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Lumbar Artificial Disc Replacement with the Charite™ Artificial Disc: Addendum to Department of Labor and Industries Artificial Disc Replacement Health Technology Assessment published November 1, 2004.

Summary

As of June 2006 the Charite disc is the only intervertebral prosthesis (artificial spinal disc) approved for marketing by the FDA. When new devices for disc replacement are approved and/or when new scientific evidence addressing the effectiveness of these devices is published the department's evidence reviews and policies will be updated.

The department's original review assessed information available for the Charite disc from the FDA IDE study that was required prior to marketing and that is the basis of the FDA's approval order and from prospective case series. The review also included prospective case series reports of patients who treated with the Charite disc.

For this update we reviewed health technology assessments from multiple organizations and an internal analysis of the available evidence for lumbar disc replacement from the Centers for Medicare & Medicare Services (CMS). These assessments include critical analysis of available scientific literature relevant to understanding the safety and effectiveness of the Charite disc as of April 2006.

One additional study relevant to this technology was published on May 15, 2006 reporting on the number of revision surgeries performed among all subjects included in the Charite IDE study.

Evidence Reviewed

McAfee et al.¹ analyzed data from 688 subjects treated under the IDE study. The analysis presents data for all Charite recipients compared to the 99 fusion cases treated from the randomized arm of the IDE study.

The objective of this study was to analyze the incidence of reoperation in all patients enrolled in the IDE study, and the reasons for reoperation.

Methods

The FDA IDE study was carried out in 14 centers within the United States. Each center was permitted to perform up to 5 disc replacements as "training cases" prior to enrolling and treating randomized subjects. Additional subjects were permitted to receive the Charite disc as "continued access" subjects. These patients were not randomized to treatment and met all inclusion criteria with the exception that positive discogram was not required.

¹ McAfee PC et al. Revisability of the CHARITE artificial disc replacement: analysis of 688 patients enrolled in the U.S. IDE study of the CHARITE Artificial Disc. Spine. 2006 May 15;31(11):1217-26

Analysis was performed of clinical chart notes, operative notes and adverse event reports for all subjects requiring reoperation following the original

Results

A total of 688 subjects are included in this report. Ninety-nine received fusion in the randomized portion of the IDE study. Of those receiving the Charite disc 71 were training cases, 205 randomized subjects and 313 continued access. All subjects received a single level implant and were treated per the IDE protocol (with the exception of positive discography for continued access subjects as noted). All subjects were observed for a minimum of 2 years.

Table 1: Number of reoperations required in each group, average amount of time from implant to revision and number of vessel injuries occurring. Percentages are in parentheses.

Variable	FDA IDE Fusion Patients	Charite Disc Patients In FDA IDE Study			
		All subjects	Training	Randomized	Continued Access
Total N	99	589	71	205	313
Reoperation	10 (10.1)	52 (8.8)	5 (7.0)	13 (6.3)	34 (10.9)
Mean days to reoperation	423	266	218	476	193
Approach-related vessel injury Original	2 (2.0)	20 (3.4)	4 (5.6)	9 (4.4)	7 (2.2)
Approach-related vessel injury Revision	0	4/24 (16.7)	1/4 (25.0)	0	3/17 (17.6)

The overall reoperation rate was 8.8% for the 589 subjects receiving a Charite disc and this is not significantly different from the 10.1% among randomized fusion subjects.

Author Conclusions

Disc replacement with the Charite disc did not preclude further procedures as the index level as close to one third were revised to a new motion preserving prosthesis and close to two were converted to fusions.

Centers for Medicare & Medicaid Services National Coverage Decision

In August 2005 CMS started a process to determine a national coverage policy for lumbar artificial disc replacement. This process resulted in an internal assessment of all evidence on the Charite artificial disc. The CMS process included 2 public comment periods to allow anyone to provide comment, relevant scientific data, or criticism of the CMS methodology in evaluation of the technology.

The resulting National Coverage Decision (NCD) for Medicare beneficiaries was published in final form on May 15, 2006. The NCD provides non-coverage for

beneficiaries over 60 years of age and leaves coverage policies for beneficiaries under 60 years to be determined by local carriers. CMS concluded that (excerpt):

After thoroughly reviewing the existing data for LADR [lumbar artificial disc replacement] with the Charite lumbar artificial disc, important questions remain regarding patient selection, adverse events, and long term outcomes. The Charite PMA trial was limited to patient ages 18 to 60 years old, excluding the age group with the highest prevalence of degenerative disc disease. Due to the lack of evidence of benefit for those Medicare beneficiaries over the age of 60, CMS will noncover LADR with the Charite lumbar artificial disc in this population.

Some evidence does exist for patients 60 years of age and under, though the results of the Charite PMA noninferiority trial are unconvincing as an adequate demonstration of health benefit and do not provide a sufficient basis for a NCD at this time.

The complete assessment from CMS is available here:

<http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=170>

The regional carrier for Medicare in Washington State and 10 other western states is Noridian Administrative Services LLC. Noridian's current policy for artificial discs states:

Noridian Administrative Services (NAS) has determined that the currently FDA-approved artificial discs do not meet the reasonable and necessary criteria for the general Medicare population and therefore are a non-covered service to Medicare beneficiaries.

The complete Noridian policy is available here:

http://www.noridianmedicare.com/provider/pubs/med_b/policy/final/11state/b2006_02.html

The Charite artificial disc is not covered for Medicare beneficiaries in Washington State.

Technology Assessments

Hayes Brief Charite Artificial Disc for Degenerative Spine Disease, April 3, 2006

The Hayes assessment of the Charite disc concludes that the evidence does not support its use. There is insufficient evidence of safety and effectiveness.

Institute for Clinical and Systems Improvement, Lumbar Artificial Intervertebral Discs December 2005

The Institute for Clinical Systems Improvement (ICSI) committee concluded that there is no long-term evidence (follow-up beyond 2 years post implant) from well-designed studies and that long-term safety remains unknown. Additionally, studies to date have not demonstrated that artificial disc implantation has benefit over other procedures. No

studies were found that compared disc replacement with other intensive multidisciplinary or non-surgical alternatives.

“Overall, the long-term efficacy of the lumbar artificial disc in terms of improving pain rates, disability, range of motion, and quality of life is unknown.”

Blue Cross Blue Shield Technology Evaluation Center, Artificial Intervertebral Disc Replacement, April 2005

The Technology Evaluation Center (TEC) concluded that there is insufficient evidence of the effectiveness of artificial discs. The TEC review includes thorough discussion of potential issues with the IDE study including the nature of the design and analysis of findings that make interpretation of results difficult.

**WorkSafe BC. Artificial cervical and lumbar disc implants:
A review of the literature, April 13, 2005.**

The Workers Compensation Board of British Columbia review of literature recommends that artificial intervertebral discs for cervical and lumbar applications should be considered still at an experimental stage.

Other Insurers

Aetna Clinical Policy Bulletin

Aetna considers the Charite artificial disc medically necessary for spinal arthroplasty for patients with degenerative disc disease at one level from L4 to S1 who have failed at least six months of conservative management.

Cigna Healthcare Coverage Position, Intervertebral Disc Prosthesis

“CIGNA HealthCare does not cover intervertebral disc (IVD) prosthesis for any indication because it is considered experimental, investigational or unproven.”

Humana

Humana considers artificial disc replacement technology experimental/investigational.

Premera Blue Cross Corporate Medical Policy, effective May 10, 2005.

Premera considers artificial intervertebral discs to be investigational.

Regence Medical Policy No. 127

Regence considers artificial intervertebral discs investigational.

Ohio Workers Compensation

Ohio Workers Compensation covers artificial discs as an alternative to fusions.

Unicare Medical Policy, Artificial Intervertebral Disc

Unicare considers artificial discs investigational/not medically necessary.

Conclusion

The department considers lumbar disc replacement with the Charite artificial disc investigational and controversial.

This conclusion is based on the department's original assessment of evidence for artificial disc technologies (November 2004) and review of subsequent publications. The CMS assessment summarizes what is currently known about the Charite disc. There is not consistent high quality evidence showing the Charite artificial disc to be safe and effective.

The long-term safety and effectiveness of the Charite disc remains unknown. Results of the only experimental study of Charite are reported after 24 months, though the disc is intended for much longer use. Long-term data from observational studies provide conflicting evidence regarding the effectiveness of the Charite disc.

Additionally, the recent publication² of reoperation rates among IDE subjects emphasizes the need for longer-term follow-up. The authors of this paper cite surgeons new to the implant procedure and less rigor in adhering to selection criteria as possible factors leading to the higher reoperation rate observed in continued access subjects. This rate (10.9%) is markedly higher than that observed in the randomized group (6.3%), though not quite statistically significant. It remains to be seen what widespread safety issues may emerge as the device is used outside of research settings³.

² McAfee PC et al. Revisability of the CHARITE artificial disc replacement: analysis of 688 patients enrolled in the U.S. IDE study of the CHARITE Artificial Disc. *Spine*. 2006 May 15;31(11):1217-26

³ McAfee PC. Cervical and Lumbar Disc Replacement- The Ease of Revision. *US Orthopedics Review* 2006. November 2005: 38-42.

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