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Governor

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PREAUTHORIZATION CHECK SHEET
CERVICAL ARTIFICIAL DISC

Claimant: _____ **Claim Number:** _____ **DOI:** _____
Surgeon: _____ **Phone Number:** _____ **Contact:** _____

- Mobi-C Secure-C Bryan-C
 Prestige-C ProDisc-C PCM-C

FDA Guidelines indicate surgery for one level only, with the exception of the Mobi-C which has been approved for replacement of two (2) adjacent cervical discs/levels

Compensability should NOT be in question at the time of preauthorization for this procedure.

*****This procedure REQUIRES peer review by spine surgeons.*****

1. Pre-operative work up should be documented in the medical notes. **ALL CRITERIA ARE REQUIRED.**
2. Dates should be documented for all diagnostic tests performed.
3. If medical data is lacking, the surgeon will be required to provide the missing information.

Surgeon meets training qualifications YES NO
COPY OF TRAINING CERTIFICATE MUST BE INCLUDED

Oswestry Neck Pain Questionnaire YES NO

Indications: Use of the cervical artificial disc following SINGLE level discectomy from C3-C7 for skeletally mature patients (18-60 years of age) with conditions that result in diseased or bulging disc (intractable radiculopathy and/or myelopathy). The Mobi-C can be used to replace two adjacent cervical discs from C3-C7 for the same pathology. (No previous fusion at the same levels or adjacent levels.)

1. MRI (Within last 12 months, must show degenerative disc disease at C3-C7).	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date: _____
2. Discogram (preferred but not required, must indicate concordant pain at C3-C7).	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date: _____
3. Plain x-rays obtained (within last 12 months):			
a. Standing AP.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date: _____
b. Standing Lateral Flexion.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date: _____

c. Standing Lateral Extension. d. Any evidence of mechanical instability or alignment. e. Documentation the x-rays were taken in the <u>upright</u> position.	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No	Date: _____
4. Complete history and physical documenting the need for surgery and any contraindications.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date: _____
5. One of the following conditions must be confirmed by imaging: a. Herniated nucleus pulposus. b. Spondylosis defined by the presence of osteophytes. c. Loss of disc height.	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No	
6. Previous spine surgeries, including locations and dates. (List below): SURGERY WILL BE DENIED IF PREVIOUS SPINAL FUSION AT THE SAME LEVEL OR ADJACENT LEVEL.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
7. Conservative therapy been tried FOR AT LEAST 6 MONTHS. If yes, specify the therapy and the dates initiated on (List below):	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
8. Active smoker (smoking)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
9. Substance abuse (drugs or alcohol)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
10. Patient Contraindications: a. Osteopenia or osteoporosis with a measured T-score<1 b. Significant degeneration/herniation at other levels. c. Prior anterior cervical surgery. d. Significant facet arthritis at the operative level or at a level not treated by the replacement of disc e. Symptomatic or congenital stenosis. (<i>Some radiology reports may mention, "Central narrowing" but the surgeon may think it is insignificant or unrelated to the patient's symptoms.</i>) f. Marked cervical instability on radiographs (radiographic signs of subluxation >3.5mm or angulation of the disc space more than 11 degrees greater than adjacent segments g. Significant kyphotic deformity or significant reversal of lordosis. h. Severe spondylosis characterized by bridging osteophytes or a loss of disc height >50% or an absence of motion <2 degrees.	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No	

i. History of chronic steroid use. <i>(If a history of long term steroid use, may still have disc if now off of steroids, bone density scan with factor > or equal 1.0, and not expected to require chronic steroid therapy in the future.)</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
j. Allergy to titanium, polyethylene, cobalt, chromium, or molybdenum.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
k. Pregnancy.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
l. Active infection, systemic (AIDS, HIV, Hepatitis) or localized spinal.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
m. Autoimmune disorder.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
n. Calcification of abdominal vasculature per plain x-rays or CT scan.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
o. History of previous major anterior vessel surgery.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
p. Obesity. <i>(Body mass index >40 or 100 lbs. over ideal body weight)</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
q. Vertebral endplate dimensionally smaller than 34.5mm in the lateral and/or 27mm in the anterior-posterior directions	<input type="checkbox"/> Yes	<input type="checkbox"/> No
r. Rheumatoid arthritis.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
s. Clinically compromised vertebral bodies at the affected level due to current or past trauma.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
t. Significant cervical anatomical deformity or compromised vertebral bodies at the index level (ankylosing spondylitis, rheumatoid arthritis)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
u. Symptoms necessitating surgical treatment at more than one cervical level.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
v. Evidence of inability to understand the procedure.	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Requesting Surgeon Signature

Date

Sent for Peer Review

Date

Notes: _____ Date: _____

References

FDA approves cervical disc implant treatment. Empowered Doctor. Retrieved 2-10-14 from: www.empowereddoctor.com/fda-approves-cervical-disc-implant-treatment

US Food and Drug Administration. Page last updated 9-6-13. Bryan Cervical Disc-P060023. Retrieved 2-6-14 from: <http://www.fda.gov/MedicalDevices/Products and MedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm162968.htm>

US Food and Drug Administration. Page last updated 9-11-13. Mobi-C Cervical Disc Prosthesis (two level) – P110009. Retrieved 2-6-14 from: <http://www.fda.gov/MedicalDevices/Products and MedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm367809.htm>

US Food and Drug Administration. Page last updated 1-17-14. PCM Cervical Disc System – P100012. Retrieved 2-6-14 from: <http://www.fda.gov/MedicalDevices/Products and MedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm327487.htm>

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