KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Artificial Spinal Discs for Lumbar or Cervical Disc Disease

- Bryan™
- Charité™
- Prestige™ Artificial Discs
- ProDisc-C™
- ProDisc-L™
- Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Lumbar Artificial Disc Replacement (LADR) (150.10) Per NCD - this service is not covered for Medicare beneficiaries over 60 years of age. For beneficiaries under 60 years of age, please see the Kaiser Permanente Medical Policy below.
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance for lumbar artificial disc replacement **for Medicare members under 60 years of age** or for cervical artificial disc replacement, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Artificial Spinal Discs for Lumbar or Cervical Disc Disease"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

I. Artificial cervical discs may be considered medically necessary for the following:
   A. For treatment in adults with symptomatic cervical degenerative disc disease when **ALL** of the following are met:
      1. FDA-approved prosthetic intervertebral discs are used;
      2. Performed at one level or two contiguous levels from C3-C7;
      3. Objective evidence in the clinical record documents cervical radiculopathy and/or myelopathy; and
      4. Patients have failed at least six weeks of conservative management (which may include rest, application of heat/ice, physical therapy, exercise, pain and/or anti-inflammatory medications).
   B. A subsequent, second-level, anterior total cervical disc replacement using an artificial intervertebral disc following complete decompression may be considered medically necessary in skeletally mature patients with symptomatic cervical disc degeneration when **ALL** of the following are met:
      1. The planned subsequent procedure is at a different cervical level then the initial cervical artificial disc replacement; and
      2. Clinical documentation that the initial cervical artificial disc replacement is fully healed; and
      3. Criteria A, 1-4 are met

Back to Top

II. Prosthetic intervertebral discs are considered investigational for **ALL** of the following:
- In patients with isolated axial neck pain without cervical radiculopathy or myelopathy;
- When requested adjacent to a prior fusion; or
- At a level of prior surgery
- When more than two levels are requested

III. Lumbar Disc Disease

Effective until October 1, 2025	Effective October 1, 2025
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.	Medical necessity review criteria as well as review for Level of Care **Artificial Spinal Discs for Lumbar Disc Disease** III. **Single Level Artificial Lumbar Discs for Degenerative Disc Disease** Lumbar artificial disc replacement is indicated for patients with discogenic low back pain who meet **ALL** of the following criteria: 1. Pain attributable to 1 disc disruption involving L3-4, L4-5, or L5-S1 segments 2. Confirmation of pathology at one of the above lumbar disc levels by advanced imaging (MRI) and without severe degenerative changes at adjacent levels 3. Primary complaint of axial pain that was unresponsive or incompletely resolved with a facet block 4. Presence of symptoms for 6 months or longer, that are not responsive to physician-supervised conservative medical management** over that period Lumbar disc arthroplasty is **NOT** indicated in **ANY** of the following scenarios: 1. Any case that does not fulfill ALL of the above criteria. 2. Presence of symptomatic degenerative disc disease **at more than ONE level** 3. Significant facet arthropathy at the index level or signs that the source of pain is primarily facet mediated 4. Presence of spinal instability with spondylolisthesis greater than Grade I 5. Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms, extending over a period of at least one year) 6. Osteopenia as evidenced by a DEXA bone mineral density T-score less than or equal to -1.0 7. Poorly managed psychiatric disorder (any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized before surgical intervention) 8. Age greater than 60 years or less than 18 years 9. Presence of infection or tumor **Lumbar disc arthroplasty removal and/or revisions** Will consider removals and revisions on a case-by-case basis after reviewing medical documentation. **IV. Artificial Lumbar Discs are considered experimental and investigational for all other indications including but not limited to disc implantation at more than one level.** ****Physician-supervised conservative medical management** defined as:

Back to Top

	Patients must have **three months** of non-operative treatment as demonstrated by a trial of one or more of the following medications:
	• Non-steroidal anti-inflammatory drugs (oral or topical)
	• Acetaminophen
	• Epidural steroid injection of corticosteroids as appropriate
	AND
	• A trial of **ALL** of the following physical measures:
	  ○ Supervised Physical therapy, attendance at >75% of sessions, minimum of 3 visits
	  ○ Flexibility and muscle strengthening exercises
	  ○ Reasonable restriction of activities
	  ○ If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable.
	  ○ Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present

If requesting this service, please send the following documentation to support medical necessity:

- Specific procedures requested with related procedure/diagnosis codes and identification of disc level(s) for surgery and device to be implanted
- Clinical notes from requesting provider &/or specialist that include a current history and physical exam
- Detailed documentation of extent and response to non-operative conservative therapy or procedural interventions
- Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Degeneration of the intervertebral disc, also known as degenerative disc disease (DDD) is the leading cause of pain and disability among adults in the United States as well as other parts of the world. Disc degeneration can occur at any level of the spine but is most common in the lower neck (cervical disc disease) and in the low back (lumbar disc degeneration). DDD may cause pain in the affected area and may also radiate along the nerves emerging from the spinal canal at that level.

Most DDDs can be treated nonoperatively to relieve the pain. Conservative treatments include physical therapy, nonsteroidal anti-inflammatory medications, and analgesics. Acupuncture, spinal manipulations, axial traction, and muscle relaxants are other alternative therapies that may be used to alleviate the pain and discomfort. A number of patients may not benefit from the non-invasive therapy and resort to surgical treatment. Spinal interbody fusion, a procedure that involves the fusion of two or more vertebrae to eliminate the pain caused by their abnormal motion, has been the surgical standard of care for lumbar DDD for decades. Anterior cervical discectomy combined with fusion (ACDF) is also a well-established treatment for cervical degenerative disc disorders. Interbody fusion reduces the pain caused by the treated segment, however the rigid fusion also leads to a reduction in normal spine motion, and an increase in the biomechanical stress at spinal levels adjacent to the fusion, which in turn accelerates degenerative changes of the discs at these levels (Lee 2004, Mobbs et al, 2007, Sasso 2008, Yang 2008, Heidecke 2008).

Recently arthroplasty performed with artificial discs have emerged as a surgical alternative to interbody fusion. The technology is rapidly developing and offers the promise to restore the normal spinal movement without the kinematic and biochemical issues of fusion. Potential benefits of disc arthroplasty include maintenance of a range of motion, avoidance of adjacent segment degeneration, restoring disc height, correcting spinal misalignment, greater maintenance of maneuverability, and earlier return to previous level of function. On the other hand, potential disadvantages of the artificial disc may include implant migration and material wear (Yang 2008, Burkus 2010, Cepoiu-Martin 2011).

Back to Top

The Charité, the first artificial intervertebral disc used, was developed Germany in the 1950s, but was not commercially available until 1987 after undergoing major design modifications. The third generation Charité (DePuy Spine) consists of two chromium alloy endplates and a sliding ultra-high molecular weight polyethylene core. The ProDisc-L (Synthes Spine, West Chester, PA) is another disc implant, also developed in Europe, for disc replacement at one level from L3-S1. It has a ball and socket design and is composed of three components; two metal endplates and a plastic inlay. More recently researchers developed artificial disc devices to replace cervical intervertebral discs. These include ProDisc-C (Synthes Spine, West Chester, PA), Bryan Cervical Disc (Medtronic Sofamor Danek, Memphis, TN), and Prestige Cervical Disc (Medtronic Sofamor Danek). ProDisc-C has a similar design to the ProDisc-L, Bryan disc prosthesis has two metal endplates and a polyethylene core, and PRESTIGE has two main pieces of stainless steel that articulate against one another with a ball and trough.

The Prestige ST, ProDisc-C and Bryan artificial disc systems have received US Food and Drug Administration (FDA) premarket application approval as Class III devices in July 2007, December 2007, and May 2009 respectively. FDA clearing of the artificial disc systems required post-approval studies to evaluate the long-term safety and effectiveness of the devices. The post-approval studies are expected to demonstrate 3, 5, 7, and 10-year data for cervical discs.

Lumbar

The Charité ® (DePuy) and ProDisc®-L (Synthes Spine) have received approval from the US Food and Drug Administration. The approval was contingent on completion of post-marketing studies to evaluate the longer-term safety and effectiveness of the devices. The post-approval studies are expected to demonstrate the 5-year data for lumbar discs. The Charité ® and ProDisc®-L devices are indicated for:

1. Spinal arthroplasty in skeletally mature patients, with pain from degenerative disc disease (DDD).
2. One level of the spine (L3-S1 for the ProDisc-L, L4-S1 for the Charité).
3. Patient may have no more than a grade 1 spondylolisthesis.
4. Patients must have failed to find pain relief after at least 6 months of non-surgical therapies.

Contraindications to total lumbar disc replacement include active infection, allergy to any of the device materials, osteoporosis, marked cervical instability, severe spondylosis, clinically compromised vertebral bodies at the level to be treated, and DDD at more than one level.

Several other contraindications are listed for each of the disc systems. Multilevel total disc replacement and disc replacement with prior spinal fusion are considered off-label uses.

Cervical

The cervical artificial discs are FDA approved for the following:

1. Reconstruction of cervical disc from C3-C7 following single-level discectomy for intractable.
2. Symptomatic cervical disc disease confirmed by imaging.
3. Patient is skeletally mature.
4. Cervical disc disease should have failed at least six weeks of non-operative treatment prior to implantation.

Contraindications to total cervical disc replacement include systemic infection, infection at the operating site, allergy to any of the device materials, osteoporosis, marked cervical instability, severe spondylosis, clinically compromised vertebral bodies at the level to be treated, and symptomatic cervical disc disease (SCDD) at more than one level.

Several other contraindications are listed for each of the disc systems. Multilevel total disc replacement and disc replacement with prior spinal fusion are considered off-label uses.

Medical Technology Assessment Committee (MTAC)

Artificial Disc in the Treatment of Back Pain

02/07/2005: MTAC REVIEW

Evidence Conclusion: The trial reviewed on Charité artificial spinal disc was randomized, controlled, and multicenter, but had some limitations. Authors concluded that the clinical outcomes and incidence if major neurological complications at 2 years of follow-up were equivalent to those of BAK fusion. The trial, however, was not designed as an equivalence study. Equivalence trials are planned and analyzed differently from superiority studies, and generally require larger sample sizes. Lack of significant superiority is not necessarily the same as

 Back to Top

equivalence, and the absence of statistical significance may be due to insufficient power to detect differences between the study groups. The comparison group in this trial was the BAK fusion technique, which was the preferred fusion procedure at the time, but might not be the current up-to-date procedure. Moreover, the 24-months follow-up period might not sufficient to determine the long-term safety and effectiveness of the implant as well as its impact on other discs and on the bony structures on the back of the spine.

Articles: The search yielded 56 articles. The majority were review articles, or reports that dealt with the design, technical aspects and/or evolution of the technology. The search revealed four articles published by the same group of authors reporting on the Charité artificial disc evaluated in a multicenter RCT in the US. The article that reported the results of the trial in all centers was selected for critical appraisal.

The search also revealed a report on the early 6 months results for the first 53 patients randomized in an ongoing multicenter RCT of ProDisc in the United States. The system is not currently FDA approved.

Geisler FH, Blumenthal SL, Guyer RD, et al. Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: Results of a multicenter, prospective, randomized investigational device exemption study of Charité intervertebral disc. *L Neurosurg (Spine 2)2004;1:143-154.* See Evidence Table.

The use of artificial disc in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain

10/04/2006: MTAC REVIEW

Evidence Conclusion: There is insufficient evidence that artificial discs approved by the FDA or pending approval are effective, particularly in the long-term. There is only one completed RCT and this is on the Charité device. There are no completed published RCTs on the Prestige or ProDisc devices. The Charité RCT may not have used appropriate equivalence trial methods, including failure to compare the new device to an intervention with proven effectiveness. The safety of the artificial discs after a minimum of 2 years appears similar to that of surgical fusion. Authors of the Charité had financial links to the manufacturer, which could introduce bias.

Articles: An April 2005 Blue Cross BlueShield TEC report was identified. In their literature search, they found one completed RCT, the same study included in the first MTAC review. There was also a systematic review (Freeman & Davenport, 2006) that searched the literature through April 2006 and also identified the same single completed RCT. *Literature on individual devices identified through Medline search:*

Charité device: Several additional publications on the RCT previously reviewed by MTAC (Geisler et al., 2004) were identified: Blumenthal et al. (2005) reported updated data on primary outcomes (more patients had reached 24-month follow-up). McAfee et al. (2005) reported on radiographic outcomes e.g. restoration of disc height. Regan et al. (2006) examined outcomes in the treatment group according to centers' surgical volume. McAfee et al. (2006) reported on the re-operation rate of patients in the RCT as well as other patients, for a total sample size of 688. The updated study on the primary outcomes (Blumenthal et al., 2005) and the study on re-operation rates (McAfee et al., 2006) were critically appraised. The other publications were not evaluated further because they do not add substantially to our ability to evaluate the long-term safety and efficacy of the Charité device. ProDisc device: The RCT identified in the previous MTAC search comparing ProDisc to surgical fusion is still ongoing. The study is taking place at 19 centers and has an enrollment goal of 500 patients. At the time of the first MTAC review, an article reporting initial findings for 53 patients at one center was identified. A 2005 article was identified that reported additional preliminary findings from the same center, this time for 78 patients. This study was not critically appraised because results from all centers are not yet available. Prestige device (not included in 2005 MTAC review): There was a 2004 publication reporting on preliminary findings from a randomized controlled trial on Prestige II conducted at four sites in Europe. This study was critically appraised. The article appears to report on all randomized patients, although not all patients had completed the final follow-up. No subsequent publications on outcomes of this RCT were identified. In addition, an older case series with 17 patients using the Prestige I device was identified, but not evaluated further due to the small size and the availability of higher-grade evidence. Blumenthal S et al. A prospective, randomized, multicenter food and drug administration investigational device exemptions study of lumbar total disc replacement with the Charité artificial disc versus lumbar fusion. Spine 2005; 30: 1568-1575. See Evidence Table. McAfee PC et al. Revisability of the Charité artificial disc replacement. Spine 2006; 31: 1217-1226. See Evidence Table. Porchet F, Metcalf NH. Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. Neurosurgery Focus 2004; 17: 36-43. See Evidence Table.

The use of artificial disc in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain

Back to Top

10/01/2007: MTAC REVIEW

Evidence Conclusion: The Prestige cervical disc system was first reviewed by MTAC before final FDA approval. At that time, there was one relatively small published RCT reporting preliminary findings (Porchet & Metcalf, 2004). At the time of data analysis, the investigators did not find a significant difference in pain and disability outcomes at 12 months for patients who underwent either artificial disc replacement or anterior cervical fusion. Limitations of this RCT included insufficient follow-up (only about two-thirds of participants had completed the 12-month follow-up and about 15% had completed the 24-month follow-up), unclear equivalence study methods, and funding from the device manufacturer. A larger multicenter RCT among patients with symptomatic single-level cervical degenerative disc disease (DDD) was identified for the evidence update (Mummanemi et al., 2007). Mummanemi and colleagues randomized 541 patients to receive either the Prestige cervical disc system or anterior cervical discectomy and fusion. Using a composite success measure developed by the investigators that considered efficacy and safety, the Prestige artificial disc system was found to be superior to ACDF in a completer analysis. In an intention to treat analysis with a "worst case scenario" analysis, Prestige was found to be non-inferior to ACDF. Advantages of the Mummanemi study were that it was randomized and there was a high follow-up rate. Disadvantages are that the study was non-blinded, and the authors have financial links with the manufacturer. In conclusion, there is fair evidence from one reasonably valid multicenter RCT that use of the Prestige artificial disc in conjunction with discectomy is at least non-inferior to ACDF in "clinical success" defined as a composite outcome incorporating efficacy and safety. The evidence would be strengthened by longer-term follow-up data and studies conducted by impartial researchers. The Porchet & Metcalf, 2004 study does not add substantially to the body of evidence, especially since only preliminary findings were reported in the published literature.

Articles: At the time of the previous MTAC review of artificial discs (October 2006), there was one published randomized controlled trial on the Prestige disc with 55 patients from 4 sites in Europe. The article reported preliminary findings of the RCT (Porchet & Metcalf, 2004). No follow-up publication was identified that reported final results of this RCT. The updated literature search identified a new, larger RCT. This study randomized 541 patients at 32 sites in the United States to discectomy with artificial disc replacement or ACDF (Mummaneni et al., 2007). This was the key study submitted to the FDA for device approval. The Mummaneni et al. RCT was critically appraised: Mummanemi PV, Burkus JK, Haid RW et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled trial. J Neurosurg Spine 2007; 6: 198-207. See Evidence Table.

The use of Prestige artificial disc in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain

02/01/2010: MTAC REVIEW

Evidence Conclusion: The published randomized controlled trials on lumbar and cervical artificial disc replacement, reviewed for this report, were all US FDA investigational device exemption (IDE) studies designed to show that artificial disc replacement is at least as good as fusion for lumbar DDD, or ACDF for cervical disc disease (non -inferiority design). Lumbar total disc replacement with artificial intervertebral discs (Charité, and ProDisc-L). The trials on artificial total lumbar disc replacement compared the procedure with interbody fusion among patients 18 to 60 years of age, who had a single level DDD at L4-5 or L5-S1 (Charité) or L3-S1 (ProDisc-L) confirmed radiographically and failed conservative treatment of at least six months. The trials were randomized, controlled and multicenter, but were not blinded and sponsored by the manufacturer which are sources of bias. All trials except the CHARITE IDE trial had a maximum study duration of two years which does not allow determining the long-term efficacy, durability, or safety of total disc replacement or its impact on adjacent risk degeneration.

CHARITE IDE trial (Guyer et al 2009) was the only published RCT with long-term follow-up. However, the five-year outcomes were reported for only 35% of the randomized participants in the original two-year trial (6 of the initial 14 investigational sites refused to participate in the five-year continuation study, and a number of patients were lost to follow-up). This reduces the statistical power of the study which was based on the initial population size. Moreover, the investigational procedure was compared to interbody fusion using the BAK cage technique, which currently is not the best-accepted fusion technique. These, together with non-blinding and other limitations of the original trial make it hard to interpret or generalize the results of the long-term follow-up. The trial on ProDisc-L (Zigler 2007) was also randomized, controlled, and multicenter. However, it had only 2-year follow-up duration which does not allow determining the long-term effectiveness, harms, or durability of the device. Moreover 11.5% of fusion patients and 9% of ProDisc-L patients were not included in the analysis, which was not based on intention to treat. There is also a concern that the investigators used a revised version of the ODI score that had not been validated.

 Back to Top

In conclusion, there is insufficient evidence to determine the long-term efficacy, durability, or safety of artificial disc replacement for patients with lumbar degenerative disc disease, or to determine whether it is associated with the risk of adjacent risk degeneration. Cervical total disc replacement with artificial intervertebral discs (ProDisc-C, Bryan, and PRESTIGE). The trials on artificial total cervical disc replacement compared the procedure in conjunction with discectomy to anterior cervical decompression and fusion (ACDF) among patients between 18 and 60 years of age (>21 years in Bryan disc trial) with radiculopathy or myelopathy from a single-level cervical disc disease From C3 to C7, that failed conservative treatment of at least 6 weeks. The trials were randomized, controlled and multicenter, but were not blinded, the postoperative care was not standardized and left to the discretion of the surgeon, and the majority of the investigators had financial ties to the manufacturer, all of which are sources of bias. Moreover the 2-year follow-up duration insufficient to examine the long-term efficacy, safety, and durability of the artificial disc replacement, or to determine whether it is associated with the risk of adjacent risk degeneration. In conclusion, the short-term results of the trials provide fair evidence that the use of the ProDisc-C, Bryan, or PRESTIGE artificial cervical disc systems in conjunction with discectomy is at least non-inferior to ACDF in “clinical success” defined as a composite outcome incorporating efficacy and safety, among patients with symptomatic single-level cervical disc disease. There is insufficient evidence however, to make any conclusion on whether total intervertebral cervical disc would need revision, would deteriorate with time, or would increase the risk of adjacent segment degenerative disc disease.

Articles: *Lumbar artificial disc replacement* the updated literature search identified two randomized controlled trials that compared total lumbar disc replacement with Charité (Guyer 2009) or ProDisc-L (Zigler 2007) systems versus lumbar fusion. Guyer et al reported on 5-year follow up of patients enrolled in the Charité IDE trial that was the key study submitted to the FDA for device approval. Zigler et al’s trial was also the key trial for FDA approval for ProDisc-L. Both RCTs was critically appraised. Guyer RD, McAfee PC, Banco RJ, et al. Prospective, randomized multicenter Food and drug Administration investigational device exemption study of lumbar total disc replacement with the Charité artificial disc and versus lumbar fusion: Five-year follow-up. Spine J. 2009; 9:374-386. See Evidence Table. Zigler J, Delamarter R, Spivak JM, et al. Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. Spine. 2007; 22:1155-1162. See Evidence Table *Cervical artificial disc replacement:* The literature search revealed two RCTs on ProDisc-C total disc replacement as well as two trials on Bryan cervical disc arthroplasty (conducted by the same principle investigators, and published in 5 articles). Two studies, one for each system (Murrey 2009 for ProDisc-C, and Heller 2009 for Bryan cervical disc arthroplasty), were selected for critical appraisal based on the methodological quality of the trial, population size and duration of follow-up. Murrey D, Janssen M, Delamarter R, et al. Results of a prospective, randomized, controlled, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. Spine. 2009; 9:275-286. See Evidence Table**.** Heller JG, Sasso RC, Papadopoulos SM, et al. Comparison of Bryan cervical disc arthroplasty with anterior cervical decompression and fusion. Clinical and radiographic results of a randomized, controlled, clinical trial. Spine. 2009; 34:107-107. See Evidence Table.

The use of artificial spinal discs in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain

02/13/2012: MTAC REVIEW

Evidence Conclusion: *CERVICAL* The three large published trials on cervical arthroplasty were industry sponsored studies submitted to the U.S. Food and Drug Administration for premarket approval of the devices: Prestige, ProDisc-C, and Bryan cervical disc. All three trials were designed as noninferiority trials i.e. attempting to show that cervical artificial disc replacement is at least as good as ACDF for cervical disc disease. They had similar inclusion and exclusion criteria, similar follow-up schedules, and similar outcome measures and success criteria defined by the FDA. The three trials are still ongoing as the FDA required that the investigators conduct post-approval studies to evaluate the longer-term safety and effectiveness of the devices. The post-approval studies are expected to provide 3, 5, 7, and 10-year data for cervical discs. Each of the three studies compared total replacement with an artificial disc (Prestige, ProDisc-C, or Bryan) in conjunction with discectomy to a single-level anterior cervical decompression and fusion (ACDF) among patients between 18 and 60 years of age (>21 years in Bryan disc trial) with a single level cervical radiculopathy or myelopathy between C- 3 and C-7 that had failed conservative treatment of at least 6 weeks. The trials were relatively large, randomized, controlled, and multicenter, but were not blinded, the postoperative care was not standardized and left to the discretion of the surgeon, and the majority of the investigators had financial ties to the manufacturers who supported the trials, all of which are sources of bias. The 24 months interim analyses of the three trials were previously reviewed by MTAC. The conclusion of the last 2010 MTAC assessment of the technology was as follows, “The short-term

 Back to Top

results of the trials provide fair evidence that the use of the ProDisc-C, Bryan, or Prestige artificial cervical disc systems in conjunction with discectomy is at least non-inferior to ACDF in “clinical success” defined as a composite outcome incorporating efficacy and safety, among patients with symptomatic single-level cervical disc disease. There is insufficient evidence however, to make any conclusion on whether total intervertebral cervical disc would need revision, would deteriorate with time, or would increase the risk of adjacent segment degenerative disc disease.” After the last MTAC review of 2010, mid-term follow-up data were published for all three trials: 48 months postoperative data for ProDisc and Bryan artificial discs and 60 months postoperative data for Prestige cervical disc. These mid-term follow-up data were only available for just over two thirds of the population in the Bryan disc trails, and around 50% for each of the 60 months follow-up data for the Prestige disc trials and the 48 months follow-up for ProDisc-C trial. The published results of all three studies show that the one level cervical disc arthroplasty appears to be at least as effective as cervical fusion in up to 2 years of follow-up. The results the extended, mid-term analyses suggest that the outcomes the artificial disc arthroplasty continues to be noninferior to those of fusion. However, the follow-up rates are poor, and the results on sustained effect and durability should be interpreted with caution. The 48 and even 60 months follow-up duration is still insufficient to determine the long-term efficacy, durability, and safety of the system, and the potential risk on adjacent risk degeneration. The trials are still ongoing and long-term results for up to 10 years follow-up are expected. In conclusion, the additional information does not change the conclusions of the previous reports; data on long-term safety and efficacy is still lacking, and there is no evidence to date to determine if one of these three FDA approved artificial discs is superior to the others. A recent update of the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) (November 2011) concluded that artificial intervertebral disc arthroplasty for the treatment of patients with cervical degenerative disc disease does not meet their criteria. The TEC update however did not include Sasso et al’s 2011 article that reports on the 48 months outcomes of all participating centers in the Bryan cervical disc trial. At the time of the TEC review only one center had published the 48-month follow-up results (BCBS 2011). *LUMBAR* As indicated in the last 2010 MTAC review, the published randomized controlled trials on lumbar artificial disc replacement were U.S. Food and Drug Administration (FDA) investigational device exemption (IDE) studies that were designed to show that artificial disc replacement is at least as good as fusion for lumbar DDD. The studies (reviewed in earlier reports) compared the procedure with interbody fusion among patients 18 to 60 years of age, who had a single level DDD at L4-5 or L5-S1 (Charité) or L3-S1 (ProDisc-L) confirmed radiographically and failed conservative treatment of at least six months. The trials were randomized, controlled and multicenter, but were not blinded and sponsored by the manufacturer which are sources of bias. All trials except the Charite IDE trial had a maximum study duration of two years, which does not allow determining the long-term efficacy, durability, or safety of total disc replacement or its impact on adjacent risk degeneration. Charite IDE trial (Guyer et al 2009) was the only published RCT with long-term follow-up. However, the five-year outcomes were reported for only 35% of the randomized participants in the original two-year trial (6 of the initial 14 investigational sites refused to participate in the five-year continuation study, and a number of patients were lost to follow-up). This reduces the statistical power of the study which was based on the initial population size. Moreover, the investigational procedure was compared to interbody fusion using the BAK cage technique, which currently is not the best-accepted fusion technique. These, together with nonblinding and other limitations of the original trial make it hard to interpret or generalize the results of the long-term follow-up. The trial on ProDisc-L (Zigler 2007) was also randomized, controlled, and multicenter. However, it had only 2-year follow-up duration which does not allow determining the long-term effectiveness, harms, or durability of the device. Moreover 11.5% of fusion patients and 9% of ProDisc-L patients were not included in the analysis, which was not based on intention to treat. There is also a concern that the investigators used a revised version of the ODI score that had not been validated. Yajun, et al's meta-analysis, 2010 (Evidence table 1) pooled the results of five studies involving 837 patients. The meta-analysis had valid methodology and analysis, and according to its reviewers, four of the five trials had good methodological quality. They indicated however, that the studies had limited population sizes and did not indicate that the assessors of the outcomes were blinded. The pooled results of the analysis showed that at 2 years of follow-up the patient functioning ability as measured by the Oswestry Disability Index (ODI) in the total disc replacement (TDR) group was better than the fusion group but, according to the authors a mean difference of 4 Oswestry points is not clinically relevant. There was also a statistically significant but clinically irrelevant difference in the pain score in favor of the TDR. After performing a sensitivity analysis excluding one large study that compared TDR with BAK cages, the difference in ODI, pain, and patient satisfaction were no longer significant. The authors concluded that TDR is not superior to fusion in treating lumbar degenerative disc disease. In conclusion, there is still insufficient published evidence to date, to determine the long-term efficacy, durability, or safety of artificial disc replacement for patients with lumbar degenerative disc disease, or to determine whether it is associated with the risk of adjacent risk degeneration.
Articles: *CERVICAL DISC* The literature search revealed four articles reporting on long-term outcomes of three pivotal clinical trials on Prestige ST, ProDisc-C, and Bryan artificial discs (one in a single center, and the other on the entire population studied). The search also identified an RCT on KineflexIC artificial disc with 2-year follow-up,

 Back to Top

and a recent meta-analysis (Cheerag, et al. 2011) that pooled the 2-year follow-up results of the three first trials. No trials comparing the three FDA approved artificial disc systems to one another were identified.

All three initial studies on Bryan, ProDisc, and Prestige cervical discs initial trials with 2-year outcomes that were submitted to the FDA for premarket approval were previously reviewed by MTAC. The reports on long-term follow-up outcomes of the studies were reviewed and their results added to the last MTAC report to update the findings and conclusions. The meta-analysis was not critically appraised as it does not add more evidence to 24 months interim results of the individual trials. Pooling these results still provide 2-year results when long-term safety, durability, and efficacy are needed. The recent RCT on KineflexIC was also not selected for appraisal as it only provides 24 months data. The following initial trials and more recent publications were critically appraised: Burkus JK, Haid RW, Traynelis VC, et al. Long-term clinical and radiographic outcomes of cervical disc replacement with The Prestige disc: results from a prospective randomized controlled trial. J Neurosurg Spine 2010; 13:308-318. See Evidence Table. Delamarter, RB, Murrey D. Janssen ME, et al. Results at 24 months from the prospective, randomized, multicenter Investigational Device Exemption trial of ProDisc-C versus anterior cervical discectomy and fusion with 4-year follow-up and continued access patients SAS Journal. 2010; 4:122–128. See Evidence Table**.** Heller JG, Sasso RC, Papadopoulos SM, et al. Comparison of Bryan cervical disc arthroplasty with anterior cervical decompression and fusion. Clinical and radiographic results of a randomized, controlled, clinical trial. Spine. 2009; 34:101-107. See Evidence Table**.** Mummanemi PV, Burkus JK, Haid RW et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled trial. J Neurosurg Spine 2007; 6: 198-207. See Evidence Table. Murrey D, Janssen M, Delamarter R, et al. Results of a prospective, randomized, controlled, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. Spine J. 2009; 9:275-286. See Evidence Table**.** Sasso RC, Anderson PA, Riew D, et al. Results of cervical arthroplasty compared with anterior discectomy and fusion: Four-year clinical outcomes in a prospective randomized, controlled, trial. J Bone Joint Surg A. 2011; 93:1684-1692. See Evidence Table**.** *LUMBAR* The literature search for studies published after the MTAC 2010 re-review of the technology, did not identify more recent reports on extended follow-up of the key trials on the Charité IDE or ProDisc-L used for the treatment of a single level generative disc disease (DDD). There was a recently published RCT (Delamarter et al 2011) conducted by the same investigators of Pro-disc-L total replacement, but for the treatment of two-level lumbar DDD which the focus of the current review is not. The search also revealed one meta-analysis of studies on artificial lumbar disc replacement for single level DDD, a systematic review, and once case series on with a 2-7 years follow-up of 57 patients who received an artificial Charite III total disc arthroplasty. The meta-analysis was selected for critical appraisal: Yajun W, Yue Z, Xiuxin H. A meta-analysis of artificial total disc replacement versus fusion for lumbar degenerative disc disease*. Eur Spine J.* 2010; 19:1250-1261. See Evidence Table.

The use of cervical artificial disc in the treatment of back pain meeting the *Kaiser Permanente Medical Technology Assessment Criteria* is inconclusive.

The use of artificial lumbar spinal discs in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease

BACKGROUND

Degenerative disc disease (DDD) is defined as any changes that occur at any level of the spine. It's the leading cause of pain and disability among adults in the United States as well as other parts of the world. Disc degeneration is most common in the lower neck (cervical disc disease) and in the low back (lumbar disc degeneration). DDD may cause pain in the affected area and may also radiate along the nerves emerging from the spinal canal at that level.

Most DDDs can be treated nonoperatively to relieve the pain. Conservative treatments include physical therapy, nonsteroidal anti-inflammatory medications, and analgesics. Acupuncture, spinal manipulations, axial traction, and muscle relaxants are other alternative therapies that may be used to alleviate the pain and discomfort. A number of patients may not benefit from the non-invasive therapy and resort to surgical treatment. Spinal interbody fusion, a procedure that involves the fusion of two or more vertebrae to eliminate the pain caused by their abnormal motion, has been the surgical standard of care for lumbar DDD for decades. Anterior cervical discectomy combined with fusion (ACDF) is also a well-established treatment for cervical degenerative disc disorders. Interbody fusion reduces the pain caused by the treated segment. However, the rigid fusion also leads to a reduction in normal spine motion, and an increase in the biomechanical stress at spinal levels adjacent to the fusion, which in turn accelerates degenerative changes of the discs at these levels [1-4].

Back to Top

Recently arthroplasty performed with artificial discs have emerged as a surgical alternative to interbody fusion. The technology is rapidly developing and offers the promise to restore the normal spinal movement without the kinematic and biochemical issues of fusion. Potential benefits of disc arthroplasty include maintenance of a range of motion, avoidance of adjacent segment degeneration, restoring disc height, correcting spinal misalignment, greater maintenance of maneuverability, and earlier return to previous level of function. In addition, many trials [5, 6] have shown that cervical disc arthroplasty (CDA) is as safe and effective as ACDF for the treatment of CDD at a single level. On the other hand, potential disadvantages of the artificial disc may include implant migration and material wear [3, 7, 8].

The Charité, the first artificial intervertebral disc used, was developed Germany in the 1950s, but was not commercially available until 1987 after undergoing major design modifications. The third generation Charité ™ (DePuy Spine) consists of two chromium alloy endplates and a sliding ultra-high molecular weight polyethylene core. The ProDisc-L (Synthes Spine, West Chester, PA) is another disc implant, also developed in Europe, for disc replacement at one level from L3-S1. It has a ball and socket design and is composed of three components; two metal endplates and a plastic inlay. More recently researchers developed artificial disc devices to replace cervical intervertebral discs. These include ProDisc-C (Synthes Spine, West Chester, PA), Bryan Cervical Disc (Medtronic Sofamor Danek, Memphis, TN), Prestige Cervical Disc (Medtronic Sofamor Danek), Mobi-C Cervical Disc (LDR Spine USA), and Kineflex|C Spinal System (SpinalMotion Inc.). ProDisc-C have a similar design to the ProDisc-L, Bryan disc prosthesis has two metal endplates and a polyethylene core, and Prestige has two main pieces of stainless steel that articulate against one another with a ball and trough.

The Prestige ST, ProDisc-C and Bryan artificial disc systems have received the US Food and Drug Administration (FDA) premarket application approval as Class III devices in July 2007, December 2007, and May 2009 respectively. The Mobi-C has received the US Food and Drug Administration (FDA) premarket application approval on August 2013.

Contraindications to total cervical disc replacement include systemic infection, infection at the operating site, allergy to any of the device materials, osteoporosis, marked cervical instability, severe spondylosis, clinically compromised vertebral bodies at the level to be treated, and symptomatic cervical disc disease (SCDD) at more than one level.

09/21/2016: MTAC REVIEW

Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease

Evidence Conclusion: Anterior cervical discectomy and fusion (ACDF) versus cervical disc arthroplasty (CDA) for two contiguous levels cervical disc degenerative disease: a meta-analysis of randomized controlled trials (Zou et al., 2016) (evidence table 1) This meta-analysis of RCT aimed to determine the safety and efficacy of cervical disc arthroplasty (CDA) at two contiguous levels cervical disc degeneration. The search was performed between January 2000 and July 2015. Evaluation of study quality was performed using the Cochrane Collaboration's tool for assessing risk of bias. Mean follow-up of included studies ranged from 20-48 months. CDA group patients showed fewer blood loss, lower post-operative complications, lower reoperation rate and better range of motion at all angles and levels. No significant difference was identified in mean surgical time, neck disability index and neck and arm pain VAS scores. Limitations remain in the variety of artificial intervertebral disc types. Furthermore, there is limited number of articles on artificial cervical disc for 2 levels.
Overall, CDA is more effective; the study has valid methodology with some limitations.

Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial (Davis et al., 2013) (evidence Table 2) This multicenter RCT, FDA investigational device exemption pivotal trial aimed to compare the Mobi-C cervical artificial disc to anterior discectomy and fusion (ACDF) for treatment of cervical DDD at 2 contiguous levels of the cervical spine. This study shows that the overall study success rates met the non-inferiority margin and provided statistical superiority of the total disc replacement (TDR) treatment over ACDF. Results should be interpreted with caution since several authors had received clinical or research support for this study from LDR, the sponsor. In addition, many other authors had financial ties with LDR.

Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results (Davis et al., 2015) (evidence Table 3) This is a 4-year follow-up result of the study performed by the same author in 2013. The follow up in the 2013 study presented earlier is 24 months. The current study follow-up is 48 months.

 Back to Top

At 48 months, total disc replacement (TDR) had greater improvement than ACDF in: neck disability index scores, 12-Item Short Form Health Survey Physical Component Summary scores, patient satisfaction, and overall success. In addition, TDR patients had lower subsequent surgery rates and showed a lower rate of adjacent-segment degeneration; TDR also maintained segmental range of motion. The study shows that TDR continue to be safe, effective and superior to ACDF at 48 months for the treatment of degenerative disc disease at 2 contiguous cervical levels.

A systematic review and meta-analysis of RCTs [9] indicated that CDA is more effective and safer than ACDF for the treatment of symptomatic cervical disc disease in mid- to long-term follow-up. However, only one study including 2-level was included in the review. A prospective, randomized study [10] compared the safety and effectiveness of the Bryan Cervical Disc in patients with myelopathy caused by two-level cervical disc disease in Han Nationality. The authors found that the Bryan Cervical Disc replacement was shown to be reliable and safe for the treatment of patients with two-level cervical disc disease.

Conclusion:

- Two-level cervical artificial disc replacement shows positive outcomes on the short-term
- There is low evidence to support the effectiveness and safety of two-level cervical artificial disc replacement over anterior cervical discectomy and fusion (ACDF) on the short-term for the treatment of cervical degenerative disc disease
- Studies with longer term follow-up are needed to confirm these findings

Articles: The literature revealed a number of articles; the following articles were selected for critical appraisal: Anterior cervical discectomy and fusion (ACDF) versus cervical disc arthroplasty (CDA) for two contiguous levels cervical disc degenerative disease: a meta-analysis of randomized controlled trials (Zou et al., 2016) See Evidence Table 1. Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial (Davis et al., 2013) See Evidence Table 2. Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results (Davis et al., 2015) See Evidence Table 3.

The use of Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/14/2024: MTAC REVIEW

TWO-LEVEL LUMBAR ARTIFICIAL DISC REPLACEMENT FOR DEGENERATIIVE DISC DISEASE

Evidence Conclusion:

- There is no published evidence, to date, to determine that 2-level total lumbar artificial disc replacement is superior to spinal fusion for the treatment of patients with discogenic pain and 2- level lumbar DDD.
- Low quality evidence from an industry sponsored open-label trial, with short follow-up duration, suggest that total lumbar disc replacement using ProDisc L may be noninferior at 2 years to spinal fusion for the treatment of highly selected patients with discogenic pain and two-level DDD who have failed conservative treatment.
- There is insufficient published evidence to determine that TDR reduces the risk of adjacent-level disc degeneration compared to spinal; arthrodesis (the primary goal of the technology)
- There is insufficient published evidence to determine the longer-term efficacy, safety, and durability of the artificial disc implanted including but not limited to implant failure, spinal stenosis, heterotopic ossification, and the health effects of potential metal wear and corrosion, and polyethylene wear debris.
- There is insufficient evidence to determine the long- term net health benefit of TDR compared to spinal fusion for the treatment patients with symptomatic 2- level lumbar DDD.

Articles:

The literature search for studies published in full in peer-reviewed medical journals identified; See Evidence Table:

- The pivotal FDA IDE RCT comparing ProDisc-L total disc replacement versus circumferential arthrodesis for the treatment of two-level lumbar DDD (Delamarter, et al 2011 reporting the 24 months results of the trial, and Radcliff, et al 2018 reporting on five-year reoperation rates).
- A retrospective analysis (Trincat, et al, 2014) of data for a series of patients who had undergone two-level lumbar TDR using ProDisc device and completed a minimum follow-up of 2 years, in one center in France.
- A retrospective study (Silvestre, et al 2009) that investigated the results of implanting bisegmental TDR with SB Charite` III artificial disc in patients with DDD who have completed 3-year follow-up after receiving the implant. The analysis also compared, the results of 2-level versus 1-level disc replacement also using SB Charite` III device.

 Back to Top

- One RCT (Hoff et al, 2016), three observational studies (Aunoble, et al 2010, Chen, et al, 2015 and Andrieu, et al 2017), and a SR with meta-analysis (Lackey, et al 2016) that assessed the effect of hybrid construct involving fusion and TDR for two- or multilevel level DDD.

Inclusion criteria for the current assessment

- RCTs that compared FDA approved device for 2-level total disc replacement versus spinal interbody fusion for the treatment of patients with discogenic pain and two-level DDD.

Exclusion criteria for the assessment

- Prospective or retrospective observational studies with no comparison groups.
- Studies that investigated the efficacy and safety of TDR using a disc device that was withdrawn from the US market and /or has not received FDA clearance for its use.
- Studies that compared one- versus two-level TDR
- Studies that compared the effect of combining TDR and fusion versus a stand-alone procedure.

The use of Two-Level Lumar Artificial Disc Replacmenet for Degenerative Disc Disease does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/14/2024: MTAC REVIEW

LUMBAR DISC ARTHROPLASTY (LUMBAR TOTAL DISC REPLACEMENT) FOR A SINGLE-LEVEL DEGENERATIVE DISC DISEASE

Evidence Conclusion:

- Low quality evidence from an industry sponsored open-label trial with limitations, suggest that total lumbar disc replacement using ProDisc-L may be noninferior (for up to 5 years) to spinal fusion for the treatment of highly selected patients with discogenic pain and single-level DDD who have failed conservative treatment.
- There is no published evidence to determine the comparative safety and efficacy of ActivL® lumbar disc and spinal fusion in patients with symptomatic single level DDD.
- There is insufficient published evidence to determine that TDR is superior or noninferior to spinal fusion in reducing adjacent-level disc degeneration (the primary goal of the technology) or preservation of the spinal natural range of motion in patients with a single level LDDD.
- There is insufficient published evidence to determine the longer-term efficacy, safety, and durability of the artificial disc implanted including but not limited to implant failure, spinal stenosis, heterotopic ossification, and the health effects of potential metal wear and corrosion, and polyethylene wear debris.
- There is insufficient evidence to determine the long- term net health benefit of TDR compared to spinal fusion for the treatment patients with symptomatic single- level lumbar DDD.

Articles:

The literature search for studies published after the 2012 MTAC review of the technology identified the following; See Evidence Table:

- Five-year results of a multicenter, FDA investigational device exemption (IDE) study of the ProDisc-L total disc replacement versus circumferential arthrodesis for the treatment of single-level degenerative disc disease. (Zigler, et al 2012).
- Five-year follow-up results (Skold et al, 2013) of a trial conducted in Sweden to compare total disc replacement (using Charite, ProDisc or Maverick devices) versus spinal fusion.
- Two publications (Garcia, et al 2015 and Yue, et al 2019) reporting on 2- & 5-years outcomes (respectively) of a RCT that compared ActivL artificial disc to two control TDR devices (ProDisc-L and Charite´) for the treatment of patients with symptomatic single-level lumbar degenerative disc disease (DDD).
- 8-year follow-up a randomized controlled multicenter trial (Furunes, et all 2017) conducted in Norway to compare ProDisc II versus multidisciplinary rehabilitation in patients with discogenic chronic low back.
- Ten systematic reviews with meta-analyses of studies comparing total disc replacement versus spinal fusion for the treatment of lumbar degenerative disc disease. The meta-analyses were overlapping; included studies of discs that were approved by the US FDA as well as others that did not receive FDA approval; half of them pooled the results of RCTs and observational studies together; and all but one MA (Zigler, et al, 2018) combined the result of RCTs investigating 1- or 2-level LDDD.
- One systematic review (Ding, e al 2017) of overlapping meta-analyses published between 2010 and 2015 that compared TDR to fusion for treating LDDD.

The use of Lumbar Disc Arthroplasty (Lumar Total Disc Replacement) for a Single-Level Degenerative Disc Disease does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

 Back to Top

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Cervical:

CPT® or HCPC Codes	Description
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
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)

Effective until October 1, 2025
Considered Not Medically Necessary:
Lumbar:

CPT® or HCPC Codes	Description
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

Effective October 1, 2025
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Lumbar:

CPT® or HCPC Codes	Description
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

Back to Top

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

******To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
02/07/2005	04/06/2010MDCRPC, 02/10/2011MDCRPC, 12/06/2011MDCRPC, 03/06/2012MDCRPC, 04/03/2012MDCRPC, 02/05/2013MDCRPC, 12/03/2013MPC, 10/07/2014MPC, 08/04/2015MPC, 06/07/2016MPC, 04/04/2017MPC, 02/06/2018MPC, 01/08/2019MPC, 01/07/2020MPC, 01/05/2021MPC, 01/04/2022MPC, 01/10/2023MPC, 06/04/2024MPC, 06/03/2025MPC	05/06/2025

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34866 and L35008
10/04/2016	Added MTAC review
11/01/2016	MPC approved criteria for two contiguous levels from C3-C7
06/04/2020	Removed deleted and inaccurate CPT code 0357T
01/04/2022	Defer to KPWA policy for Medicare members for lumbar disc replacement if younger than 60 years old and for cervical disc replacement for all ages.
05/06/2025	MPC approve criteria for Single Level Artificial Lumbar Discs for Degenerative Disc Disease. 60-day notice required; effective 10/01/2025.

Back to Top