Medicare Medical Policy

Artificial Intervertebral Discs

MEDICARE MEDICAL POLICY NUMBER: 263

Effective Date: 10/1/2023

Last Review Date: 9/2023

Next Annual Review: 9/2024

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

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 Artificial Intervertebral Discs 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 "not medically necessary" by the Company medical policy. *See Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

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)*.

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.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations.

During the MAO review, an evidence-based process must be used. This includes using authoritative evidence, such as studies performed by government agencies (i.e., the FDA), well-designed clinical studies that appeared in peer reviewed journals, and evaluations performed by independent technology assessment groups. *(Medicare Managed Care Manual, Ch. 4, §90.5)* In addition to review of the quality of the body of studies and the consistency of the results, additional consideration may be given to determine if the evidence can be generalized to the Medicare population.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

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]

BILLING GUIDELINES AND CODING

CODES*		
CPT	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)
	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)
	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)
	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

HCPCS	None	

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
9/2022	Annual review, no changes (converted to new format 2/2023)
10/2023	Annual review, no changes to criteria but language revision due to prior Company policy change from "Investigational" to "not medically necessary", update title