



Clinical Review Criteria Related to Mobi-C Artificial Cervical Disc

I. Criteria for Approval:

- A. Minuteman Health Insurance (MHI) will cover the Mobi-C cervical intervertebral disc (IVD) prosthesis for degenerative cervical disc disease with intractable radiculopathy neck/arm pain and/or myelopathy as medically necessary in a skeletally mature individual at 1 or 2 contiguous levels when ALL of the following criteria are met:
1. Single or 2level degenerative disc disease **only** from C3 to C7 confirmed by radiographic studies (CT, MRI, X-rays),
 2. Chronic neck/arm pain causing a disability and/or neurological deficit that is unresponsive to at least six weeks of conservative treatment (such as reduced activities, exercise, analgesics, physical therapy), and
 3. The IVD will be used in the reconstruction of a cervical disc at C3-C7 following single level discectomy.

II. Required Documentation:

- A. Clinical notes from treating Provider to include treatment plan over six-week period of time, CT scan and/or MRI or X-ray reports.

III. What is Not Covered:

- A. The IVD prosthesis is considered experimental/investigational for all of the following:
1. Multi-level implantation
 2. Combined use of a prosthesis and spinal fusion (hybrid surgery)
 3. Prior fusion at another cervical level
 4. Prior surgery at the treated level
 5. Multilevel disc disease
 6. Absence of neck and/or arm pain

7. Progressive neurological deficit or deterioration
8. Rheumatoid arthritis or other autoimmune disease
9. Paget's disease, osteomalacia or any other metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia)
10. Facet joint arthropathy (facet arthritis)
11. Unstable cervical spine
12. Malignancy
13. Weakened bone from past trauma
14. Mobi C with laminectomy

CPT Codes

- 22856** Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end-plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical
- 22861** Revision including replacement of total disc arthroplasty (artificial disc) anterior approach, single interspace; cervical

ICD-10 Procedure Codes

0RR30JZ – Replacement of Cervical Vertebral Disc with Synthetic Substitute, Open Approach

References:

NCQA Standard, UM 2, Clinical Criteria for Utilization Management Decisions, Element A

American Academy of Orthopaedic Surgeons. Technology Overview. Cervical Disc Arthroplasty. March 2010. Available at URL address :

<http://www.aaos.org/research/overviews/cervicaldisc.pdf>

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Burkus JK, Traynelis VC, Haid RW, Jr., et al. Clinical and radiographic analysis of an artificial cervical disc: 7-year follow-up from the Prestige prospective randomized controlled clinical trial: Clinical article. J Neurosurg Spine. Oct 2014;21(4):516-528. PMID 25036218

(Last Accessed 4/27/16)

Bae HW, Kim KD, Nunley PD, et al. Comparison of Clinical Outcomes of One and Two-level Total Disc Replacement: 4-year Results from a Prospective, Randomized, Controlled, Multicenter IDE Clinical Trial. Spine (Phila Pa 1976). Mar 17 2015. PMID 25785955

(Last Accessed 4/27/16)

Davis RJ., Kim KD., Hisey MS., Hoffman GA., Bae HW., Gaede SE., Rashbaum RF., Nunley PD., Peterson DL., Stokes JK. 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. J Neurosurg: Spine. 2013; 19:532-545.
(Last Accessed 4/27/16)

Summary of Changes:

02/09/2017

- I., Criteria for Approval: A.: Added the underlined:
MHI will cover the Mobi-C cervical intervertebral disc (IVD) prosthesis for degenerative cervical disc disease with intractable radiculopathy neck/arm pain and/or myelopathy as medically necessary in a skeletally mature individual at 1 or 2 contiguous levels when ALL of the following criteria are met:
 - A., 1.: Added the underlined:
Single- or 2-level degenerative disc disease **only** from C3 to C7 confirmed by radiographic studies (CT, MRI, X-rays),
- III., What is Not Covered, A.:
Deleted 6. (Neck or arm pain of unknown etiology)
Added 14.: Mobi-C with laminectomy