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To: Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Blvd. (Mailstop C1-09-06)
Baltimore, MD 21244.

This is a formal request for an NCD on the CHARITE-Lumbar Artificial Disc Replacement. This device was approved by the FDA in the Fall of 2004. [1, 2, 3] It has been used in Europe for over 15 years in various forms. The benefit categories are: Inpatient Hospital Services and Physicians' Services.

The population in question is the elderly Medicare patient. Given the contraindications of osteoporosis, the fact that none of the studies were done in patients over the age of 60, and the fact that CHARITE is marketed primarily to the young, active patient, I question its use in the elderly Medicare beneficiary. I am worried about the misuse of CHARITE until better data is available.

Clinical issues: While the manufacturer states that cases involving the insertion of a spinal disc device are clinically similar to cases having a spinal fusion, the operations are not the same. While the patients may be similar in their signs, symptoms, and diagnoses, the spinal disc device patients do not undergo fusion of their spines. The manufacturer states that the CHARITE disc is inserted through an anterior approach, and in that respect the surgery is similar to anterior fusions. However, the lumbar spine can be fused using an anterior or posterior approach to the patient, and DRGs 497 and 498 include both of these approaches to the spine. Revision surgery to remove the CHARITE disc can be potentially life-threatening.

In examining both the scientific literature and the popular press, I find the following deficits:

The majority of studies are from Europe and are merely case series. In the several years that the disc has been on the market in Europe, it is disappointing that no true long term randomized or comparator study has been completed.[4] Case series are an inadequate study design to determine the degree to which an observed patient improvement (in this case, pain relief or improved function) is a result of natural healing processes, regression to the mean, or placebo effects, or is affected by other factors.

Van Ooij[5], et al, detailed the complications from artificial disc placement. The patient population was disabled patients operated for degenerative disc disease with a CHARITE disc prosthesis 1-13 years previously. Their recurrent or persistent back and leg pain was

caused mainly by disc degeneration at neighboring levels, hyperlordosis of the operated segment, subsidence and migration. Van Ooij and colleagues continue highlighting several issues with the artificial discs. Finally, they note that "Although theoretically appealing, [especially in younger patients], there are currently insufficient data to assess the performance of intervertebral disc arthroplasty adequately. Introduction of this new technology has not followed the principles of scientific prudence, and despite almost 20 years of clinical application, there is doubt concerning the safety and efficacy of the method."

Although two studies were recently published in Spine, these were the formal publication of the FDA IDE studies. Major deficits with these studies are the relatively short duration of follow up and failure to include an older Medicare-aged study population.[6,7] Other problems noted in an accompanying commentary include the fact that the artificial disc group was compared to a fusion procedure of dubious efficacy; the fact that two-thirds of patients continued to take narcotic pain medications after surgery (even when judged "successful"); and almost 40% failed to have significant restoration of spine motion.[8]

In the popular press, some issues discussed in many professional societies have come to light. On June 7, 2005 the Wall Street Journal published an article "Back Fire: J&J's New Device For Spine Surgery Raises Questions; Artificial Disk Aims to Help Body's Natural Movement; Some See risk if It Slips: 'Big Money Riding on This." [9] The article discusses a "vigorous debate" in the clinical and scientific community that has emerged about the durability and effectiveness of the CHARITE disc compared with spinal fusion. Some surgeons are predicting many patients will suffer complications over the next 10 to 15 years and will need to have the CHARITE disc removed.

In sum, the CHARITE disc is a new technology whose real place in spine therapy remains to be determined. It is untested in adults over the age of 60, in whom osteoporosis (often undiagnosed) is common, and in whom we might reasonably expect higher complication rates and lower success rates. I hope that CMS will open an NCD on this topic to investigate further, and potentially issue a national non-coverage decision, at least until better scientific evidence is available. Thanks for considering this issue.

Sincerely,

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REFERENCES

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4. Note that Lemaire, a case series with some long term data that is often cited, is available only in French, and is not part of this literature review

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