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Governor

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DIVISION OF WORKERS' COMPENSATION
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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 REQURED**
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)	☐ Yes	☐ No	Date:
2. Discogram (Preferred but not required, must indicate concordant pain at L3-S1 for Prodisc)	☐ Yes	☐ No	Date:
3. Plain x-rays obtained (within last 12 months):			
a. Standing AP	☐ Yes	☐ No	Date: _____
b. Standing Lateral Flexion	☐ Yes	☐ No	Date: _____
c. Standing Lateral Extension	☐ Yes	☐ No	Date: _____
d. Any evidence of mechanical instability or alignment	☐ Yes	☐ No	Date: _____
e. Documentation the x-rays were taken in the *upright* position.	☐ Yes	☐ 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.	☐ Yes ☐ Yes ☐ Yes	☐ No ☐ No ☐ No
5. Complete history and physical documenting the need for surgery and any contraindications.	☐ Yes	☐ 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:**	☐ Yes	☐ No
7. Conservative therapy been tried FOR AT LEAST 6 MONTHS. If yes, specify the therapy and the dates initiated on (List below):	☐ Yes	☐ No
8. Active smoker (smoking)	☐ Yes	☐ No
9. Substance abuse (drugs or alcohol)	☐ Yes	☐ 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. *(Some radiology reports may mention, "Central narrowing" but the surgeon may think it is insignificant or unrelated to the patient's symptoms.)* 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. *(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.)* j. Radiographic confirmation of facet joint disease or degeneration. (*Unless facet pain is ruled out by negative facet injections)* 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)	☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes	☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No

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