Cervical Disc Arthroplasty

**Prestige™ Cervical Disc**

The Prestige™ Cervical Disc is a stainless steel artificial disc, which incorporates a proprietary ball-and-trough design. It is designed to treat cervical disc disease by maintaining motion.

The Prestige™ Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The Prestige™ Cervical Disc is implanted through an open anterior approach. Intractable radiculopathy and/or myelopathy should present with at least one of the following items producing symptomatic nerve root and/or spinal cord compression which is documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurological deficit), and radiographic studies (e.g., CT, MRI, x-rays, etc.): 1) herniated disc, and/ or 2) osteophyte formation.

**Bryan™ Cervical Disc**

The Bryan™ Cervical Disc consists of a polyurethane nucleus designed to fit between two titanium alloy surfaces (shells). The bone-contacting surface of each shell includes a titanium porous coating to encourage bony in-growth and long-term stability. A polyurethane sheath surrounds the nucleus and is attached to the shells with titanium wire, forming a closed compartment. Titanium alloy seal plugs provide for retention of a lubricant. Anterior stops on each shell are intended to prevent posterior migration of the device.

The Bryan™ Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/ or myelopathy. The Bryan device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy is defined as any combination of the following: disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy, or spondylotic myelopathy resulting in impaired function and at least one clinical neurological sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using computed tomography (CT), myelography and CT, and/or magnetic resonance imaging (MRI). Patients receiving the Bryan™ Cervical Disc should have failed at least six weeks of non-operative treatment prior to implantation of the Bryan™ Cervical Disc.
PHYSICIAN REIMBURSEMENT

Physicians use Current Procedural Terminology (CPT®) codes to report all of their services. These codes are uniformly accepted by all payers. Medicare and most indemnity insurers use a fee schedule to pay physicians for their professional services, assigning a payment amount to each CPT code. Under Medicare’s Resource-Based Relative Value Scale (RBRVS) methodology for physician payment, each CPT code is assigned a point value, known as Relative Value Units (RVU), which is then multiplied by a conversion factor to determine the physician payment. Many other payers use Medicare’s RBRVS fee schedule or a variation of it. Industrial or work-related injury cases are usually reimbursed according to the official fee schedule for each state.

Use of CPT codes is governed by various coding guidelines published by the American Medical Association (AMA) and other major sources such as physician specialty societies. In addition, the National Correct Coding Initiative (NCCI), a set of CPT coding edits created and maintained by the Centers for Medicare and Medicaid Services (CMS), has become a national standard.

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>RVU</th>
<th>2019 Medicare Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>22856</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical</td>
<td>47.66</td>
<td>$1,717.62</td>
</tr>
</tbody>
</table>


FACILITY REIMBURSEMENT

Inpatient Reimbursement

Hospital payment for inpatient services/procedures is usually based on Diagnosis-Related Groups (DRG), case rates, per diem rates or a line item payment methodology. Medicare uses the Medicare Severity-DRG (MS-DRG) payment methodology to reimburse hospitals for inpatient services. Each inpatient stay is assigned to one payment group, based on the ICD-10-CM codes assigned to the major diagnoses and procedures. Each DRG has a payment rate which bundles the reimbursement for all services the patient received during the inpatient stay. Most insurers usually pay the hospital on a contractual basis (i.e., case rate or per diem rate) that has been negotiated between the hospital and insurance carrier.

ICD-10-CM Procedure Codes

Hospitals use ICD-10-CM procedure codes to report inpatient services. The following ICD-10-CM codes are used to report cervical disc arthroplasty procedures.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0RR30JZ</td>
<td>Replacement of cervical disc with synthetic substitute, open approach</td>
</tr>
<tr>
<td>0RP30JZ</td>
<td>Removal of synthetic substitute from cervical disc, open approach</td>
</tr>
<tr>
<td>0RW30JZ</td>
<td>Revision of synthetic substitute in cervical disc, open approach</td>
</tr>
</tbody>
</table>

Diagnosis-Related Groups (DRG)

Medicare uses the Medicare Severity–Diagnosis-Related Group (MS-DRG) payment methodology to reimburse hospitals for inpatient services. Each inpatient stay is assigned to one payment group, based on the ICD-10-CM codes assigned to the major diagnoses and procedures. Each MS-DRG has a payment rate that bundles the reimbursement for all services the patient received during the inpatient stay. The following chart shows the estimated Medicare payment amounts for the MS-DRG to which cervical disc arthroplasty procedures may group.
CERVICAL DISC ARTHROPLASTY

FACILITY REIMBURSEMENT

Medicare Severity—Diagnosis Related Group (MS-DRG) Assignment

<table>
<thead>
<tr>
<th>MS-DRG</th>
<th>Description*</th>
<th>MDC</th>
<th>Relative Weight†</th>
<th>FY19 Medicare Payment†</th>
</tr>
</thead>
<tbody>
<tr>
<td>028</td>
<td>Spinal Procedures with MCC</td>
<td>01</td>
<td>5.3748</td>
<td>$32,490.16</td>
</tr>
<tr>
<td>029</td>
<td>Spinal Procedures with CC or Spinal Neurostimulator</td>
<td>01</td>
<td>3.1557</td>
<td>$19,075.91</td>
</tr>
<tr>
<td>030</td>
<td>Spinal Procedures without CC/MCC</td>
<td>01</td>
<td>2.1757</td>
<td>$13,151.90</td>
</tr>
<tr>
<td>518</td>
<td>Back and Neck Procedures except Spinal Fusion with MCC or Disc/Device/ Neurostimulator</td>
<td>08</td>
<td>3.1002</td>
<td>$18,740.41</td>
</tr>
</tbody>
</table>

Under the MS-DRG system, cases may be assigned to a number of other MS-DRGs, based on individual patient diagnosis and presence or absence of additional surgical procedures performed. Additional MS-DRGs include but are not limited to: MS-DRGs 907, 908, 909; MS-DRGs 957, 958, 959; and MS-DRGs 981, 982, 983.

* MCC – Major Complication and/or Comorbidity. CC – Complication and/or Comorbidity.
† Source: FY2019 Medicare Hospital Inpatient Prospective Payment System, Final Rule. Federal Register, August 2, 2018. Updated with Correction Notice dated September 28, 2018. Assumes payment for a hospital with wage index and geographic adjustment factor of 1.000 and submitted quality data and is a meaningful EHR user.

Outpatient Reimbursement

Facilities use the Healthcare Common Procedure Coding System (HCPCS) to report outpatient services. Under Medicare’s methodology for outpatient payment, each HCPCS code is assigned to one Ambulatory Payment Classification (APC). Each APC has a relative weight which is multiplied by a conversion factor to determine the facility payment. An APC is assigned to each significant service. Although some services are bundled and not separately payable, total payment to the facility is the sum of the APC amounts for the services provided during the outpatient encounter.

Beginning January 1, 2015, Medicare implemented a policy for comprehensive APCs (C-APCs) for device-dependent procedures. Procedures assigned to these C-APCs, with J1 status indicators, are considered to be primary services. When one of these procedures is reported on an outpatient claim, all covered Part B services on the claim are packaged with the primary “J1” service for the claim, except services with OPPS SI=F,G,H,L and U; ambulance services; diagnostic and screening mammography; all preventative services; and certain Part B inpatient services. This results in a single Medicare payment and a single beneficiary copayment under the OPPS for the comprehensive service based on all included charges on the claim.

Many payers use Medicare’s APC methodology or a similar type of fee schedule to reimburse facilities for outpatient services. Other payers use a percentage of charges mechanism, depending on their contract with the hospital.

2019

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>APC</th>
<th>Status Indicator</th>
<th>Medicare Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>22856</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical</td>
<td>5116</td>
<td>J1</td>
<td>$15,402.46</td>
</tr>
<tr>
<td>C1889</td>
<td>Implantable/insertable device for device intensive procedure, not otherwise classified</td>
<td>N/A</td>
<td>N</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Medicare requires hospitals to use HCPCS II C-codes in conjunction with procedures that require the implantation of a device that are assigned to a device-intensive APC under the Medicare Hospital Outpatient Prospective Payment System. Code C1889 may be appropriate to meet this Medicare requirement, although no additional payment is made for the implant(s).

**Status/Payment Indicators:**

Each HCPCS code in the Outpatient Prospective Payment System (OPPS) is assigned a status indicator to signify whether a discount (payment reduction) applies to the respective APC payment. The following status indicator is assigned to this procedure:

- **J1** Hospital Part B services paid through a comprehensive APC
- **N** Packaged into APC rates (No separate payment)

### Coverage of Cervical Disc Arthroplasty in the Hospital Outpatient Setting

As of January 1, 2013, Medicare now covers cervical disc arthroplasty (22856) in the outpatient setting. Prior to 2013, this procedure was limited to inpatient services. Commercial payers may allow for the procedure to be performed in this setting. Hospitals should contact the payer and review their payer contracts to ensure coverage and payment for this procedure in the outpatient setting.

### Ambulatory Surgery Centers

Ambulatory Surgery Centers (ASCs) use CPT and HCPCS codes to report their services. Medicare's payment methodology is based on the hospital outpatient APCs, but using payments unique to ASCs.

Many payers use a similar type of fee schedule to reimburse ASCs, while other payers use alternate mechanisms depending on their contracts with the ASC.

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>Status Indicator</th>
<th>2019 Medicare Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>22856</td>
<td>Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical</td>
<td>J8</td>
<td>$11,338.99</td>
</tr>
</tbody>
</table>


### Payment Indicators

Each code in the ASC Payment System is assigned a payment indicator to signify certain payment rules. The following status indicator is represented in this procedure:

- **J8** Device-intensive procedure; paid at adjusted rate.
Reimbursement Support Center
General questions about spine reimbursement for surgeon or hospital

Phone: 866-743-1220
Internet: www.medtronicspinal.com/spineline

Therapy Access Solutions
Provides assistance with a prior authorization or denials for patients whose medical needs are consistent with FDA approved/cleared indications or are otherwise in accordance with payer policies. Contact Medtronic’s Therapy Access Solutions at (866) 446-3873 or email them at rs.memspinetherapyaccess@medtronic.com for assistance.
The Bryan™ Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from C3–C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The Bryan device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy is defined as any combination of the following: disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy, or spondylotic myelopathy resulting in impaired function and at least one clinical neurological sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using computed tomography (CT), myelography and CT, and/or magnetic resonance imaging (MRI). Patients receiving the Bryan™ Cervical Disc should have failed at least six weeks of non-operative treatment prior to implantation of the Bryan™ Cervical Disc. The Bryan™ Cervical Disc should not be implanted in patients with an active infection or with an allergy to titanium, polyurethane or ethylene oxide residues., active systemic infection or infection at the operating site; osteoporosis defined as a DEXA bone mineral density T-score equal to or worse than -2.5; moderate to advanced spondylosis characterized by bridging osteophytes, marked reduction or absence of motion, of collapse of the intervertebral disc space of greater than 50% of its normal height; marked cervical instability on radiographs (e.g., radiographic signs of subluxation greater than 3.5 mm or angulation of the disc space more than 11 degrees greater than adjacent segments); significant cervical anatomical deformity or compromised vertebral bodies at the index level (e.g., ankylosing spondylitis, rheumatoid arthritis, or compromise due to current or past trauma); significant kyphotic deformity or significant reversal of lordosis; or symptoms necessitating surgical treatment at more than one cervical level.

The Bryan™ Cervical Disc should only be used by surgeons who are experienced in the surgical procedure and have undergone adequate training with the device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, such as neurological complications. The safety and effectiveness of this device has not been established in patients with the following conditions: axial neck pain as solitary symptom; not skeletally mature; prior cervical spine surgery, including prior surgery at the index level; facet joint pathology of involved vertebral bodies; active malignancy; Paget’s disease, osteomalacia, or other metabolic bone disease; chronic or acute renal failure or history of renal disease; taking medications known to potentially interfere with bone/soft tissue healing (e.g. steroids); pregnant; unstable cardiac disease: diabetes mellitus requiring daily insulin management; and extreme obesity as defined by the NIH Clinical Guidelines Body Mass Index (i.e., BMI ≥40); less than 21 years of age and were not refractory to at least six weeks of unsuccessful conservative treatment or had signs of progression or spinal cord/nerve root compression with continued non-operative care. Implanted metal alloys release metallic ions into the body. The long term effect of these ions on the body is not known. Patients in the clinical study were instructed to use non-steroidal anti-inflammatory drugs (NSAIDs) for two weeks postoperatively. Dosing and frequency were left to the discretion of the physician. It has been reported in the literature that short-term postoperative use of NSAIDs may reduce the instance of heterotopic ossification.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Please see the package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information.
**BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR THE PRESTIGE™ CERVICAL DISC**

The Prestige™ Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from levels C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy.

The Prestige device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy should present with at least one of the following items producing symptomatic nerve root and/or spinal cord compression which is documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurological deficit), and radiographic studies (e.g., CT, MRI, x-rays, etc.): 1) herniated disc, and/or 2) osteophyte formation.

The Prestige™ Cervical Disc should not be implanted in patients with an active infection or with an allergy to stainless steel.

The Prestige™ Cervical Disc should only be used by surgeons who are experienced in the surgical procedure and have undergone adequate training with the device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, such as neurological complications.

The safety and effectiveness of this device has not been established in patients with the following conditions: more than one cervical level with DDD; not skeletally mature; clinically significant cervical instability; prior fusion at adjacent cervical level; severe facet joint pathology of involved vertebral bodies; prior surgery at treated level; osteopenia, osteomalacia, or osteoporosis as defined by bone mineral density T-score of -3.5, or -2.5 with vertebral crush fracture; spinal metastases; chronic or acute renal failure or history of renal disease; taking medications known to potentially interfere with bone/soft tissue healing (e.g. steroids); pregnant; cervical instability; severe insulin dependent diabetes; and were not refractory to at least six weeks of unsuccessful conservative treatment or had signs of progression or spinal cord/nerve root compression with continued non-operative care.

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Medical necessity will dictate site of service for each individual patient. Physicians should confirm inpatient or outpatient admission criteria before selecting site of service.

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