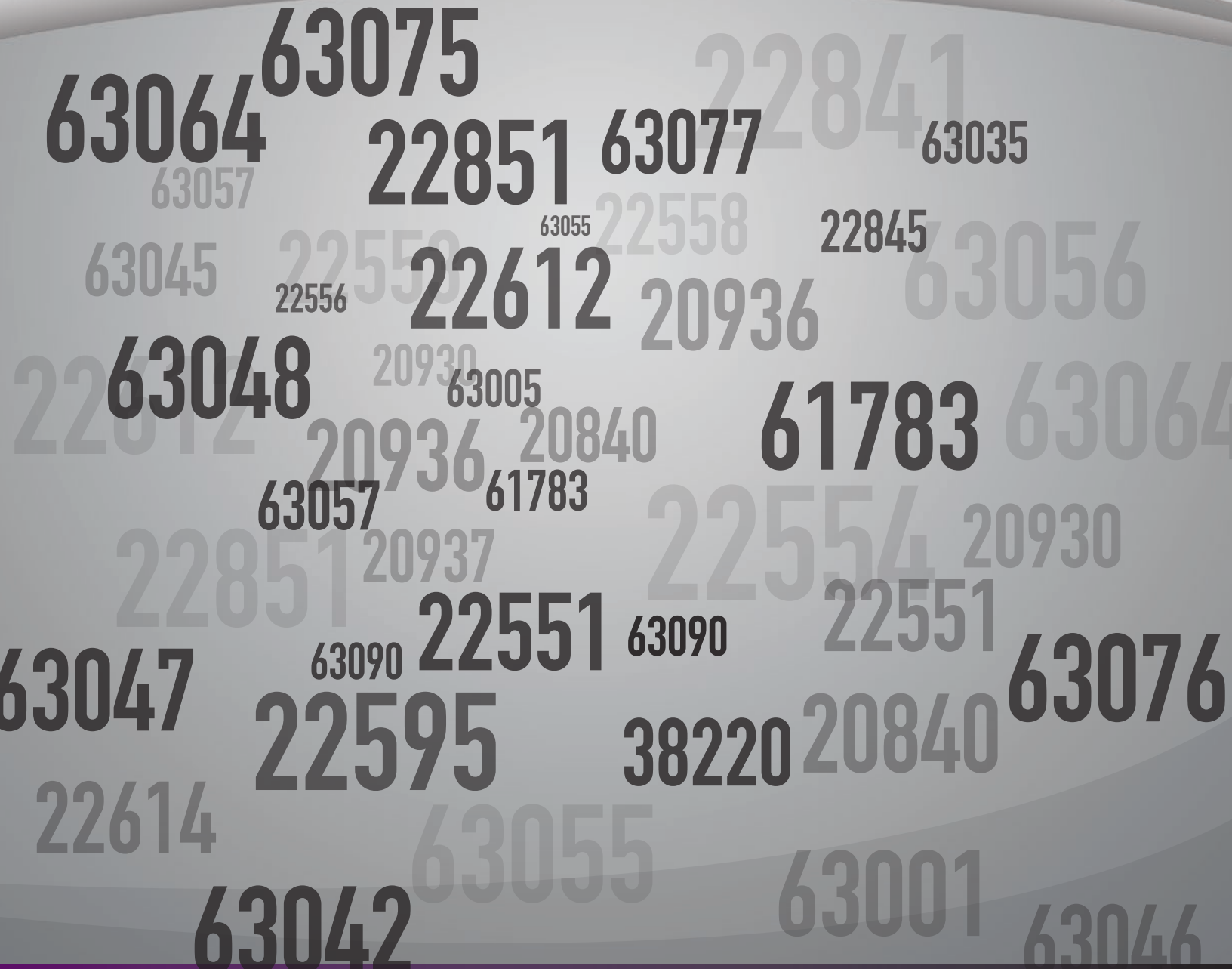


Cervical Disc Arthroplasty

2015 Reimbursement Guide

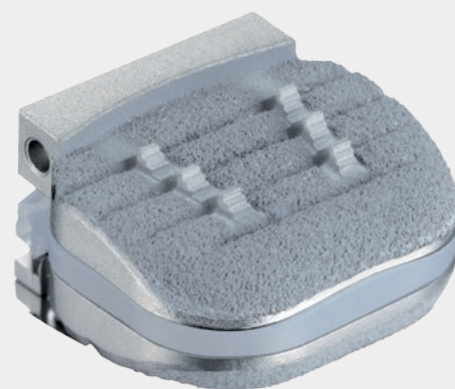


PCM® DESCRIPTION AND INDICATIONS FOR USE

The PCM Cervical Disc is a two-piece articulating device comprised of two cobalt chromium molybdenum (CoCrMo) alloy metal endplates, one cephalad and one caudal, and an ultra-high molecular weight polyethylene (UHMWPE) spacer fixed to the caudal endplate. It is indicated for use in skeletally mature patients for reconstruction of a degenerated cervical disc at one level from C3-C4 to C6-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit), with or without neck pain, or myelopathy due to a single-level abnormality localized to the disc space and manifested by at least one of the following conditions confirmed by radiographic 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 PCM Cervical Disc is implanted using an anterior approach. Patients should have failed at least six weeks of conservative treatment prior to implantation of the PCM Cervical Disc.

ESTABLISHING MEDICAL NECESSITY

Documentation is the key to providing the payor with the information necessary for making a decision whether to approve or deny cervical disc arthroplasty.



ICD-9-CM DIAGNOSIS CODES

All claim forms must include ICD-9-CM diagnosis codes to report the patient's condition. The diagnosis codes indicate why the procedure was performed. Providers should select the most appropriate ICD-9-CM diagnosis code(s) with the highest level of specificity to describe the patient's condition.

Below is a listing of diagnosis codes and definitions that may apply to patients requiring cervical disc arthroplasty using PCM®. This is a listing of possible codes that represent only typical diagnoses associated with the procedure and is not intended to be a complete list. Payor coverage restrictions may further refine this list, based upon their interpretation of medical necessity.

ICD-9-CM Code	Diagnosis Description
721.0	Cervical spondylosis without myelopathy
721.1	Cervical spondylosis with myelopathy
722.0	Displacement of cervical intervertebral disc without myelopathy
722.4	Degeneration of cervical intervertebral disc
722.71	Intervertebral cervical disc disorder with myelopathy, cervical region
722.81	Postlaminectomy syndrome, cervical region

PRIOR AUTHORIZATION

Many commercial payors require prior authorization (sometimes called pre-certification) for cervical disc arthroplasty. Medicare does not provide or require "prior authorization" for services.

The steps in the prior authorization process typically are as follows:

1. Collect Information

- Verify patient's name and address
- Collect all patient and insurance information
- Identify diagnoses and include CPT® code 22856

2. Contact Payor

- Verify existence of benefits
- Verify existence of coverage for intended procedure(s)
- Determine payor requirements for prior authorization

Verbal authorization may be given, and should be documented. However, for written authorization, the payor may require the following:

- Letter of Medical Necessity (LOMN)
- Patient records
- Explanation of the procedure
- PCM product information

3. Send Requested Information

- Submit all requested information and forward to the contact/department responsible for the prior authorization decision.

4. Follow Up

- Follow up with the carrier until a decision has been made; document all follow-up efforts and the carrier's response.

5. Appeal Denials

- If coverage is denied, determine the process for appealing the decision.

LETTER OF MEDICAL NECESSITY

It is not always necessary to submit a Letter of Medical Necessity (LOMN). However, a letter from the treating physician may help to ensure approval for cervical disc arthroplasty using the PCM® device. The LOMN should contain the following elements:

- Rationale to support why the procedure is appropriate for the patient
- Complete description of cervical disc arthroplasty
- Medical diagnosis, history, procedures, pathology, medications, and other data relevant to the patient and to the procedure
- Examples include:
 - Is skeletally mature
 - Needs disc reconstruction at one level between C3 and C7
 - Has failed at least six weeks of conservative treatment or shows signs of progressively worsening symptoms, despite treatments outside of surgery
 - Has at least one of the following:
 - Intractable radiculopathy (arm pain and/or a neurological deficit), which can have associated neck pain as well
 - Myelopathy (due to abnormality localized to the level of the disc space)
 - Has at least one of the following for each level which is being operated on, confirmed by radiographic imaging
 - Herniated nucleus pulposus (i.e., herniated disc)
 - Spondylosis (i.e., the presence of osteophytes)
- Loss of disc height (compared to neighboring levels)
- Statement of medical necessity and appropriateness of cervical disc arthroplasty
- Expected outcome
- Medical opinion of the potential outcome if the procedure is not performed

PHYSICIAN CODING AND PAYMENT

When physicians bill for services being performed, they use Common Procedural Terminology (CPT®) codes. Each CPT code has an assigned number of relative value units (RVUs) that attempt to compare the physician work, malpractice costs, and practice expenses associated with a given procedure or service to those associated with all other procedures or services. Medicare annually revises a dollar conversion factor that, when multiplied by CPT code RVUs, results in the national Medicare reimbursement for that code.

Single-level cervical disc arthroplasty procedures are currently described by CPT code 22856: Total disc arthroplasty (artificial disc), anterior approach, including discectomy with endplate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical. The scope of the code includes approach, access, site preparation, discectomy with decompression and removal of any osteophytes or other pathologic disc material, implant placement, and closure. There are additional codes for revision and removal procedures.

PHYSICIAN CODING AND PAYMENT (CONT.)

The following chart outlines the 2015 CMS Physician Fee Schedule for the relevant CPT[®] codes:

CPT Code	Diagnosis Description	2015 Medicare Payment Rate
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with endplate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection), single interspace; cervical	\$1,661.16
22861	Revision, including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	\$1,999.76
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	\$2,202.49

HOSPITAL INPATIENT CODING AND PAYMENT

Medicare inpatient hospital payment is based on a classification system determined by the patient's diagnosis and procedure(s) performed. Under Medicare Severity – Diagnosis Related Groups (MS-DRGs), Medicare pays a fixed amount for hospital services regardless of the actual cost the hospital incurs when providing the services. Only one MS-DRG is assigned to a patient for a particular hospital admission.

CMS has assigned distinct ICD-9-CM procedure codes to cervical disc arthroplasty primary and revision procedures:

84.62	Insertion of total spinal disc prosthesis; cervical
84.66	Revision, including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical

For 2015, these procedure codes map to MS-DRG 518: Back and Neck Procedures Except Spinal Fusion with MCC or Disc Device/Neurostimulator. FY2015 unadjusted Medicare payment for this MS-DRG is \$17,987.55.

HOSPITAL OUTPATIENT AND AMBULATORY SURGERY CENTER CODING AND PAYMENT

Physician coding drives hospital outpatient and ambulatory surgery center procedure coding. For Medicare, the CPT code billed by the physician is assigned to a correlating hospital outpatient Ambulatory Payment Classification (APC) code. As of January 1, 2013, Medicare covers cervical disc arthroplasty (22856) in the outpatient setting. Medicare 2015 hospital outpatient payment is the following: APC 0425 with a payment of \$10,220.00. For Medicare, this payment is inclusive of the PCM[®] implant.

However, some commercial payor contracts allow for implant carve-outs, which would allow the hospital to receive payment outside the global procedure rate for the PCM implant and are payor and contract specific. Regardless, hospitals will report the implant under Revenue Code 0278: Other Implants.

PAYOR COVERAGE

The payor coverage landscape for cervical artificial disc replacement (CAD) is a fluid and increasingly positive one. Medicare does not have a national coverage decision. Therefore, coverage is determined by the local Medicare Administrative Contractors (MACs). Most MACs are silent regarding cervical disc arthroplasty. However, it is always wise to research the current MACs' coverage position, as it may change at any time.

Aetna, Cigna, and UnitedHealthcare, as well as many BlueCross BlueShield plans, provide cervical disc arthroplasty coverage. It is always wise to be familiar with the coverage requirements and restrictions for the relevant contracted payors.

For your reference, the current cervical disc arthroplasty-PCM® coverage requirements for various large, national commercial payors include the following (subject to change when updated by the payors):

Aetna (effective February 2015)

- Aetna considers FDA-approved prosthetic intervertebral discs (e.g., MOBI-C®, Secure®-C Artificial Cervical Disc, the Prestige® Cervical Disc, ProDisc-C™ Total Disc Replacement, Bryan® Cervical Disc) medically necessary for the treatment of skeletally mature persons with symptomatic (e.g., radicular neck and/or arm pain and/or functional/neurological deficit) cervical degenerative disc disease or herniated disc at one level from C3 to C7, confirmed by radiographic studies (e.g., CT, MRI, x-rays), and who have failed at least 6 weeks of conservative management.
- Aetna considers lumbar prosthetic intervertebral discs (e.g., the Charite™ Artificial Disc, and the ProDisc-L Total Disc Replacement) experimental and investigational for lumbosacral degenerative disc disease and for all other indications.
- Aetna considers prosthetic intervertebral discs experimental and investigational for persons who have degenerative disk disease at more than one level.
- Aetna considers lumbar partial disc prosthetics (e.g., Nubac™, DASCOR® Disc Arthroplasty System) experimental and investigational because of insufficient evidence of their effectiveness.
- Aetna considers concurrent or planned sequential artificial cervical disc replacement with cervical spinal fusion experimental and investigational for the management of neck pain, spinal disorders, and all other indications.

Cigna (effective January 2015)

Cigna covers surgical implantation of FDA-approved cervical intervertebral disc (IVD) prosthesis for degenerative cervical disc disease with intractable radiculopathy and/or myelopathy as medically necessary in a skeletally mature individual when ALL of the following criteria are met:

- Unrelenting neck and arm pain, resulting in disability and/or neurological deficit that are refractory to at least six weeks of standard medical and surgical management (e.g., reduced activities, exercise, analgesics, physical therapy).
- Single-level disc degeneration has been confirmed on complex imaging studies (i.e., computerized tomography [CT] scan, magnetic resonance imaging [MRI]).
- The planned implant will be used in the reconstruction of a cervical disc at C3-C7, following single-level discectomy.
- The individual is a candidate for single-level anterior cervical decompression and interbody fusion.

References:

2015 CMS Physician Fee Schedule
2015 CMS OPPS Final Rule
FY2015 CMS IPPS Final Rule

QUESTIONS? CONTACT NUVASIVE® SPINE REIMBURSEMENT SUPPORT BY CALLING 800-211-0713 OR EMAILING reimbursement@nuvasive.com. THE INFORMATION PROVIDED IS GENERAL CODING INFORMATION ONLY; IT IS NOT ADVICE ABOUT HOW TO CODE, COMPLETE, OR SUBMIT ANY PARTICULAR CLAIM FOR PAYMENT. IT IS ALWAYS THE PROVIDER'S RESPONSIBILITY TO DETERMINE AND SUBMIT APPROPRIATE CODES, CHARGES, MODIFIERS, AND BILLS FOR THE SERVICES THAT WERE RENDERED. PAYORS OR THEIR LOCAL BRANCHES MAY HAVE THEIR OWN CODING AND REIMBURSEMENT REQUIREMENTS. BEFORE RENDERING IOM SERVICES, PROVIDERS SHOULD OBTAIN PREAUTHORIZATION FROM THE PAYOR.

PAYOR COVERAGE (CONT.)

Cigna does not cover the surgical implantation of a cervical intervertebral disc (IVD) prosthesis for ANY other indication, including the following because each is considered experimental, investigational or unproven:

- The planned procedure includes the combined use of a prosthesis and spinal fusion (i.e., hybrid surgery)
 - Simultaneous multilevel implantation is planned
 - The individual had prior fusion at an adjacent cervical level
 - The individual had prior surgery at the treated level
 - Osteopenia, osteomalacia, or osteoporosis (T-score of -3.5, or -2.5, with vertebral crush fracture)
 - Neck or arm pain of unknown etiology
 - Absence of neck and/or arm pain
 - Progressive neurological deficit or deterioration
 - Infection, systemic or local
 - Rheumatoid arthritis or other autoimmune disease
 - Paget's disease, osteomalacia, or any other metabolic bone disease
 - There is radiological evidence of ANY of the following:
 - Clinically significant cervical instability, such as kyphotic deformity or spondylolisthesis (e.g., > 3.5 mm subluxation or > 11 degrees angulation)
 - 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)
 - Multilevel degenerative disc
 - Spinal metastases
 - Non FDA-approved cervical disc prosthesis
- Page 3 of 36 Coverage Policy Number: 0104

UnitedHealthcare (effective February 2015)

Cervical artificial total disc replacement of FDA-approved prosthesis for degenerative cervical disc disease with symptomatic intractable radiculopathy and/or myelopathy is proven and medically necessary in a skeletally mature individual when at least one of the following criteria are met:

- Herniated disc
- Osteophyte formation

And both of the following:

- Documented patient history of neck and/or arm pain and/or a functional/neurological deficit associated with the cervical level to be treated
- Failed at least six weeks of non-operative treatment prior to implantation (only applicable for elective surgery; emergent surgery, or does not require prior non-operative treatment)

Cervical artificial disc replacement is proven and medically necessary for treatment of persons with symptoms of degenerative disc disease at one level even if they have radiological evidence of degenerative disc disease at multiple levels. Radiologic evidence of degenerative disc disease is common in persons who are middle aged and older and does not necessarily correlate with clinical symptoms.

Cervical artificial total disc replacement is proven and medically necessary for the treatment of symptomatic contiguous two level degenerative disc disease in skeletally mature patients when used according to U.S. Food and Drug Administration (FDA) labeled indications. (Note: not all cervical artificial discs have FDA labeling for contiguous two level degenerative disc disease. Only cervical artificial discs FDA labeled for contiguous two level disease are proven and medically necessary for this indication. Refer to the FDA Section below.)

PAYOR COVERAGE (CONT.)

Cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent) performed at the same surgical setting is unproven and not medically necessary. This is commonly referred to as a hybrid surgery.

There is insufficient published clinical evidence in peer-reviewed medical literature demonstrating the safety and efficacy of combination cervical spine surgery at multiple adjacent or non-adjacent levels.

Humana (effective January 2015)

Humana members may be eligible under the Plan for cervical artificial intervertebral disc replacement when ALL of the following criteria are met:

- DDD or herniated disc at ONE level from C3 to C7 confirmed by a complex imaging study (e.g., CT, MRI); AND
- Documentation of skeletal maturity; AND
- Failure of conservative treatment (e.g., analgesics, physical therapy); AND
- FDA approved implant to be utilized in accordance with FDA labeling and will be implanted via an anterior approach; AND
- Functional neurological deficit (e.g., neuromuscular weakness, sensory deficit); OR
- Intractable neck and radicular arm pain

Coverage Limitations

Humana members may NOT be eligible under the Plan for cervical artificial intervertebral disc replacement for any indications other than those listed above including, but may not be limited to:


- Multilevel cervical disc replacement; OR
- Partial cervical disc replacement; OR
- Planned procedure including a combined use of a cervical artificial intervertebral disc replacement and spinal fusion; OR
- Prior fusion at an adjacent cervical level; OR
- Prior surgery at the treated level



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