Medical Policy

Nerve Repairs for Peripheral Nerve Injuries Using Allografts, Autografts, and Conduits

Policy Number: OCA 3.701
Version Number: 13
Version Effective Date: 01/01/18

Product Applicability

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>☒ New Hampshire Medicaid</td>
<td>☒ MassHealth</td>
</tr>
<tr>
<td>☒ NH Health Protection Program</td>
<td>☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct</td>
</tr>
<tr>
<td></td>
<td>☒ Senior Care Options ◊</td>
</tr>
</tbody>
</table>

Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

Nerve autografts are considered medically necessary for the repair of peripheral nerve injuries. Synthetic conduits (e.g., NeuraGen™ Nerve Guide and NeuraWrap™ Nerve Protector) and nerve allografts (e.g., Avance® Nerve Graft) are considered experimental and investigational for the repair and closure of nerve gaps from peripheral nerve injuries. Prior authorization is required for these treatments.

It will be determined during the Plan’s prior authorization process if the service is considered medically necessary for the requested indication. See the Plan’s Medically Necessary medical policy, policy

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number OCA 3.14, for the product-specific definitions of medically necessary treatment. Review the Plan’s *Experimental and Investigational Treatment* medical policy, policy number OCA 3.12, for the product-specific definitions of experimental or investigational treatment.

**Description of Item or Service**

**Avance® Nerve Graft:** A processed nerve allograft intended for the surgical repair of peripheral nerve discontinuities.

**NeuraGen™ Nerve Guide:** A semi-permeable bovine collagen tube designed to be used as an interface between damaged nerves and the surrounding tissue, creating a conduit for axonal growth across a gap between the ends of severed nerves.

**NeuraWrap™ Nerve Protector:** An absorbable collagen implant that provides a non-constricting encasement for injured peripheral nerves for protection of the neural environment.

**Nerve Allograft:** Transplantation of a cadaver donor nerve (or nerve segment) into a recipient for the repair and closure of a nerve gap resulting from a peripheral nerve injury.

**Nerve Autograft:** Transplantation of a nerve or nerve segment from one area of the body to another area of the body for the repair and closure of a nerve gap from a peripheral nerve injury. Potential donor sites that may be used include the sural nerve and the anterior branch of the medial antebrachial cutaneous (MABC) nerve.

**Medical Policy Statement**

1. Nerve autografts are considered medically necessary for the repair of peripheral nerve injuries.

2. Synthetic conduits (e.g., NeuraWrap™ Nerve Protector and NeuraGen™ Nerve Guide) and nerve allografts (e.g., Avance® Nerve Graft) are considered experimental and investigational for the repair and closure of nerve gaps in peripheral nerve injuries.

**Limitations**

Synthetic conduits (e.g., NeuraWrap™ Nerve Protector and NeuraGen™ Nerve Guide) and nerve allografts (e.g., Avance® Nerve Graft) are considered experimental and investigational for the repair and closure of nerve gaps in peripheral nerve injuries.

**Applicable Coding**

Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description: Code Covered When Medically Necessary</th>
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<tbody>
<tr>
<td>64911</td>
<td>Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve</td>
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<thead>
<tr>
<th>CPT Code</th>
<th>Description: Code Considered Experimental and Investigational</th>
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<tbody>
<tr>
<td>64910</td>
<td>Nerve repair; with synthetic conduit or vein allograft (e.g., nerve tube), each nerve</td>
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Plan note: Examples of synthetic conduits include the NeuraWrap™ Nerve Protector and the NeuraGen™ Nerve Guide

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<tr>
<th>CPT Code</th>
<th>Description: Code Considered Experimental and Investigational</th>
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<tbody>
<tr>
<td>64912</td>
<td>Nerve repair; with nerve allograft, each nerve, first strand (cable)</td>
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<tr>
<td>64913</td>
<td>Nerve repair; with nerve allograft, each additional strand (List separately in addition to code for primary procedure)</td>
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**Clinical Background Information**

Peripheral nerve injuries may occur due to blunt or penetrating trauma or acute compression. Injury to a motor nerve results in a loss of muscle function, and injury to a sensory nerve resulting in a loss of sensation in the affected nerve's sensory distribution and/or pain. Reconstruction of nerve continuity can be accomplished by direct repair when nerve tissue loss is minimal and the ends of the severed nerve lie in close proximity. Nerve grafting is recommended in nerve injury cases in which a gap is present between the proximal and distal end of the nerve. Several methods of nerve grafting have been proposed as a treatment for peripheral nerve injuries, including synthetic conduits, nerve autografts, and nerve allografts.
Types of synthetic conduits include the NeuraWrap™ Nerve Protector and the NeuraGen™ Nerve Guide, both developed by Integra LifeSciences Corporation. NeuraWrap™ Nerve Protector is an absorbable collagen implant that provides a non-constricting encasement for injured peripheral nerves for protection of the neural environment. NeuraGen™ Nerve Guide is indicated for peripheral nerve repair in cases where a nerve is completely severed; it is a semi-permeable absorbable bovine collagen tube that is designed to be used as an interface for damaged nerves and the surrounding tissue by creating a conduit for axonal growth across a gap between the ends of severed nerves. Peripheral nerves regenerate spontaneously but will not establish functional connections unless the nerve endings or stumps are reconnected surgically. Use of the NeuraWrap™ Nerve Protector or NeuraGen™ Nerve Guide conduit has been proposed as a method of improving the restoration of function when repairing severed peripheral nerves.

Other methods used for repair of severed peripheral nerves include nerve autografts and nerve allografts. The use of autologous nerve grafts for bridging gaps in nerve continuity require the sacrifice of healthy nerves, but this method is the gold standard for nerve repair. Nerve allograft transplantation from cadavers offers an alternative without the morbidities associated with nerve autografts, but these grafts are rapidly rejected unless appropriate immunosuppression is achieved. Avance® Nerve Graft (AxoGen, Inc.) is the only off-the-shelf commercially available processed nerve allograft intended for the surgical repair of peripheral nerve discontinuities. Through a proprietary cleansing process for recovered human peripheral nerve tissue, the graft preserves the essential inherent structure of the extracellular matrix while cleansing away cellular and noncellular debris. Published evidence is very limited; initial human study results demonstrate suggest that it is superior to collagen nerve conduit but not to autograft.

At the present time, there is insufficient scientific evidence in the peer-reviewed medical literature to support the efficacy of synthetic conduits and nerve allografts for bridging the defects resulting from peripheral nerve injuries. The published literature to date consists only of very small case studies and case series, non-standardized assessment of outcomes, lack of comparator groups, lack of statistical analysis of findings, and heterogeneity in patient populations. In addition, the type and severity of the nerve injury varied substantially between studies. There are no published guidelines or position statements for the use of the synthetic conduits or nerve allografts. Additional studies are needed to determine whether or not the use of synthetic conduits or nerve allografts provide an improvement in health outcomes when used to repair peripheral nerve injuries.

At the time of the Plan’s most recent policy review, no clinical guidelines were found from the Centers for Medicare & Medicaid Services (CMS) for nerve autografts, nerve allografts, and/or synthetic conduits for peripheral nerve repair. Determine if applicable CMS criteria are in effect for these services in a national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request for a Senior Care Options member.

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References


<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Original Policy Approved by</th>
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<tr>
<td>Regulatory Approval: N/A</td>
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| Internal Approval:  
10/14/08: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) 
10/28/08: Utilization Management Committee (UMC) 
11/18/08: Quality Improvement Committee (QIC) | 02/01/09 
Version 1 | Medical Policy Manager as Chair of MPCTAC | MPCTAC, QIC, and UMC |

*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Heath Plan New Hampshire Medicaid Product(s): 01/01/13
*Effective Date for Senior Care Options Product(s): 01/01/16

**Policy Revisions History**

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
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11/25/09: QIC |                         |             |
| 11/01/10    | No changes except updated references. | Version 3                                  | 11/23/10: MPCTAC  
12/22/10: QIC |                         |             |
| 11/01/11    | No changes except updated references. | Version 4                                  | 11/16/11: MPCTAC  
12/20/11: QIC |                         |             |
| 07/01/12    | References updated and language added to Applicable Coding section. | Version 5                                  | 07/18/12: MPCTAC  
08/22/12: QIC |                         |             |
| 07/30/12    | Off cycle review for Well Sense Health Plan. Revised Summary statement and revised Medical Policy Statement section. | Version 6                                  | 08/03/12: MPCTAC  
09/05/12: QIC |                         |             |
| 07/01/13    | Review for effective date 09/01/13. | 09/01/13                                  | 07/17/13: MPCTAC |

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<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tr>
<td>08/15/13</td>
<td>Reformatted text in Summary, Description of Item or Service, Medical Policy Statement, and Clinical Background Information sections without changing the content. Updated references.</td>
<td>Version 7</td>
<td>08/15/13: QIC</td>
<td>04/01/14: Review for effective date 08/01/14. Updated Summary, Description of Item or Service, Medical Policy Statement, Applicable Coding, Limitations, and Clinical Background Information sections to include NeuraWrap™ Nerve Protector as a type of synthetic conduit considered experimental and investigational for the repair of peripheral nerve injuries. Changed service considered experimental and investigational from a brand of synthetic conduits to all synthetic conduits. Updated references. No change made to the applicable code list.</td>
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<tr>
<td>04/01/14</td>
<td>Review for effective date 08/01/14. Updated Summary, Description of Item or Service, Medical Policy Statement, Applicable Coding, Limitations, and Clinical Background Information sections to include NeuraWrap™ Nerve Protector as a type of synthetic conduit considered experimental and investigational for the repair of peripheral nerve injuries. Changed service considered experimental and investigational from a brand of synthetic conduits to all synthetic conduits. Updated references. No change made to the applicable code list.</td>
<td>Version 8</td>
<td>04/16/14: MPCTAC</td>
<td>05/14/14: QIC</td>
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<tr>
<td>03/01/15</td>
<td>Review for effective date 05/01/15. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available.</td>
<td>Version 9</td>
<td>03/18/15: MPCTAC</td>
<td>04/08/15: QIC</td>
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<tr>
<td>03/01/16</td>
<td>Review for effective date 05/01/16. Revised the Summary, Description of Item or Service, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Administrative change made to the Medical Policy Statement and Limitations sections.</td>
<td>Version 11</td>
<td>03/16/16: MPCTAC</td>
<td>04/13/16: QIC</td>
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<td>01/01/17</td>
<td>Review for effective date 03/01/17. Updated References section.</td>
<td>Version 12</td>
<td>01/18/17: MPCTAC</td>
<td>02/08/17: QIC</td>
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<td>12/01/17</td>
<td>Review for effective date 01/01/18.</td>
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Policy Revisions History

| Industry-wide updates to codes included in the Applicable Coding section. | Version 13 | industry-wide code changes. |

Last Review Date

12/01/17

Next Review Date

01/01/18

Authorizing Entity

MPCTAC

Other Applicable Policies

Medical Policy - *Experimental and Investigational Treatment*, policy number OCA 3.12
Medical Policy - *Medically Necessary*, policy number OCA 3.14

Reference to Applicable Laws and Regulations


The Commonwealth of Massachusetts. Massachusetts General Law. Chapter 118E. Division of Medical Assistance. Accessed at: [https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVII/Chapter118E](https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVII/Chapter118E)

Disclaimer Information: +

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these

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guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.