Medtronic

Billing and coding guide

Prestige LP™
Cervical Disc System

The Prestige LP™cervical disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at one or two contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and a t least one of the following conditions confirmed by imaging (CT, MRI, X-Rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. The Prestige LP™cervical disc is implanted using an anterior approach. Patients should have failed at least 6 weeks of non-operative treatment or have had the presence of progressive symptoms or signs of nerve root/spinal cord compression in the face of continued non-operative management prior to implantation of the Prestige LP™cervical disc.

Physician reimbursement

Physicians use Current Procedural Terminology (CPT®) codes to report 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.

CPT Code	Description	RVU	Medicare Payment
22856	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	49.12	$1,608.19
+22858	second level, cervical (List separately in addition to code for primary procedure)	15.11	$494.70

Source: See references

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/PCS 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. Other payers may also use DRGs or a variation on them, but many payers 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-PCS codes to report inpatient services. The following ICD-10-PCS codes may be used to report cervical disc arthroplasty procedures.

Code	Description
0RR30JZ	Replacement of cervical disc with synthetic substitute, open approach
0RP30JZ	Removal of synthetic substitute from cervical disc, open approach
0RW30JZ	Revision of synthetic substitute in cervical disc, open approach

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 and PCS codes assigned to the major diagnoses and procedures. Each MS-DRG has a flat payment rate that bundles the reimbursement for all services and devices the patient received during the inpatient stay. The following chart shows the estimated Medicare payment amounts for the MS-DRGs to which the replacement of a cervical disc procedure may group.

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

MS-DRG	Description	MDC	Relative Weight*	Medicare Payment
028	Spinal Procedures with MCC	01	6.0261	$40,317
029	Spinal Procedures with CC or Spinal Neurostimulator	01	3.4282	$23,443
030	Spinal Procedures without CC/MCC	01	2.319	$16,059
518	Back and Neck Procedures except Spinal Fusion with MCC or Disc/Device/ Neurostimulator	08	3.6518	$25,568

Under the MS-DRG system, cases may be assigned to 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. Assumes payment for a hospital with wage index and geographic adjustment factor of 1.000.

Source: See references.

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 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.

Outpatient

		Hospital		
HCPCS Code	Description	APC	Status Indicator	Medicare Payment
22856	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	5116	J1	$17,756.28
+22858	second level, cervical (List separately in addition to code for primary procedure)	N/A	N	N/A
C1889	Implantable/insertable device for device intensive procedure, nototherwise classified.	N/A	N	N/A

Source: See references.

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 APC payment)

Coverage of Cervical Disc Arthroplasty in the Hospital Outpatient Setting

As of January 1, 2017, the Medicare outpatient status indicator for the second level cervical disc arthroplasty CPT add-on code (+22858) was changed to 'N' meaning that its reimbursement is packaged into the payment for the single interspace APC rate. Prior to 2017 it was considered an inpatient procedure. Providers should contact their local Medicare Administrative Contractor for coverage information. Providers should also contact commercial payers and review their 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.

CPT	Description	Status Indicator	Medicare Payment
22856	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	J8	$13,187.97
+22858	second level, cervical (List separately in addition to code for primary procedure)	N1	N/A

Source: See references.

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.

N1 Packaged service/item; no separate payment made.

Coding and reimbursement assistance

SpineLine™

Provides coding, billing and reimbursement assistance for procedures performed using Medtronic products.

E-mail: RS.CSTreimbursementsupport@medtronic.com

Web: medtronic.com/SpineLine

References

Source: 2024 Medicare Fee Schedule, Final Rule, Federal Register. No geographic adjustments. 2/24

Important product information

Indications For Use

The Prestige LP™cervical disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at one level or two contiguous levels for intractable radiculopathy (arm pain and/ or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. The Prestige LP™cervical disc is implanted using an anterior approach. Patients should have failed at least 6 weeks of non-operative treatment or have had the presence of progressive symptoms or signs of nerve root/spinal cord compression in the face of continued non-operative management prior to implantation of the Prestige LP™cervical disc.

Contraindications

The Prestige LP™cervical disc should not be implanted in patients with the following conditions:

- Active systemic infection or localized infection at the surgical site;
- Osteoporosis or osteopenia defined as a DEXA bone mineral density T-score ≤ -1.0;
- Allergy or sensitivity to titanium, aluminum or vanadium;
- Marked cervical instability on neutral resting lateral or flexion/ extension radiographs; translation >3.5mm and/or >11° rotational difference from that of either level adjacent to the treated levels;
- Severe spondylosis at the level to be treated, characterized by bridging osteophytes, loss of disc height >50%, an absence of motion (<2°) as this may lead to a limited range of motion and may encourage bone formation (e.g. heterotopic ossification, fusion);
- Severe facet joint arthropathy;
- Significant cervical anatomical deformity or clinically compromised vertebral bodies at the affected level(s) due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion or nonunion) or disease (e.g., ankylosing spondylitis, rheumatoid arthritis); or
- Significant kyphotic deformity or significant reversal of lordosis.

Warnings

The Prestige LP™cervical disc should only be used by surgeons who are experienced with anterior cervical spinal procedures and have undergone adequate hands-on training in the use of this specific device. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the Prestige LP™cervical disc should use this device. Medtronic will offer hands-on training to physicians prior to their first use of the device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurological complications.

Correct sizing and placement of the device is essential to optimal performance. Information regarding proper implant size selection, implant site preparation, and the use of instrumentation before, during and after Prestige LP™surgery is provided in the Prestige LP™cervical disc Surgical Technique manual. Users are advised to read and understand the surgical technique manual and instructions for use prior to surgery.

Due to the proximity of vascular and neurological structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage with the use of this device. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants, or if pulsatile erosion of the vessels occurs because of close apposition of the implants. Care must be taken to identify and protect these structures.

Heterotopic Ossification (HO) is a potential complication associated with artificial cervical discs and could lead to reduced cervical motion.

Devices with metal-on-metal articulating surfaces (such as the Prestige LP Cervical Disc) may release wear debris, metallic particles or metal ions locally near the device and/or systemically. The short and long term effects of the wear debris, metallic particles and metal ions on the body are not known, but certain groups of patients may be at a higher risk including patients who are pregnant, patients who are planning to get pregnant, and patients who have renal disease.

Precautions

The safety and effectiveness of this device has not been established in patients with the following conditions:

- Axial neck pain as the solitary symptom;
- Skeletally immature patients, pediatric or adolescent children (<21 years old), or those over the age of 78;
- Prior cervical spine surgery, including prior surgery at the index level

  or adjacent levels;
- More than two cervical discs or two non-adjacent cervical discs that require surgical treatment;
- Facet joint pathology of involved vertebral bodies;
- Spinal metastases;
- An endocrine or metabolic disease that affects bones such as Paget's disease, osteomalacia, renal osteodystrophy, Ehlers-Danlos Syndrome, or osteogenesis imperfecta;
- Chronic or acute renal failure or history of renal disease;
- Taking medications known to potentially interfere with bone/soft tissue healing (e.g., steroids);
- Diabetes mellitus requiring daily insulin management;
- Serious mental illness;
- Being treated for alcohol and/or drug abuse; and
- Pregnant.

Pre-operative

Patient selection is extremely important. In selecting patients for a total disc replacement, the following factors may negatively affect the success of the procedure: the patient's occupation or activity level; prior injury or ongoing illness (e.g., Alzheimer's disease, emphysema); alcoholism or drug abuse; and certain degenerative diseases (e.g., degenerative scoliosis, ankylosing spondylitis) that may be so advanced at the time of implantation that the expected useful life of the device is substantially diminished.

In order to minimize the risk of periprosthetic vertebral fractures, surgeons must consider all co-morbidities, past and present medications, previous treatments, etc. Surgeons should screen patients to determine if a DEXA bone mineral density measurement is necessary. If DEXA is performed, the patient should not receive the Prestige LP™cervical disc (per the contraindications listed above) if the DEXA bone mineral density T-score

is ≤ -1.0, as the patient may be osteoporotic or osteopenic.
The patient should be informed of the potential adverse effects (risk/ complications) contained in this insert (see POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH).

Preoperative planning may be used to estimate the required implant size and to assure that the appropriate range of sizes is available for surgery. Specific preoperative planning is necessary when performing

a two-level procedure. The procedure should not take place if the appropriate range of sizes will not be available.

Inspect all instruments prior to surgery and replace any worn or damaged items. Instruments which have been used excessively may be more likely to break.

Intra-operative

Correct selection of the appropriate implant size is extremely important to ensure the placement and function of the disc. When performing a two-level procedure, to ensure sufficient access to the two affected disc spaces, make the skin incision centered at the middle vertebral body.

A standard incision for the exposure of two levels is required. See the surgical technique manual for step-by-step instructions on the surgical technique, including determining the correct implant size.

Use aseptic technique when removing the Prestige LP™cervical disc components from the innermost packaging. Carefully inspect each component and its packaging for any signs of damage, including damage to the sterile barrier. Do not use Prestige LP™cervical disc components if the packaging is damaged or the implant shows signs of damage.

Use care when handling a Prestige LP™cervical disc component to ensure it does not come in contact with objects that could damage the implant. Exercise care to ensure implantation instruments do not contact the highly polished articulating surfaces of the endplates.

Damaged implants are no longer functionally reliable. Visual inspection of the Prestige LP™cervical disc assembly is recommended prior to implantation. If any part of the assembly appears damaged, do not use the device.

When preparing the disc space, remove anterior or posterior osteophytes as needed, taking care to perform a complete discectomy while minimizing bone removal, as excessive bone removal may weaken the vertebral endplates or vertebral body.

Correct positioning of the rail punch is critical prior to performing the rail preparation step. Care should be taken to correctly position the rail punch during this step.

Ensure proper alignment and placement of the Prestige LP™cervical disc as misalignment may cause excessive wear and/or early failure of the device.

In a two-level procedure, when placing the first implant, pay special attention to implant height selection. The goal is to balance the discs to achieve normal sagittal balance and disc space height. Before placing the first implant, it is important to verify normal sagittal balance and disc space height by using the Implant Trials. Achieve this by preoperative templating, careful trialing under lateral fluoroscopy, and comparing the facet and intradiscal heights in healthy adjacent levels. Implant Trials should fit snugly without distracting the disc spaces.

The Prestige LP™cervical disc components should not be used with components or instruments of spinal systems from other manufacturers. See the surgical technique manual for step-by-step instructions.

The Prestige LP™cervical disc implants are designed for single patient use only. Do not re-use, re-process, or re-sterilize the implants. Even if the device appears undamaged, re-use, re-processing, or re-sterilization may compromise the structural integrity of the implant and the intended function of the device which could result in patient injury.

Post-operative

Patients in the clinical study of the Prestige LP™cervical disc were instructed to use non-steroidal anti-inflammatory drugs (NSAIDs) for two weeks postoperatively. It has been reported in the literature that short- term postoperative use of NSAIDs may reduce the instance of heterotopic ossification (HO). To reduce the instance of HO, it is recommended that the Prestige LP™device be implanted in subjects able to tolerate the use of NSAIDs for two weeks post-operatively. Patients should be instructed in postoperative care procedures and should be advised of the importance of adhering to these procedures for successful treatment with the device. Patients should be advised to avoid any activities that require repeated bending or twisting, heavy lifting, and challenging activities such as athletic activities. Gradual increase in physical activity will depend on individual patient progress.

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Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

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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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