Medical Policy

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

Policy Number: OCA 3.701
Version Number: 11
Version Effective Date: 05/01/16

Product Applicability

+ All Plan+ Products

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<th>Well Sense Health Plan</th>
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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 policy, Medically Necessary (policy number OCA 3.701).

**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**

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 results 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 nervous systems.

Plan Note: Examples of synthetic conduits include the NeuraWrap™ Nerve Protector and the NeuraGen™ Nerve Guide.
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.

References


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

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.


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<thead>
<tr>
<th>Original Approval Date</th>
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<th>Policy Owner</th>
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<tr>
<td>Regulatory Approval: N/A</td>
<td>02/01/09 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)</td>
<td>MPCTAC, QIC, and Utilization Management Committee (UMC)</td>
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<td>Internal Approval: 10/14/08: MPCTAC 10/28/08: UMC 11/18/08: QIC</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12

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

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*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

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<th>Summary of Revisions</th>
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<tr>
<td>11/01/10</td>
<td>No changes except updated references.</td>
<td>Version 3</td>
<td>11/23/10: MPCTAC 12/22/10: QIC</td>
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<td>11/01/11</td>
<td>No changes except updated references.</td>
<td>Version 4</td>
<td>11/16/11: MPCTAC 12/20/11: QIC</td>
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<tr>
<td>07/01/12</td>
<td>References updated and language added to Applicable Coding section.</td>
<td>Version 5</td>
<td>07/18/12: MPCTAC 08/22/12: QIC</td>
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<tr>
<td>07/30/12</td>
<td>Off cycle review for Well Sense Health Plan. Revised Summary statement and revised Medical Policy Statement section.</td>
<td>Version 6</td>
<td>08/03/12: MPCTAC 09/05/12: QIC</td>
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<td>07/01/13</td>
<td>Review for effective date 09/01/13. 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>09/01/13 Version 7</td>
<td>07/17/13: MPCTAC 08/15/13: QIC</td>
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<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>08/01/14 Version 8</td>
<td>04/16/14: MPCTAC 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,</td>
<td>05/01/15 Version 9</td>
<td>03/18/15: MPCTAC 04/08/15: QIC</td>
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<th>Description</th>
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<td>11/25/15</td>
<td>Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available.</td>
<td>01/01/16</td>
<td>MPCTAC (electronic vote)</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>05/01/16</td>
<td>MPCTAC Version 11</td>
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Last Review Date
03/01/16

Next Review Date
01/01/17

Authorizing Entity
QIC

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)

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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 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.

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