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RMHP Lumbar Total Disc Arthroplasty (TDA)

MCG Health
Ambulatory Care
27th Edition

AUTH: RMHP-AC-5083 (AC)

Link to Codes

Clinical Indications for Procedure

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- This healthcare procedure is/was needed for the appropriate care of the RMHP Member because of **ALL** of the following
  - A participating RMHP specialist recommended total lumbar disc arthroplasty. Select the health plan for this Member. **1 or more** of the following
    - The Member has **RMHP Individual and Family Plan (IFP)** commercial health plan coverage. Per MCG, Current role remains uncertain. Based on review of existing evidence, there are currently no clinical indications for this technology. See Inappropriate Uses for more detailed analysis of the evidence base.
    - The Member has **RMHP CareAdvantage or Dual Special Needs Plan (DSNP)** Medicare health plan coverage and meets these conditions **ALL** of the following
      - The Member is **over 60 years of age**. Effective for services performed on or after August 14, 2007, CMS has found that LADR is not reasonable and necessary for the Medicare population over 60 years of age; therefore, LADR is non-covered for Medicare beneficiaries over 60 years of age.
      - The Member is **60 years of age or under.** The case will be pended for a Medical Director physician review. Per NCD 150.10,

Medicare has left the determination to be made on a local basis. The requester will be notified of the decision per protocol.

- The Member has **RMHP PRIME (Medicaid) or CHP Plus** health plan coverage and meets these conditions **ALL** of the following
    - The Member has unremitting low back pain and significant functional impairment from degenerative disc disease which is limited to the **single spinal level** at which the lumbar TDA is planned
    - This procedure will be performed on a single spinal level
    - The Member is skeletally mature
    - The device that will be used is FDA approved and will be used in accordance with FDA labeling.
    - Within the last twelve months, the Member has completed six consecutive months of structured, physician supervised conservative medical management, which includes **ALL** of the following
        - Exercise, including core stabilization exercises
        - Medication with nonsteroidal and/or steroidal drugs (unless contraindicated)
        - Physical therapy, including passive and active modalities
        - Lifestyle modifications
    - The Member does **NOT** have contraindications to the procedure **ALL** of the following
        - The Member does NOT have active systemic infections or infection localized to the site of implantation
        - The Member does NOT have osteopenia or osteoporosis (T score less than -1.0)
        - The Member does NOT have bony lumbar spinal stenosis
        - The Member does NOT have isolated radicular compression syndrome, especially due to disc herniation
        - The Member does NOT have Pars defect
        - The Member does NOT have clinically compromised vertebral bodies at the affected levels due to current or past trauma
        - The Member does NOT have spondylolisthesis of grade >1
        - The Member does NOT have severe facet arthritis
        - The procedure will NOT involve Category III CPT code 0165T. See Reviewer Guidance.

Alternatives to Procedure

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- Alternatives include(1)(2)(3)(4):
    - Exercise program
    - Lumbar diskectomy or microdiskectomy, with or without lumbar fusion
    - NSAIDs(5)

- Physical therapy. See Spine Soft Tissue Dysfunction Rehabilitation [AC] for further information.
- Spinal manipulation therapy. See Spinal Manipulation Therapy (SMT), Chiropractic and Other [AC] for further information.

Evidence Summary

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Background

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Disk arthroplasty (artificial intervertebral disk implantation or replacement) was developed as an alternative to spinal fusion to maintain spinal segment mobility and theoretically prevent subsequent disk degeneration of adjacent segments, which is a complication of spinal fusion.(6)(7)(8)(9) **(EG 2)** Studies demonstrate that the pooled radiographic prevalence of adjacent segment disease after cervical spine and lumbar surgery (fusion, total disk arthroplasty, or other procedure) is 33% and 27%, respectively, with the prevalence of symptomatic adjacent segment disease being 6.3% and 8.5%, respectively.(10) **(EG 2)**

Criteria

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For cervical degenerative disk disease (single-level), A meta-analysis of 6 multicenter randomized controlled trials including 2121 patients that compared single-level cervical disk arthroplasty with anterior cervical diskectomy and fusion found that disk arthroplasty was associated with increased neurologic and overall success and a decreased reoperation rate; there was no significant difference between groups with regard to Neck Disability Index scores. The authors concluded that total disk arthroplasty resulted in clinical outcomes that were comparable to or better than anterior cervical diskectomy and fusion, but recommended further long-term studies.(11) **(EG 1)** A systematic review of 5 randomized controlled trials (959 patients who underwent single-level surgery and 82 patients who underwent 2-level surgery) that compared cervical disk arthroplasty with anterior cervical diskectomy and fusion found, at a minimum of 48 months' follow-up, that disk arthroplasty was associated with a lower rate of reoperation, improved Neck Disability Index scores, and improved neck and arm pain scores; there was no significant difference between groups in incidence of adjacent segment disease. The authors concluded that cervical disk arthroplasty is a reasonable option for patients with symptomatic cervical disease, but recommended further research on patient outcomes.(12) **(EG 1)** A randomized controlled trial comparing single-level cervical disk arthroplasty with anterior cervical diskectomy and fusion found, at 2-year follow-up, that there was no significant difference between groups with regard to Neck Disability Index success, improvement in neck and worst arm pain scores, and rates of secondary surgical intervention.(13) **(EG 1)** Results from randomized trials have found insufficient evidence of superiority of reduction of subsequent adjacent segment degeneration for cervical disk arthroplasty as compared with anterior cervical diskectomy and fusion.(12)(7)(8) **(EG 1)** A European study of patients treated with cervical disk arthroplasty reported an 11% reoperation rate and a 60% rate of spontaneous fusion at 17-year follow-up.(14) **(EG 2)**

Inconclusive or Non-Supportive Evidence

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For cervical degenerative disk disease (multilevel), A manufacturer-funded randomized controlled trial comparing 2-level cervical disk arthroplasty with anterior cervical diskectomy and fusion found, at 4-year follow-up, that although disk arthroplasty was associated with greater Neck Disability Index success and a reduced subsequent surgical intervention rate, there was no significant difference between groups with regard to improvement in neck and arm pain scores. The authors noted that additional studies and longer follow-up would more clearly define the comparative safety and efficacy of multilevel disk arthroplasty and arthrodesis.(15) **(EG 1)** A literature review concluded that there is insufficient evidence to support the superiority of 2-level cervical disk arthroplasty as compared with anterior cervical diskectomy and fusion and recommended unbiased randomized controlled trials for further evaluation.(16) **(EG 2)**

For lumbar degenerative disk disease, A systematic review with multivariate analysis concluded that there was insufficient evidence to support the use of lumbar disk arthroplasty to reduce adjacent segment disk degeneration.(9) **(EG 1)** A systematic review of randomized controlled trials found that although disk arthroplasty had slightly better pain and function outcomes than lumbar fusion, the issue of whether or not disk arthroplasty prevents adjacent segment disease was not properly assessed in any of the studies. The authors concluded that although disk arthroplasty appears to be effective for short-term treatment of low back pain in selected patients, the long-term harms and complications are unknown, and spine surgeons should be cautious about adopting this technology on a large scale.(17) **(EG 1)** A systematic review and meta-analysis of 7 randomized controlled trials (1584 patients) comparing lumbar total disk replacement with fusion for the treatment of lumbar degenerative disk disease found, at 2-year follow-up, that total disk replacement was associated with improved disability index and pain scores, although the mean differences in scores between the 2 groups for both metrics were not clinically significant. There were no significant differences between groups with regard to reoperation rates and proportion of patients who returned to part-time or full-time work.(18) **(EG 1)** A practice guideline stated that there is insufficient evidence to adequately evaluate the long-term benefits and harms of lumbar disk arthroplasty. The guideline authors also noted that all randomized trials comparing disk arthroplasty with fusion have been funded by the device manufacturers; in addition, the authors noted that the control group for one of these trials used a type of fusion (stand-alone cage) that is no longer widely used due to frequent poor outcomes.(1) **(EG 2)** A randomized noninferiority trial of 193 patients comparing lumbar disk arthroplasty to fusion for single-level degenerative disease found, at 5-year follow-up, that there was no significant difference between the groups with regard to postoperative disability index, 36-Item Short Form Health Survey (SF-36) score, and pain scores. The study did not include an analysis of the effect of disk arthroplasty on adjacent segment disease.(19) **(EG 2)** A manufacturer-funded randomized controlled trial comparing lumbar disk arthroplasty to fusion for contiguous 2-level disk disease found, at 24-month follow-up, that there was no significant difference in operative success rates and pain score improvement between the groups, although disk replacement was associated with improved disability scores and reduced rates of narcotic use. The authors noted several structural limitations with the study, including short duration of follow-up and lack of postoperative blinding, which may have created patient bias in favor of disk arthroplasty. Longer-term follow-up was recommended to assess the risk of implant wear and adjacent segment degeneration.(20) **(EG 1)**

Policy History

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2023 annual review and approval by committee hierarchy per written protocol.

History Summary: 12/30/2016 New guideline to NTAG, 2/16/17 CM Committee, 2/22/17 MAC Meeting approved. 2018 Annual review - approved by committees with no changes. 2019 Annual review approved by relevant committees with no changes. 1/6/2020 Clarified Indications, added Reviewer Guidance, updated LCD review date, added Fee Schedule findings and Fee Schedule references with review date. 2020 Annual review approved by relevant committees with no changes. 2021 Annual review approved by committee hierarchy with no changes. 1/3/2022 Annual internal review with clarified time frame for conservative treatment trial. 2022 annual review and approval by committee hierarchy.

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Health First Colorado Fee Schedule reviewed 3/25/2023. 0165T not listed NIC. CPT 22857, 22860 (new 1/1/2023 add-on) and 22862 priced.

Reviewer Guidance

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For **Medicaid and CHP Plus** plans: The procedure can NOT involve Category III CPT code 0165T. The Procedure must be accurately reported with CPT 22857, 22860 (add-on) or 22862. **NOTE** : add-on code 0165T is not listed on HCPF Health First Colorado Fee Schedule reviewed 3/25/2023, not in contract and therefore non-covered for Medicaid and CHP Plus plan members. New add-on code CPT code 22680 effective 1/1/2023 is priced on Fee Schedule reviewed 3/25/2023.

IFP/Commercial Plans: Not a Benefit - Experimental - current role remains uncertain (CRRU) per MCG.

Medicare Plans: Follow NCD 150.10 in the References Section. NON Covered over age 60. Age 60 or under, send to Medical Director for case-by-case local review. New add-on code CPT 22860 effective 1/1/2023 is carrier priced per Medicare Physician Fee Schedule (MPFS) reviewed Feb 2023.

10/1/2022 per Orthonet, 0165T removed from PA list and policy - not covered. Does not require PA but also non-covered.

1/1/2023 removed 1063T obsolete/deleted code.

2/1/2024 reviewed, no changes

References continued

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CPT® : 22857, 22860, 22862

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