2024 Comprehensive Reimbursement Resource Guide

Prepared by Musculoskeletal Clinical Regulatory Advisers, LLC. Version November 2023.

prodisc® CERVICAL

Portfolio of Cervical Total Disc Replacement (TDR) Devices

(prodisc C, prodisc C Vivo, prodisc C SK, prodisc C Nova)

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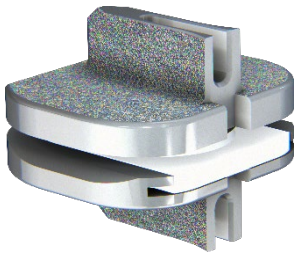
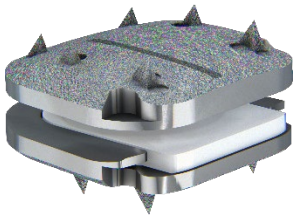
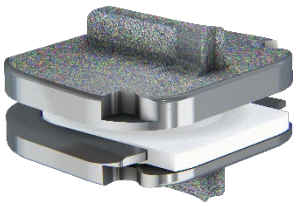
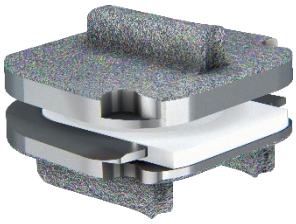
Reimbursement Disclaimer: This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of November 2023 and is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third-party payers is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. When making coding decisions, we encourage you to seek input from the American Medical Association (AMA), relevant medical societies, Centers for Medicare & Medicaid Services (CMS), your local Medicare Administrative Contractor, (MAC) and other health plans to which you submit claims. Items and services that are billed to payers must be medically necessary and supported by appropriate documentation. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payers. The decision as to how to complete a reimbursement form, including the amount to bill, is exclusively the responsibility of the provider.

PRODUCT TECHNOLOGY OVERVIEW

TECHNOLOGY DESCRIPTION

The pro**disc** Cervical Portfolio Total Disc Replacement devices include four FDA approved devices:

pro**disc** C	pro**disc** C Vivo	pro**disc** C SK	pro**disc** C Nova
			

All four devices in the pro**disc** Cervical Portfolio are composed of three components – two cobalt chrome alloy (CoCrMo) endplates and an ultra-high molecular weight polyethylene (UHMWPE) inlay.

FDA INFORMATION ON PRODISC CERVICAL PORTFOLIO FOR 1 LEVEL

The FDA Pre-Market Approved (PMA) the pro**disc** C for 1 level indication on December 17, 2007. (P070001)[i]

The FDA Pre-Market Approved (PMA) the pro**disc** C SK, pro**disc** C Nova, and pro**disc** C Vivo for 1 level indication on July 7, 2022. (P070001/S019)[ii]

INDICATIONS FOR USE

The pro**disc** Cervical Total Disc Replacement Portfolio (pro**disc** C, pro**disc** C SK, pro**disc** C Nova, and pro**disc** C Vivo) devices are indicated in skeletally mature patients for reconstruction of a single disc from C3–C7 following discectomy for intractable symptomatic cervical disc disease (SCDD). Symptomatic cervical disc disease is defined as neck or arm (radicular) pain and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or x-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or loss of disc height. The pro**disc** Cervical Portfolio Total Disc Replacement device is implanted via an open anterior approach. Patients receiving the pro**disc** Cervical Portfolio Total Disc Replacement device should have failed at least six weeks of nonoperative treatment prior to implantation of the pro**disc** Cervical Portfolio Total Disc Replacement device.

CONTRAINDICATIONS

- Active systemic infection or infection localized to the site of implantation
- Osteoporosis defined as DEXA bone density measured T-score ≤ -2.5
- Marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation > 3 mm and/or > 11° of rotational difference to either adjacent level
- Allergy or sensitivity to the implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)
- 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 (e.g., heterotopic ossification, fusion
- Clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion, or nonunion)
- Patients with SCDD at more than one level
- Fractures, infections, tumours
- Spinal stenosis by hypertrophic spondylarthrosis
- Facet joint degeneration
- Increased segmental instability
- Ossification of posterior longitudinal ligament (OPLL)
- Advanced cervical anatomical deformity (e.g., ankylosing spondylitis, scoliosis) at the operative or adjacent levels
- Osteopenia
- Advanced cervical degenerative facet joint changes, and
- Cervical spine mal-alignment conditions (e.g. scoliosis or kyphosis.)
- Osteoporosis, Osteochondrosis, and severe Osteopenia
- Acute or chronic systemic, spinal, or localized infections
- Systemic and metabolic diseases
- Any medical and surgical conditions precluding the benefits of spinal surgery
- Foreign body sensitivity to the implant materials
- Dependency on pharmaceutical drugs, drug abuse or alcoholism
- Pregnancy
- Severe obesity (Body Mass Index above 40)
- Lack of patient cooperation

DEVICE &/OR IMPLANT PROCEDURE

The diseased disc is removed, and the area is shaped to allow the device to fit in snugly. The prodisc® C artificial disc system is inserted in the space that is created. The disc is fitted to the vertebra above and below, and the device can now move similar to the neck's natural motion. Once the device is in place, the incision is closed, and the patient is discharged after a period of observation. Each of artificial total disc replacements in the prodisc® C portfolio of devices has its own unique endplate design and fixation method.

MEDICARE COVERAGE DETERMINATIONS (NCD/LCD)

Currently, there is a National Coverage Determination (NCD) related to the pro**disc** Cervical Portfolio of devices that does not cover over 60 years of age. Check with your local Medicare Administrative Contractor (MAC) regarding any Local Coverage Determinations (LCDs) related to the prodisc Cervical Portfolio of devices. Medicare may cover the prodisc Cervical Portfolio of devices on a case-by-case basis, with evidence of medical necessity. While traditional Medicare does not require or allow prior authorization or prior approval for procedures, Medicare Advantage plans are managed by commercial payers who may require prior authorization

for Medicare Advantage patients. Check with your plan administrator for any prior authorization requirements.

PRIVATE PAYER COVERAGE DETERMINATIONS

Commercial insurance coverage policies vary, and many require prior authorization for any procedure. We encourage health care professionals (HCPs) to contact payer(s) directly with questions regarding coverage policies or guidelines for the prodisc Cervical Portfolio of devices.

MEDICARE PHYSICIAN CODING AND 2024 MEDICARE PAYMENT

CPT CODE[iii]	DESCRIPTION	2024 RVUs	2024 MEDICARE NATIONAL AVERAGE PHYSICIAN PAYMENT[iv]
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	$1,608.40
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	70.49	$2,308.14
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	62.98	$2,062.23

MEDICARE BILLING AND PAYMENT

For hospital inpatient and outpatient procedures, device category HCPCS codes (i.e. C-codes) for implantable devices, along with the associated charge for the device may be reported. Complete and accurate reporting of implantable devices and the associated HCPCS codes assures accurate payment and provides necessary data for the reimbursement system.

MEDICARE HOPSITAL OUTPATIENT/ASC CODING AND 2024 MEDICARE PAYMENT

CPT CODE	DESCRIPTION	SI	APC	2024 MEDICARE NATIONAL AVERAGE PAYMENT HOPD[v]	SI	PI	2024 MEDICARE NATIONAL AVERAGE PAYMENT ASC[vi]
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	JI	J8	$17,774.76	N/A	N/A	$13,197.03
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	N/A	N/A	Not allowed in the HOPD Setting of care	N/A	N/A	Not allowed in the ASC Setting of care

				for Medicare			for Medicare
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	N/A	N/A	Not allowed in the HOPD Setting of care for Medicare	N/A	N/A	Not allowed in the ASC Setting of care for Medicare

Private Payers may allow for this procedure to be done in the HOPD/ASC settings of care

HOSPITAL INPATIENT CODING AND 2024 MEDICARE PAYMENT

The ICD-PCS (procedure) code and possible MS-DRG assignments are provided below along with the 2024 Medicare national average payment rates.

CLINICAL DIAGNOSIS NAME	ICD-10-CM CODE	ICD-10-PCS CODE	MS-DRG[vii]	ICD-10-PCS Code DESCRIPTION	2024 MEDICARE PAYMENT
Total Disc Arthroplasty	M25.78 M47.22 M47.892 M50.10	0RR30JZ Cervical 0RR50JZ Cervical	518	Back and Neck procedures Except Spinal Fusion with MCC or Disc Device/Neurostimulator	$25,568
Revision	M96.69 T84.216A T84.226A T84.296A T84.418A T84.428A T84.498A	0RW30JZ Cervical 0RW50JZ Cervicothoracic			
Removal	M96.69 T84.216A T84.226A T84.296A T84.418A T84.428A T84.498A	0RP30JZ Cervical 0RP50JZ Cervicothoracic	497	Local Excision and Removal Internal Fixation Devices Except Hip and Femur without CC/MCC	$9,994

HCPCS CODES

HCPCS Code(s)[viii]	HCPCS Code Description
C1889	Implantable/insertable device, not otherwise classified

POSSIBLE ICD-10-CM (DIAGNOSIS) CODES (This is not a complete list)

M25.78	Osteophyte, vertebrae
M47.22	Other spondylosis with radiculopathy, cervical region
M47.892	Other spondylosis, cervical region
M50.10	Cervical disc disorder with radiculopathy, unspecified cervical region

ICD-10-CM CODES FOR REMOVAL & REPLACEMENT/REVISION

M96.69	Fracture of other bone following insertion of orthopedic implant, joint prosthesis, or bone plate
T84.216A	Breakdown (mechanical) of internal fixation device of vertebrae, initial encounter
T84.226A	Displacement of internal fixation device of vertebrae, initial encounter
T84.296A	Other mechanical complication of internal fixation device of vertebrae, initial encounter
T84.418A	Breakdown (mechanical) of other internal orthopedic devices, implants, and grafts, initial encounter
T84.428A	Displacement of other internal orthopedic devices, implants and grafts, initial encounter
T84.498A	Other mechanical complication of other internal orthopedic devices, implants, and grafts, initial encounter
T84.63XA	Infection and inflammatory reaction due to internal fixation device of spine, initial encounter
T84.7XXA	Infection and inflammatory reaction due to other internal orthopedic prosthetic devices, implants and grafts, initial encounter
T84.81XA	Embolism due to internal orthopedic prosthetic devices, implants and grafts, initial encounter
T84.82XA	Fibrosis due to internal orthopedic prosthetic devices, implants and grafts, initial encounter
T84.83XA	Hemorrhage due to internal orthopedic prosthetic devices, implants and grafts, initial encounter
T84.84XA	Pain due to internal orthopedic prosthetic devices, implants and grafts, initial encounter
T84.85XA	Stenosis due to internal orthopedic prosthetic devices, implants and grafts, initial encounter
T84.86XA	Thrombosis due to internal orthopedic prosthetic devices, implants and grafts, initial encounter
T84.89XA	Other specified complication of internal orthopedic prosthetic devices, implants, and grafts, initial encounter
T84.9XXA	Unspecified complication of internal orthopedic prosthetic device, implant, and graft, initial encounter
Z47.2	Encounter for removal of internal fixation device

REFERENCES

[i] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P070001

[ii] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P070001S019

[iii] CPT 2023 Professional Edition, ©2022 American Medical Association (AMA); CPT is a trademark of the AMA.

[iv] https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1770-f

[v] https://www.cms.gov/files/document/cy2023-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-final-rule.pdf Addenda A&B

[vi] https://www.cms.gov/license/ama?file=/files/zip/2023-nfrm-addendum-aa-bb-dd1-dd2-ee-and-ff.zip ASC Addendum AA, BB, DD1, DD2, EE, and FF

[vii] https://www.cms.gov/files/zip/fy2023-ipps-fr-impact-file.zip Table 5 MS-DRGs, Relative Weighting Factors and Geometric and Arithmetic Mean Length of Stay 2023 MS- DRG IPPS Final Rule CMS-1771-F

[viii] https://www.cms.gov/medicare/coding/hcpcsreleasecodesets/hcpcs-quarterly-update