

## Artificial Disc Replacement

MPM 1.3

<b>Disclaimer</b>	<b>Refer to the member's specific benefit plan and <i>Schedule of Benefits</i> to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in these criteria.</b>
<b>Description</b>	Artificial disc replacement is an alternative to spinal fusion for the treatment of symptomatic disc disease. These devices are designed to maintain the function of the natural spine by preserving motion, and to potentially limit the incidence of adjacent segment degeneration. Artificial disc replacements are available for the lumbar and cervical spine. <b>Presbyterian Health Plan covers cervical artificial disc replacement, but does not cover lumbar artificial disc replacement.</b>
<b>Coverage Determination and Clinical Indications</b>	<p><b>Prior Authorization is required. Log on to Pres Online to submit a request: <a href="https://ds.phs.org/preslogin/index.jsp">https://ds.phs.org/preslogin/index.jsp</a></b></p> <p><b>Lumbar Artificial Disc Replacement:</b></p> <p>The long-term safety of lumbar artificial disc replacement has not been established.<sup>2</sup> Therefore, lumbar artificial disc replacement is <b>not</b> a covered benefit.</p> <p><b>Cervical Artificial Disc Replacement:</b></p> <p>This technology has been reviewed by the Technology Assessment Committee and the Medical Policy Committee. The BRYAN® Cervical Disc, PRESTIGE® Cervical Disc and the ProDisc™-C Total Disc Replacement are covered for a single level procedure for the treatment of symptomatic disc disease when <b>all</b> of the following indications are met:</p> <ol style="list-style-type: none"><li>1. Skeletally mature patient without renal failure, severe diabetes, osteoporosis, severe spondylosis, severe facet pathology, cervical instability, localized fracture, or localized or systemic infections.</li></ol> <p style="text-align: center;"><b>AND</b></p> <ol style="list-style-type: none"><li>2. Single-level disc degeneration of C3 to C7, confirmed by imaging studies such as CT or MRI, with <b>one</b> of the following diagnoses:<ul style="list-style-type: none"><li>• Herniated disc; <b>or</b></li><li>• Osteophyte formation; <b>or</b></li><li>• Loss of disc height</li></ul></li></ol> <p style="text-align: center;"><b>AND</b></p>

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3. The patient must present with **symptoms**, which must correspond with the planned level of disc replacement:
- Intractable radiculopathy (nerve root compression) and/or myelopathy (functional disturbance or pathological change in the spinal cord) causing neck and/or arm pain; **or**
  - Functional and/or neurological deficit.

**AND**

4. Six weeks of nonoperative alternative treatments have failed. These treatments may include physical therapy, medications, braces, chiropractic care, bed rest, spinal injections or exercise programs. Documentation of treatments and failure to improve is required.

**The disc must be approved by the U.S. Food and Drug Administration (FDA). All other artificial disc systems are considered experimental and investigational.**

**All other indications, including multilevel degenerative disc disease, are considered experimental and investigational.**

**Exclusions**

The following indications are specifically **excluded** from coverage, as the safety and effectiveness of the cervical disc devices have not been established in patients with the following conditions:

- Previous surgical intervention at the involved level;
- Prior or proposed fusion at an adjacent cervical level;
- More than one cervical level requiring artificial disc replacement;
- Clinically compromised vertebral bodies at the affected level due to current or past trauma (including but not limited to the radiographic appearance of fracture callus, malunion or nonunion).

**Contraindications**

The FDA has determined the following contraindications for cervical artificial disc replacement products, including the BRYAN® Cervical Disc, the PRESTIGE® Cervical Disc and the ProDisc™-C Total Disc Replacement:

- Active systemic infection or infection localized to the site of implantation.
- Osteoporosis defined as DEXA bone density measured T-score  $\leq -2.5$ .
- Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation  $>3$  mm and/or  $11^\circ$  of rotational difference to either adjacent level.
- Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium, stainless steel).
- Severe spondylosis characterized by bridging osteophytes or a loss of disc height  $>50\%$  or an absence of motion ( $<2\%$ ), as this may lead to limited range of motion and may encourage bone formation.

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- Clinically compromised vertebral bodies at the affected level due to current or past trauma (including but not limited to the radiographic appearance of fracture callus, malunion or nonunion).
- Symptomatic cervical degenerative disc disease at more than one level.<sup>4</sup>

**Coding**

**The coding listed in this Medical Policy is for reference only. Covered and non-covered procedures are within this list.**

CPT Codes	Description
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
0092T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection), additional interspace, cervical
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar

ICD-9© Diagnosis Codes	Description
722.4	Degeneration of cervical intervertebral disc
722.52	Degeneration of lumbar or lumbosacral intervertebral disc

**References:**

1. Centers for Medicare and Medicaid Services. National Coverage Determination for Lumbar Artificial Disc Replacement (LADR) (150.10). Effective Date: 8-14-07.
2. Hayes Directory. Copyright © 2009 Winifred S. Hayes, Inc. Lumbar Total Disc Replacement for Degenerative Disc Disease. April 1, 2009.
3. FDA Summary of Safety and Effectiveness Data, PMA P060023. Device Trade Name: BRYAN® Cervical Disc. Date of FDA Notice of Approval: 05-12-09. FDA Overview, which includes the summary and package labeling, accessed 09-22-09 on the Internet at:  
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm162968.htm>

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4. FDA Summary of Safety and Effectiveness Data, PMA P060018. Device Trade Name: PRESTIGE® Cervical Disc System. Date of Panel Recommendation: 09-19-06. FDA Overview, which includes the summary and package labeling, accessed 09-22-09 on the Internet at:  
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm076928.htm>
5. FDA Summary of Safety and Effectiveness Data, PMA P070001. Device Trade Name: ProDisc™ -C Total Disc Replacement. Date of Notice of Approval of Application: 12-17-07. FDA Overview, which includes the summary package labeling, accessed 09-22-09 on the Internet at:  
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm074813.htm>
6. Hayes Directory. Copyright © 2009 Winifred S. Hayes, Inc [Artificial Disc Replacement for Cervical Degenerative Disc Disease](#) June 2011

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This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available on the Internet at:  
<http://www.phs.org/phs/healthplans/providers/healthservices/Medical/index.htm>

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