



State of Wyoming

Department of Workforce Services



Mark Gordon
Governor

DIVISION OF WORKERS' COMPENSATION
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Cheyenne, Wyoming 82002
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Robin Sessions Cooley
Director

PREAUTHORIZATION CHECK SHEET LUMBAR ARTIFICIAL DISC

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

PRODISC-L

FDA GUIDELINES INDICATE SURGERY FOR ONE LEVEL ONLY.

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 Low Back Disability Questionnaire YES NO

Indications: Degenerative disc disease at **ONE** level, level L3-S1 (Prodisc), causing discogenic low back pain, confirmed by patient history, physical examination, radiographic studies and procedure(s) to isolate the causative disc. Patients must have no more than a grade 1 spondylolisthesis, have failed at least 6 months of verified conservative therapy, and be skeletally mature (18 to 60 years of age).

1. MRI (Within last 12 months, must show degenerative disc disease L3-S1 for Prodisc)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date: _____
2. Discogram (Preferred but not required, must indicate concordant pain at L3-S1 for Prodisc)	<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	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date: _____
d. Any evidence of mechanical instability or alignment	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date: _____
e. Documentation the x-rays were taken in the <u>upright</u> position.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date: _____

4. Ferguson view at the operative level is documented and notation addressing the shape of the endplate. a. Ferguson view NOT needed if MRI or CT clearly indicates endplate spacing adequate. b. If documentation is NOT ideal for implantation, the surgeon MUST indicate how they will address the shape of the endplate.	<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No
5. Complete history and physical documenting the need for surgery and any contraindications.	<input type="checkbox"/> Yes	<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. Scoliosis > 11 degrees of sagittal deformity c. Greater than grade 1 spondylolysis at the affected level d. Spondylolisthesis, retrolisthesis or anterolisthesis at the operative level of > 3mm. e. Symptomatic central 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. Subarticular stenosis caused by facet joint hypertrophy with nerve compression in the lateral recess. g. Tumor, Neoplasm h. Arachnoiditis 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>) j. Radiographic confirmation of facet joint disease or degeneration. (<i>Unless facet pain is ruled out by negative facet injections</i>) k. Facet joint ankylosis. l. Allergy to titanium, polyethylene, cobalt, chromium, or molybdenum. m. Pregnancy. n. Leg pain present due to nerve compression other than isolated foraminal stenosis at the affected level, or contained herniation, which can be removed by anterior discectomy. o. Noncontained or extruded herniated nucleus pulposus. p. Active infection, systemic (AIDS, HIV, Hepatitis or localized spinal)	<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"/> 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 <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

q. Autoimmune disorder.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
r. Calcification of abdominal vasculature per plain x-rays or CT scan.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
s. History of previous major anterior vessel surgery.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
t. Obesity. (Body mass index > 40 or 100 lbs. over ideal body weight)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
u. Vertebral endplate dimensionally smaller than 34.5 mm in the lateral and/or 27 mm in the anterior-posterior directions.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
v. Rheumatoid arthritis.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
w. Clinically compromised vertebral bodies at the affected level due to current or past trauma.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
x. Isolated radicular compression syndromes, especially due to disc herniation.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
y. Pars defect.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
z. Bony lumbar stenosis.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
aa. 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

US Food and Drug Administration. Page last updated 9/5/13. Prodisc-L Total Disc Replacement-P050010. Retrieved 2/6/14 from:
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm077620.htm>