Artificial Disc Replacement Surgery
SRG-020

Iowa Medicaid Program	Prior Authorization	**Effective Date**	07/16/2021
Revision Number	5	**Last Reviewed**	01/17/2025
Reviewed By	Medicaid Medical Director	**Next Review**	01/16/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	07/16/2021

Descriptive Narrative

Disc degeneration is a complex biochemical process that occurs due to a loss of normal water content within the disc, with the following consequences over time:

- Deterioration of the mechanical shock absorbing properties of the disc,
- Bulging of the disc, and
- Loss of disc height.

The most frequent cause attributed to degenerative disc disease (DDD) is the natural aging process, although various associated factors may accelerate the process. Not all individuals with radiologic evidence of disc degeneration experience symptoms or pain.

When conservative treatment of DDD fails, the current surgical approach is to perform a spinal fusion at the symptomatic level. Over 200,000 spinal fusions are performed in the United States annually. However, in recent years, growing concern has developed regarding outcomes of spinal fusion. By removing motion at the operative level, the procedure alters the biomechanics of the back, leading to premature disc degeneration at adjacent levels, and potentially creating the need for additional surgical intervention as the biomechanical stress placed on those levels causes the discs to fail. This is of particular concern for younger patients.

Artificial intervertebral disc replacement is an alternative to cervical and lumbar spinal fusion surgery for those individuals suffering from back or neck pain due to DDD. The artificial disc was designed to restore normal disc height, preserve flexibility of the spine, and decrease degeneration of adjacent discs, which can occur because of spinal fusion surgery.

Examples of US Food and Drug Administration (FDA) approved for the cervical spine include, but may not be limited to: BRYAN cervical disc, MOBI-C cervical

disc, PCM cervical disc, Prestige cervical disc, ProDisc-C total disc replacement, and SECURE-C artificial cervical disc. Those FDA approved for the lumbar spine include, but may not be limited to: activL artificial disc and ProDisc-L total disc replacement (see tables below).

FDA Approved Cervical Artificial Disc Implants	Approved Vertebral Levels
Prestige® ST Cervical Disc System	Single level C3-C7
ProDisc-C® Total Disc Replacement	Single level C3-C7
Bryan® Cervical Disc	Single level C3-C7
Secure®-C Cervical Disc	Single level C3-C7
PCM Cervical Disc	Single level C3-C7
M6-C Artificial Cervical Disc	Single level C3-C7
Mobi-C®	Single level or two contiguous levels C3-C7
Prestige LP®	Single level or two contiguous levels C3-C7

FDA Approved Lumbar Artificial Disc Implants	Approved Vertebral Levels
ProDisc-L ® Lumbar	Single level L3-S1
activL® Artificial Disc	Single level L4-S1

Criteria

Cervical Disc Arthroplasty

Cervical disc arthroplasty is considered medically necessary when **ALL** the following are met:

1. Member has **ONE** of the following (radiculopathy **OR** myelopathy):
   a. Radiculopathy related to nerve root compression caused by one- or two-level degenerative disease between C3-C4 and C6-C7, with or without neck pain, and **BOTH** of the following are met:
      1) Objective neurologic findings that correlate with a cervical nerve root impingement, and/or unremitting radicular pain; **AND**
      2) Imaging studies demonstrating nerve root compression due to herniated disc or spondylotic osteophyte correlating with the distribution of signs and symptoms; **OR**
   b. Myelopathy related to central spinal stenosis caused by one- or two-level degenerative disease between C3-C4 and C6-C7, with or without neck pain, when **BOTH** of the following are met:
      1) Clinical signs and symptoms of myelopathy are present which may include: loss of dexterity, urinary urgency, new-onset bowel or bladder incontinence, frequent falls, hyperreflexia, Hoffmann sign, increased tone or spasticity, gait abnormality, or pathologic Babinski sign; **AND**

    2) Imaging studies demonstrating cervical cord compression due to herniated nucleus pulposus or osteophyte formation; **AND**
2. Member is 18 years of age or older; **AND**
3. No significant facet arthritis at the level of disc replacement; **AND**
4. An FDA-approved cervical artificial intervertebral device will be implanted and used in accordance with FDA labeling; **AND**
5. Failure of 6 weeks of conservative management including, but not limited to physical therapy, home exercise program, NSAIDs, epidural steroid injections, and activity/lifestyle modification (unless a particular modality is not tolerated or contraindicated); **AND**
6. Replacement of a degenerated cervical disc is limited to two levels (Mobi or Prestige LP Cervical Disc devices) from C3-C7; **AND**
7. The member does not have a previous fusion at any surgical level; **AND**
8. Absence of smoking or use of tobacco* products for at least 4 weeks prior to surgery.

Cervical disc arthroplasty is considered **investigational** in any of the following circumstances:

1. Cervical total disc arthroplasty at more than two levels or at two non-contiguous levels; **OR**
2. Hybrid constructs in a single procedure, involving cervical fusion with cervical total disc arthroplasty; **OR**
3. Cervical total disc arthroplasty in an individual with a previous fusion at another cervical level; **OR**
4. Osteoporosis defined as dual energy x-ray absorptiometry (DEXA) bone density measured T-score of negative 2.5 or lower.

The need for conservative treatment is not necessary if signs/symptoms of compression/stenosis require immediate attention due to neurological changes.

Lumbar Disc Arthroplasty

Lumbar disc arthroplasty is considered medically necessary when **ALL** the following have been met:

1. Member is between 18 and 60 years of age; **AND**
2. Presence of back pain for 6 months or greater that interferes with ADLs; **AND**
3. Primary complaint of axial pain determined to be of discogenic origin; **AND**
4. Presence of single level, advanced disc disease at L3-L4, L4-L5, or L5-Sl, as documented by MRI and plain radiographs demonstrating moderate to severe degeneration of the disc; **AND**
5. Failure of 6 months of conservative therapy including, but not limited to physical therapy, home exercise program, NSAIDs, epidural steroid

injections, and activity/lifestyle modification (unless a particular modality is not tolerated or contraindicated); **AND**
6. Absence of significant facet arthritis at the level of disc replacement; **AND**
7. Absence of smoking or use of tobacco products* for at least 4 weeks prior to surgery; **AND**
8. Use of an implant that is FDA approved for the intended level of disc replacement (ProDisc-L Lumbar single level L3-S1, activL Artificial Disc single level L4-S1).

*Evidence shows that tobacco use is considered a risk factor for poor healing. Tobacco use (e.g., cigarettes, cigars, pipes, vaping, or smokeless tobacco in the form of chew or snuff) within the previous 4 weeks is a contraindication for the procedure.

Lumbar disc arthroplasty is considered **investigational** in any of the following circumstances:
1. For disease above L3-L4 or L4-L5 depending on FDA approved levels; **OR**
2. Presence of osteopenia or osteoporosis (defined as DEXA bone density measured T-score less than -1.0); **OR**
3. Disc replacement at more than one spinal level; **OR**
4. Hybrid lumbar total disc arthroplasty/lumbar fusion (lumbar total disc arthroplasty at one level at the same time as lumbar fusion at a different level); **OR**
5. Arthroplasty using devices other than those which are FDA approved, or use of an FDA approved device in a manner which does not meet FDA requirements; **OR**
6. Presence of prior lumbar fusion or artificial disc placement.

Thoracic Spine

Disc arthroplasty is considered **investigational** for treatment of disc disease in the thoracic spine. The available scientific evidence for thoracic arthroplasty remains insufficient to permit conclusions concerning the effect of this technology on net health outcomes.

Revisions

Revision of a lumbar intervertebral disc prosthesis is considered medically necessary when imaging confirms failure of the implanted device (e.g., loosening, dislodgement, fracture, infection).

Urgent

Urgent conditions do not require pre-authorization. A review to determine medical necessity of the intervention is generally performed following the procedure.

The requirement for a period of conservative treatment as a prerequisite to a surgical procedure is waived when there is evidence of progressive nerve or spinal cord compression resulting in a significant neurologic deficit, or when cauda equina syndrome or conus medullaris syndrome is present, and urgent intervention is indicated.

Coding

The following list of codes is provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

CPT	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.
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).
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical.
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).
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar.
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).
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).

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual and as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

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Two-Level Lumbar Total Disk Replacement for Two-Level Degenerative Disk Disease. Hayes Review, Evolving Evidence Review Nov 15, 2024

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]			[#]
Signature			

Change Date	Changed By	Description of Change	Version
01/17/2025	CAC	Annual Review. References and Coding sections updated.	5
Signature			
William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
01/19/2024	CAC	Added 0164T to Coding section.	4
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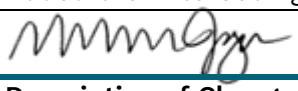
William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/21/2023	CAC	Annual Review.	3
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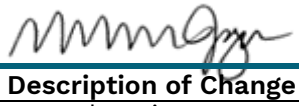
William (Bill) Jagiello, DO			

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07/15/2022	CAC	Annual Review.	2
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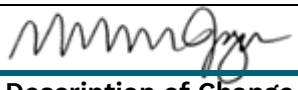
William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/16/2021	CAC	Criteria implementation.	1
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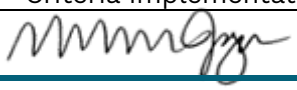
William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee