Medical Policy

Lumbar Artificial Disc Replacement

Policy Number: OCA 3.42
Version Number: 13
Version Effective Date: 06/01/16

Product Applicability

- All Plan* Products

Well Sense Health Plan
- New Hampshire Medicaid
- NH Health Protection Program

Boston Medical Center HealthNet Plan
- MassHealth
- Qualified Health Plans/ConnectorCare/Employer Choice Direct
- Senior Care Options ◊

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

The Plan considers the implantation of a lumbar artificial intervertebral disc and nucleus disc devices (lumbar total disc replacement) to be experimental and investigational for any indication. Plan prior authorization is required.

It will be determined during the Plan’s prior authorization process if the service is considered experimental and investigational for the requested use. See the Plan’s policy, Experimental and Investigational Treatment (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment. Review Plan policy, Cervical Artificial Disc Replacement

*Lumbar Artificial Disc Replacement

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(policy number OCA 3.421), rather than this Policy for guidelines related to the use of artificial intervertebral cervical discs.

**Description of Item or Service**

**Artificial Intervertebral Disc Replacement:** A total artificial disc replaces the entire disc, including nucleus, annulus, and end plate and consists of a polyurethane nucleus designed to fit between two (2) titanium alloy surfaces. An artificial disc nucleus is designed to replace only the degenerative nucleus; most of the annulus is left intact. This device consists of a hydrogel core that can absorb fluid and expand when implanted. Replacement of the intervertebral disc or the disc nucleus with an artificial device is proposed as an alternative to interbody fusion to treat symptomatic degenerative disc disease. An artificial intervertebral disc replacement is also known as an artificial disc replacement or total disc replacement.

**Lumbar Artificial Disc Replacement:** Also known as a lumbar total disc replacement, a lumbar artificial disc replacement involves the replacement of a degenerating lumbar (L3 to S1) intervertebral disc with an artificial or prosthetic disc to treat symptomatic degeneration disc disease. The artificial disc is designed to maintain the physiological range of motion and stability of the natural spine and restore disc height and vertebral alignment, and, as a result, relieve pain and prevent adjacent disc degeneration. Traditionally, spinal fusion surgery (rather than artificial disc surgery) has been the treatment of choice for individuals who have not found pain relief for chronic back pain through non-surgical treatment, and the pain has significantly affecting the individuals' quality of life and ability to function. With lumbar artificial disc replacement, pain relief may result from the removal of the painful lumbar disc, and motion is maintained with the use of a prosthetic lumbar implant.

**Medical Policy Statement**

The Plan considers the use of all artificial lumbar intervertebral discs and lumbar nucleus disc devices to be experimental and investigational for any indication.

**Limitations**

This service is considered experimental and investigational. The removal, revision, and/or replacement of lumbar artificial discs require Plan Medical Director review.

**Definitions**

**Lumbar Degenerative Disc Disease (DDD):** A progressive loss of disc height and instability of the lumbar spinal segment(s) and associated degenerative processes, resulting in a loss of flexibility, elasticity, and shock absorbing characteristics of the intervertebral disc(s). DDD involves changes in the spinal vertebrae which can destabilize the anterior spinal column and cause radiculopathy (i.e., nerve compression leading to neurological deficits and/or pain in the back, leg[s], hips, and/or buttocks), as well as myelopathy (compression of the spinal cord).
### Applicable Coding

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health 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 Codes</th>
<th>Description: Codes Considered Experimental and Investigational</th>
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</thead>
<tbody>
<tr>
<td>22857</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar</td>
</tr>
<tr>
<td></td>
<td>(Note: For additional interspace, use 0163T.)</td>
</tr>
<tr>
<td>22862</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc) anterior approach, single interspace; lumbar</td>
</tr>
<tr>
<td>22865</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar</td>
</tr>
<tr>
<td>0163T</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar</td>
</tr>
<tr>
<td></td>
<td>(Note: List separately in addition to code for primary procedure. Use 0163T in conjunction with 22857.)</td>
</tr>
</tbody>
</table>

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*Lumbar Artificial Disc Replacement

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<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Notes</th>
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<tr>
<td>0164T</td>
<td>Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar</td>
<td>(Note: List separately in addition to code for primary procedure. Use 0164T in conjunction with 22865.)</td>
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<tr>
<td>0165T</td>
<td>Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar</td>
<td>(Note: List separately in addition to code for primary procedure. Use 0165T in conjunction with 22862.)</td>
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Clinical Background Information

Approximately 80 percent of the adult population in the United States will experience significant low back pain sometime during their lifetime, the majority of which is due to degenerative disc disease (DDD). Spinal fusion (lumbar or cervical) is among the top three (3) most frequently performed musculoskeletal procedures in the United States. Common complications of fusion can include instrument failure, nerve injuries, failure to achieve solid fusion, bone donor site complications, and/or increased degeneration in the spinal segments adjacent to the fusion.

Initial treatment for lumbar DDD consists of physical therapy, nonsteroidal anti-inflammatory drugs (NSAIDs), narcotic analgesics, muscle relaxants, epidural steroid injections, and massage therapy. If conservative therapy fails, surgical options may be considered. Spinal fusion is considered the standard treatment for patients who fail conservative therapy. However, spinal fusion is associated with significant side effects, including accelerated adjacent disc degeneration, pseudarthrosis, surgical access-related collateral damage, spinal stenosis due to secondary facet joint degeneration, symptomatic facet and iliosacral joint problems, and/or associated recurring back pain.

Artificial disc replacement is a proposed method to alleviate pain associated with DDD as an alternative to spinal fusion surgery. Prosthetic discs were developed to replace the function of the native disc that includes range of motion and shock absorption. In comparison to spinal fusion surgery, potential benefits of artificial disc technology may include quicker recovery time, more spine mobility after surgery, less stress on adjacent discs, and no need to harvest and use a bone graft. Artificial disc implantation is typically performed by an orthopedic surgeon or neurosurgeon on an inpatient basis.

There are several lumbar disc replacement devices that have been FDA approved. Complications of artificial disc replacement surgery can include loosening and migration of the prosthesis (which may require emergency surgery to remove the disc), adjacent disc degeneration, polyethylene and metallic wear (which occur with load-bearing implants that allow motion), salvage procedures in case of failure, vascular injuries, and/or thrombolytic complications. According to the Food and Drug Administration (FDA), an artificial disc is contraindicated in individuals with spinal instability, prior major spinal surgery, spinal infection, ankylosing spondylitis or pregnancy, rheumatoid arthritis, autoimmune disease, diffuse idiopathic skeletal hyperostosis, severe spondylosis with bridging osteophytes or ossification of the posterior longitudinal ligament, disc height loss greater than 50 percent, metal

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allergy to components of the prosthesis, severe osteoporosis/osteopenia, active malignancy, metabolic bone disease, trauma, segmental instability, three (3) or more levels requiring treatment, insulin dependent diabetes mellitus, human immunodeficiency virus, hepatitis B/C, morbid obesity, absence of motion less than two (2) degrees, and/or posterior facet arthrosis.

The results of the studies to date suggest that lumbar artificial intervertebral disc replacements may be effective in carefully selected individuals; however, there is insufficient evidence in the published peer reviewed medical literature indicating the long-term safety and effectiveness of these devices. Questions remain regarding the long-term outcomes, and additional studies are needed that compare outcomes from the implantation of lumbar artificial disc with conventional spinal fusion.

At the time of the Plan’s most recent policy review, the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) #150.10 for lumbar artificial disc replacement (LADR) states that LADR is not reasonable and necessary for the Medicare population older than 60 years of age; therefore, LADR is not covered for these beneficiaries. For Medicare beneficiaries 60 years of age and younger, there is no NCD for LADR. Verify CMS criteria in the applicable NCD or local coverage determination (LCD) in effect on the date of the prior authorization request for a Senior Care Options member.

**References**


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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Approved by</th>
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<tr>
<td>Regulatory Approval: N/A Internal Approval: 12/06/05</td>
<td>02/06/06 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>Quality and Clinical Management Committee (Q&amp;CMC)</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for Senior Care Options Product(s): 01/01/16

Effective 02/06/06 to 06/01/16, the policy title was *Cervical and Lumbar Artificial Disc Replacement*. Effective 06/01/16, the revised policy title is *Lumbar Artificial Disc Replacement*. A new policy was developed for cervical artificial disc replacement as of 06/01/16, *Cervical Artificial Disc Replacement* (policy number OCA 3.421).

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
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<tr>
<td>02/06/07</td>
<td>Updated references.</td>
<td>Version 2</td>
<td>01/08/07: MPCTAC 02/06/07: Q&amp;CMC</td>
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<td>12/01/07</td>
<td>No changes.</td>
<td>Version 3</td>
<td>01/22/08: UMC 02/19/08: QIC</td>
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<td>12/01/08</td>
<td>No changes to the clinical criteria. Updated references and coding.</td>
<td>Version 4</td>
<td>01/27/09: MPCTAC 01/27/09: Utilization Management Committee (UMC) 02/25/09: QIC</td>
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<td>12/01/09</td>
<td>No changes to medical criteria. Updated references.</td>
<td>Version 5</td>
<td>12/23/09: MPCTAC 02/24/10: QIC</td>
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<td>12/01/10</td>
<td>No changes to medical criteria. Updated references.</td>
<td>Version 6</td>
<td>12/28/10: MPCTAC 01/26/11: QIC</td>
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<tr>
<td>12/01/11</td>
<td>No changes to medical criteria. Updated references.</td>
<td>Version 7</td>
<td>12/12/11: MPCTAC 12/20/11: QIC</td>
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<tr>
<td>02/01/13</td>
<td>References updated, updated code definitions, revised introductory paragraph in Applicable Coding section, revised Summary section, referenced Experimental and Investigational Treatment policy, revised Medical Policy Statement section (formerly</td>
<td>Version 8</td>
<td>02/20/13: MPCTAC 03/21/13: QIC</td>
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<td>02/01/14</td>
<td>Review for effective date 03/01/14. Updated references.</td>
<td>03/01/14: MPCTAC 02/26/14: QIC</td>
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<td>12/01/14</td>
<td>Review for 2015 code changes with effective date of 03/01/15. Updated applicable code list.</td>
<td>03/01/15: Version 10 12/02/14: MPCTAC (electronic vote) 12/10/14: QIC</td>
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<td>02/01/15</td>
<td>Review for effective date 04/01/15. Updated Description of Item or Service, Definitions, Clinical Background Information, and References sections. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available.</td>
<td>04/01/15: Version 11 02/18/15: MPCTAC 03/11/15: QIC</td>
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<td>02/01/16</td>
<td>Review for effective date 06/01/16. Revised Summary, Description of Item or Service, Medical Policy Statement, Limitations, Definitions, Applicable Coding, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Updated policy title and removed services related to cervical artificial disc replacement from this policy.</td>
<td>06/01/16: Version 13 02/17/16: MPCTAC 03/09/16: QIC</td>
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**Last Review Date**

02/01/16
Next Review Date
02/01/17

Authorizing Entity
QIC

Other Applicable Policies
Medical Policy - Cervical Artificial Disc Replacement, policy number OCA 3.421
Medical Policy - Experimental and Investigational Treatment, policy number OCA 3.12

Reference to Applicable Laws and Regulations

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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