrugated walls that is proposed to provide a protective environment for peripheral nerve injuries by creating a conduit for axonal growth across a nerve gap of less than 3 cm while preventing the ingrowth of scar tissue. The added flexibility of the nerve guide allows for it to be bent without collapsing.

NeuroMatrix Collagen Conduit: Is a resorbable type 1 collagen-based tubular matrix implant that is proposed for the repair of severed peripheral nerves. The tubular nerve guide bridges the severed nerve and provides a protective environment for the regeneration of the nerve across a gap of less than 3 cm.

NeuroMend Collagen Wrap Conduit: Is a resorbable bovine, type 1 collagen encasement or wrap proposed to promote healing of minimally damaged peripheral nerves while providing a barrier to scar-forming cells. It allows for a 25% self-curling overlap which can eliminate the need for a running suture. It can be used to wrap nerves from 1.0 to 12.0 mm in diameter.

Evidence Review

Description

Peripheral nerve injuries are common; they are usually caused by traumatic injury, and often result in impaired functional recovery. The hands and arms are the most common sites of injury. The standard treatment for peripheral nerve injuries is microsurgical repair, either by nerve sutures, or when there are large nerve gaps and direct repair is not possible, autologous nerve grafting is performed. Alternative treatments to the standard direct suture repair or autologous grafting are emerging as potential substitutes for the standard treatment.

Background

Peripheral nerve injuries are common; they are usually caused by traumatic injury, and often result in impaired functional recovery and possibly neuropathic pain. The most common sites for injuries are the arms and hands. Traditionally the standard treatment for peripheral nerve injuries is microsurgical repair, either by nerve sutures, or when there are large nerve gaps and direct repair is not possible, nerve grafting is seen as the most viable option. Grafting can be in the form of either autologous or allogeneic grafts.

Peripheral nerves are capable of self-regeneration after some injuries. Thus, when direct suture repair is used to repair short gaps (< 5 mm), the nerve is able to regenerate and nerve function is restored. However, when there are larger nerve gaps, these cannot be repaired by direct suturing due to the excessive tension that occurs between the nerve stumps. Autologous nerve grafts are then used for repairing nerve gaps up to 5 centimeters in length. However,

autologous nerve grafts have known shortcomings: the success rate is limited to sensory function and only about 50% of individuals achieve satisfactory results, there can be nerve size mismatch, the procedure requires two surgical sites, there are a limited number of donor nerve sites (the most common site is the sural nerve in the leg), scarring can occur, and there can be donor site morbidity.

Alternative treatments to the standard direct suture repair or autologous grafting have emerged as potential substitutes. The challenge in repairing damaged nerves is to guide regenerating sensory, motor, and autonomic axons to the distal, degenerating nerve segment to optimize the chances of reinnervation at the proximal site. Allogeneic grafting (Avance nerve allograft), hollow nerve conduits (NeuraGen, NeuroMatrix, or Neuroflex) or coaptation aids (AxoGuard nerve connector) are proposed as promising tools for repair of severed peripheral nerves in an attempt to overcome these challenges.

Allografts (Avance nerve graft [Axogen]) are sterile, processed, human nerve allografts that have undergone a cleansing process to remove cells, cellular debris, and certain proteins while preserving the extracellular matrix to provide structural support for regenerating axons. It is available in multiple lengths and diameters and when stored frozen, has a shelf life up to three years. Once thawed, it must be used within 12 hours. The thawed allograft is surgically implanted to connect the distal and proximal ends of a severed peripheral nerve and sutured into place. The graft then revascularizes and is remodeled into an individual's own tissue. No donor nerve surgery is required.

Hollow nerve conduits (NeuraGen [Integra LifeSciences], NeuroMatrix [Stryker], or Neuroflex [Stryker]) are absorbable, collagen based, tubular implants that are designed to serve as a conduit between the nerve and surrounding tissue providing a protective environment for axonal growth to occur across a nerve gap. These nerve guides are available in a variety of lengths and diameters and degrade over time. Postoperatively the affected area is immobilized for several weeks to avoid tension on the repaired nerve and prevent any possible migration of the guide leading to failure of the repair. Physical and occupational therapy are also needed postoperatively to aid in the restoration of sensation and muscle function.

Coaptation aid (AxoGuard nerve connector [Axogen]) is an extracellular matrix connecting aid for severed peripheral nerves. The implant allows for close approximation with the severed nerve ends that have a less than 5 mm gap. The connector can help alleviate tension at the repair site versus the suture pull tension that may occur in a direct suture repair. The porcine small intestine submucosa extracellular matrix of the connector allows for the natural healing process to occur by isolating and protecting the nerve so that the individual's own cells incorporate into the extracellular matrix to remodel and form tissue similar to the nerve epineurim. It is stored at room temperature.

Nerve wraps or protectors (AxoGuard nerve protector [Axogen], NeuraWrap nerve protector [Integra LifeSciences] or NeuroMend [Stryker]) are implants used to protect injured nerves reinforcing nerve reconstruction while preventing soft tissue attachments and nerve entrapment. An individual's own cells incorporate into the extracellular matrix to remodel and form a tissue separating layer. These are used in peripheral nerve injuries when the nerve might be only partially severed and there is no gap. The implants may be porcine small intestine or bovine collagen based. They are available in a variety of lengths and diameters. They are stored at room temperature and have a general shelf-life of 18 months.

Summary of Evidence

For individuals with peripheral nerve injuries who receive nerve repairs with allografts, the evidence includes one randomized controlled trial and one retrospective cohort study. The comparative study compared Avance nerve graft with hollow nerve conduits. Per Hayes (2020), there was no significant difference between allograft in complete recovery compared with nerve conduits (83% versus 50%) in response in function or sensation. Hayes concluded, "The body of evidence evaluating the effectiveness and safety of Avance for repair of peripheral nerve discontinuities is very low quality, which prevents conclusions from being drawn regarding the effectiveness and safety. Well-designed comparative studies are needed, particularly with autologous grafts as the comparator, to ascertain the efficacy and safety of Avance for peripheral nerve repair."

For individuals with peripheral nerve injuries who receive nerve repairs with hollow conduits, coaptation aids, nerve wraps or nerve protectors, the evidence includes prospective and retrospective case series of very small sample sizes with weaknesses in the study designs. There was a lack of comparator groups, assessment of outcomes was not standardized, there was a lack of statistical analysis of findings, and there was heterogeneity in the individual populations studied. Randomized controlled trials with long-term follow-up are needed to further evaluate whether this technology results in an improvement in the net health outcome.

In 2023 Frostadottir[50], et al concluded that there is much in the scientific literature regarding processed nerve allografts, but for the most part, these are case series and uncontrolled studies. There are very limited RCTs and non-randomized controlled trials. In the PICO (patient, intervention, comparison, outcome) analysis of their systematic review and critical appraisal, the authors state, "Despite more than 8500 published articles, the benefits of the use of processed nerve allografts remain unclear." The authors note that the few controlled studies that exist have a high risk of bias due to small patient cohorts, poor study design, lack of blinding, lack of a

control group, as well as publication bias. Thus, their conclusion is that they are unable to determine the usefulness of processed nerve allografts in current clinical practice.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT03964129	BMAC Nerve Allograft Study	15	June 2021 Unknown
NCT05199155	Phase II Study Evaluating the Safety and Efficacy of NerVFIX Treatment for Trauma or Accidental Nerve Section of the Wrist	15	Dec 2023 (terminated)

NCT: national clinical trial.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence (NICE)

In 2017, the NICE Interventional procedures guidance (IPG597) Processed nerve allografts to repair peripheral nerve discontinuities recommended that the current evidence on the safety and efficacy of processed nerve allografts to repair digital nerves discontinuities is adequate to support its use. However, the current evidence on its efficacy to repair discontinuities in other peripheral nerve sites is limited in quantity and should only be used with special arrangements for clinical governance, consent and audit or further research.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In 2018, the US Food and Drug Administration (FDA) granted Regenerative Medicine Advanced Therapy (RMAT) designation to Avance Nerve Graft (Axogen Inc.). Avance Nerve Graft is considered human tissue for transplantation and is processed in accordance with the FDA requirements for Human Cellular and Tissue-based products (HCT/P) under 21 CFR Part 1271 regulations and the guidelines of the American Association of Tissue Banks (AATB).

In 2016, the FDA granted a 510(k) clearance (K162741) for the AxoGuard nerve connector (Axogen Inc., manufactured by Cook Biotech Inc.) as substantially equivalent to previously marketed devices. It is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. Product Code: JXI

In 2014, the FDA granted a 510(k) clearance (K132660) for the AxoGuard nerve protector (Axogen Inc. manufactured by Cook Biotech Inc. under the name Nerve Cuff) as substantially equivalent to previously marketed devices (Surgisis Nerve Cuff). It is indicated for the repair of peripheral nerve injuries in which there is no gap or where a gap closure is achieved by flexion of the extremity. Product code: JXI

In 2014, the FDA granted a 510(k) clearance (K131541) for Neuroflex collagen conduit (Stryker Orthopedics, previously Collagen Matrix Inc. under the name Flexible Collagen Nerve Cuff) as substantially equivalent to previously marketed devices (Collagen Nerve Cuff). It is indicated for the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve in the foot to reduce the formation of symptomatic or painful neuroma. Product code: JXI

In 2006, the FDA granted a 510(k) clearance (K060952) for NeuroMend collagen wrap conduit (Stryker Orthopedics, previously Collagen Matrix Inc. under the name Collagen Nerve Wrap) as substantially equivalent to previously marketed devices (Collagen Nerve Cuff and NeuraWrap). It is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue and where gap closure can be achieved by flexion of the extremity. Product code: JXI

In 2004, the FDA granted a 510(k) clearance (K041620) for the NeuraWrap nerve protector (Integra LifeSciences Corp.) as substantially equivalent to previously marketed devices. It is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue. Product code: JXI

In 2001, the FDA granted a 510(k) clearance (K012814) for the NeuroMatrix collagen conduit (Stryker Orthopedics, previously Collagen Matrix Inc. under the name Collagen Nerve Cuff) as substantially equivalent to previously marketed devices (NeuraGen Nerve Guide). It is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. Product Code: JXI

In 2001, the FDA granted a 510(k) clearance (K011168) for the NeuraGen Nerve Guide (Integra LifeSciences Corp.) as substantially equivalent to previously marketed devices. It is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. Product Code: JXI

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History

Date	Comments
07/01/21	New policy, approved June 8, 2021, effective for dates of service on or after October 1, 2021, following 90-day provider notification. Add to Surgery section. Synthetic conduits and nerve allografts are considered investigational for the repair or closure of nerve gaps from peripheral nerve injuries.
09/01/22	Annual Review, approved August 8, 2022. Policy reviewed; references updated. Policy statements unchanged.
11/01/23	Annual Review, approved October 23, 2023. Policy reviewed. Reference added. Policy statement unchanged.
01/01/25	Annual Review, approved December 23, 2024. Policy reviewed; references added. Policy statement unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.