MEDICAL POLICY	Back: Artificial Intervertebral Discs (Medicare Only)
Effective Date: 9/1/2022  9/1/2022 Medical Officer Date	Medical Policy Number: 263 Medical Policy Committee Approved Date: 5/2020; 6/2021; 7/2022

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Service	Medicare Guidelines
*Lumbar Artificial Disc Replacement for Members **Over** 60 years of Age* *For **hybrid** LADR procedures, see separate row below.*	National Coverage Determination (NCD) for Lumbar Artificial Disc Replacement (LADR) (150.10) **NOTE:** The NCD 150.10 addresses LADR for members **over 60 years** of age; however, it leaves LADR for members **60 years of age and younger** to local Medicare Contractor (MAC) discretion. Since the local MAC (Noridian, Jurisdiction F) does not have an applicable coverage determination, see separate row below.
Cervical Artificial Disc Replacement ***Hybrid** Cervical and Lumbar Procedures (fusion with artificial intervertebral disc implantation)*	Company medical policy for **Back: Artificial Intervertebral Discs (All Lines of Business Except Medicare)** I. These procedures may be considered **medically necessary** when Company medical policy criteria are met. II. These procedures are considered **not medically necessary** for Medicare Plan members either when Company medical policy criteria are **not** met ***or*** when a service is always deemed to be "investigational" by the Company medical policy.

	"Investigational" services are considered not medically necessary for Medicare Plan members. See Policy Guidelines below.

POLICY GUIDELINES

Medicare and Medical Necessity

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.), Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

For Medicare, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
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
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)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
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)
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
Not Covered	
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), 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)

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical

necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

Food and Drug Administration (FDA)

The first artificial disc to be FDA approved for use in the lumbar spine was the CHARITÉ® artificial disc. CHARITÉ® was subsequently replaced by the INMOTION® artificial disc, which was approved under the CHARITÉ® Artificial Disc Registration. CHARITÉ® received a FDA premarket approval decision on 10/26/2004, but has subsequently been officially withdrawn on 1/5/2012.[1]

Additional devices have since received approval from the FDA, including but not necessarily limited to, the following:

- ProDisc®-L received a FDA premarket approval decision on 8/14/2006, indicated for spinal arthroplasty in skeletally mature patients with DDD at 1 level from L3-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than Grade I spondylolisthesis at the involved level. Patients receiving the ProDisc®-L Total Disc Replacement should have failed at least 6 months of conservative treatment prior to implantation of the ProDisc® Total Disc Replacement.[2]
- activL® received a premarket approval decision on 6/11/2015, and is indicated for reconstruction of the disc at 1 level (L4-L5 or L5-S1) following single-level discectomy in skeletally mature patients with symptomatic DDD with no more than grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. The activL® artificial disc is implanted using an anterior retroperitoneal approach. Patients receiving the activL® artificial disc should have failed at least 6 months of nonoperative treatment prior to implantation of the device.[3]

REFERENCES

1. Food and Drug Administration (FDA). CHARITÉ®. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P040006. Accessed 5/31/2022.
2. Food and Drug Administration (FDA). ProDisc®. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?c_id=56&t_id=350789. Accessed 5/31/2022.
3. Food and Drug Administration (FDA). activL®. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120024. Accessed 5/31/2022.