

HERC Coverage Guidance – Artificial Disc Replacement Disposition of Public Comments

General Comments

| Stakeholder | # | Comment | Disposition |
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| <i>North American Spine Society</i> Burr Ridge, IL | 1 | We are thankful for the opportunity to comment on the recently proposed draft policy from Oregon Health Evidence Review Commission (HERC) to change the current coverage determination for artificial disc replacement. In reviewing the proposed policy we note that OR HERC has used Washington State Health Care Authority Health Technology Assessment Program - HTA report: Artificial discs replacement (ADR). Olympia, WA: Health Technology Assessment Program published in 2008. NASS agrees that degenerative disc disease, low back pain, cervical disc herniation with radiculopathy, cervical degenerative disc disease and the treatment options for these health problems provide rationale for guidance development including: <ul style="list-style-type: none"> • Represents a significant burden of disease • Represents important uncertainty with regard to efficacy or harms • Represents important variation or controversy in clinical care • Represents high costs, significant economic impact • Topic is of high public interest | Thank you for your comment. |
| | 2 | In regard to lumbar disc replacement the HERC Coverage Guidance: ADR should be covered service only when all following criteria met: <ul style="list-style-type: none"> • Lumbar artificial disc replacement <ul style="list-style-type: none"> ○ 1) Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency <p>NASS Comment - Defining appropriate non-operative care has been an issue in a number of spine trials.¹ Undoubtedly, patients should undergo at least 6 months of aggressive non-operative management before surgery. However, these plans vary in their time requirements, cost, and reported effectiveness.² More importantly, the best data on multi-disciplinary rehabilitation programs comes from Scandinavia.³ These programs may not be generalizable to North America in general or Oregon in particular. If a data driven approach is to be used in considering surgical management, it should also be considered when the treating providers have documented months of expensive and time-consuming non-operative treatment.</p> | The HTAS understands the variability in multidisciplinary rehab programs, but does not feel this negates the importance of an adequate trial of non-operative care. |
| | 3 | <ul style="list-style-type: none"> • Lumbar artificial disc replacement <ul style="list-style-type: none"> ○ 2) Patients must be 60 years or under <p>NASS Comment - Agree</p> | Thank you for your comment. |
| | 4 | <ul style="list-style-type: none"> • Lumbar artificial disc replacement <ul style="list-style-type: none"> ○ 3) Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes: <ul style="list-style-type: none"> ▪ Failure of at least six months of conservative treatment ▪ Skeletally mature patient | The HTAS agrees that the evidence pertaining to multilevel disc replacement may be re-examined in |

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| | | <ul style="list-style-type: none"> ▪ Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging <p>NASS Comment - At this point, data supporting multilevel lumbar artificial disc replacement remains limited, but there are some reports of successful use of two level ADRs and Hybrid constructs incorporating fusion and disc replacement.⁴ In 2011, Delamarter and coworkers published minimum two year follow-up data on 2 level ProDisc-L implantations.⁵ Clinical success rates of 58.8 percent in the total disc replacement group compared favorably to the one level study and to the 47.8 percent success achieved in the arthrodesis group. NASS believes that as evidence continues to develop, the optimal management of these groups should be periodically re-examined and open for comment.</p> | the future, if indicated. |
| | 5 | <ul style="list-style-type: none"> • Cervical artificial disc replacement <ul style="list-style-type: none"> ○ 1) Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes: <ul style="list-style-type: none"> ▪ Skeletally mature patient ▪ Reconstruction of a single disc following single level discectomy for intractable symptomatic cervical disc disease (radiculopathy or myelopathy) confirmed by patient findings and imaging. <p>NASS Comments - At this point, data supporting multilevel cervical artificial disc replacement remains limited, but there are reports of successful use of multilevel level ADRs. Shin and others compared 20 patients with 2 level cervical ADR with 20 patients with anterior discectomy and fusion.⁶ At 2 year follow-up, the ADR patients had better NDI recovery; less postoperative neck pain, faster C2-C7 ROM recovery, and less adjacent ROM increase. Goffin and colleagues reported favorable 4 and 6 year follow-up data of Bryan cervical disc prosthesis patients, including 9 two level patients.⁷ Huppert and others noted similar outcomes when comparing 175 patients treated at one level with 56 treated at two or more levels.⁸ NASS believes that as evidence continues to develop, the optimal management of these groups should be periodically re-examined and open for comment</p> <p>Thank you for extending the opportunity to NASS to review and comment on this the Oregon HERC coverage guidance. Do not hesitate to contact us directly with any further questions or concerns.</p> | The HTAS agrees that the evidence pertaining to multilevel disc replacement may be re-examined in the future, if indicated. |
| Neurological Surgeon Portland, OR | 6 | Page 2 – “As much as 40% of chronic low back pain may originate in the intervertebral disc.” The reference for this statement is from a paper which used discography to make this determination. Given the tenuous evidence for discography as discussed in another document I have reviewed from your group, this begs the whole question of how to know if a specific patient’s back pain originates from a single disc and therefore might be ameliorated by an artificial disc. | Thank you; coverage guidance revised to reflect this information. |
| | 7 | Page 2 – “the current surgical standard of care for lumbar degenerative disc disease is lumbar fusion”. I would rather see a statement like - as there is currently no definitive way to determine a discogenic source of pain (see statement on discography), there is no agreed upon or Class I evidence based surgical standard for treatment of degenerative disc disease, but fusion, discectomy, intradiscal electrocoagulation therapy (IDET), various dynamic fusion devices, and disc arthroplasty have been in use for this condition. | Thank you; coverage guidance revised to reflect this information. |
| | 8 | Page 2-3 – The constant intermingling of the cervical and lumbar statements is confusing to me and I think would be much better | Thank you; |

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| | | separated. I say this because the lumbar devices are indicated only for back pain and not for nerve root decompression (which comes back around to the discography problem); whereas, the cervical devices are indicated not so much for neck pain, but for an alternative to fusion in an otherwise standard nerve root and/or spinal cord decompression procedure. These two procedures are therefore not interchangeable and should be discussed separately. | coverage guidance revised to separate cervical and lumbar disease. |
| | 9 | Page 5 – “and/or >110 of rotational difference”. Should this be 11 degrees? It is surely not 110 degrees. | Thank you; this typographical error has been corrected. |
| | 10 | Page 6 – Lytic spondylolisthesis, not “lyric”. | Thank you; this typographical error has been corrected. |
| | 11 | The FDA approvals are for single level surgery, but you will surely face the question of whether a patient with a successful single level placement can subsequently undergo another “single level” placement at another level at another surgery. | HTAS appreciates this comment, but is not prepared to address additional “single level” surgeries in the document. |

Comments on Lumbar Artificial Discs

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| <i>Neurological Surgeon</i> Portland, OR | 12 | One major issue with lumbar artificial discs is the very difficult nature of revision surgery. If the device needs to be removed by a repeat anterior approach, the scarring around the great vessels has been reported to make this extremely difficult with a high incidence of vascular injuries, some of which have been life threatening. Patients should be aware that the follow up is not long enough to prognosticate on the need for revision and that revision surgery can be complicated. | HTAS appreciates this concern. However, the evidence does not address revision surgery; therefore the HTAS believes that this issue is outside the scope of this document. |

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| | 13 | As corollaries to this, some would suggest that patients with atherosclerosis are not good candidates for surgery as vascular injury may occur even at the first surgery. Age is only a surrogate marker for vasculopathy and some younger patients may have atherosclerotic vessels which are difficult to safely mobilize. I have always used a vascular surgeon as the access surgeon for anterior lumbar surgery, but some neurosurgeons and orthopedic spine surgeons do their own approaches. Should there be a requirement for the use or availability of a vascular surgeon? | See comment #12 |

Comments on Cervical Artificial Discs

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| <i>Neurological Surgeon</i> Portland, OR | 14 | The literature review and assessment you have included was done in 2008. Additional pertinent papers have appeared since then. For example: 1. Bartels RHMA, et al: No justification for cervical disk prostheses in clinical practice: A meta-analysis of randomized controlled trials. <i>Neurosurgery</i> 2010; 66:1153-1160. These authors reviewed 9 reports with a total of 1533 patients. Complication rates did not differ between fusion and arthroplasty. Although many parameters at 12 and 24 months favored arthroplasty over fusion, the authors concluded that because the studies were not blinded, bias was likely the explanation for the perceived benefit. Therefore, they could not conclude that any benefit to arthroplasty was proven. | Thank you for providing this reference. |
| | 15 | 2. Zechmeister I, et al: Artificial total disc replacement versus fusion for the cervical spine: a systematic review. <i>Eur Spine J</i> 2011; 20:177-184. These authors concluded from their review of the literature that the results show non-inferiority but not superiority of arthroplasty. Complication rates did not differ between fusion and arthroplasty. They acknowledge (correctly I believe) that much of the variation in outcomes has to do with patient selection for surgery and not the specific technique used. As no cost data was yet available, they did not recommend arthroplasty for routine use until it could be shown to be more cost effective than fusion. | At this point in time, the HTAS is not requiring evidence of cost savings as a requirement for coverage of a technology. |
| | 16 | 3. Hadley M: The real value of cervical arthroplasty? <i>J Neurosurg Spine</i> 2011; 15:345-6. In this editorial response to a companion paper by Coric et al describing 269 patients randomized to fusion or arthroplasty, the author noted that only this trial and one other by Burkus et al had follow up of two years or more. Consequently, we do not know the failure rate of these devices in the long term nor how failures should be treated. He is also concerned about the unknown aspects of long term exposure to the alloys and organic components of these devices and the degradation products of these components. | Thank you for providing this reference. HTAS will continue to monitor the literature on this procedure, and re-review if indicated. |
| | 17 | 4. There is some concern about gradual ossification and loss of motion at cervical arthroplasties. For example Tu TH et al (<i>J Neurosurg Spine</i> 2012) found that at 38 months, heterotopic ossification was detectable on CT in 56.1% and from 3.7 to 10.3% of Bryan discs had ossified to the point of immobility. Another small report by Chung SB et al (<i>Acta Neurochir Wien</i> 2012) found motion limiting ossification at 24-36 months after Bryan disc implantation in 37% of their patients. A meta-analysis of this problem by Chen J et al (<i>Eur J Spine</i> 2011) found advanced heterotopic ossification in 11.1 and 16.7% of reported patients at 12 and 24 | See comment #16 |

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| | | months of followup. These reports all raise the concern that at some future date, a significant percentage of arthroplasties may well have become fusions. Whether the delayed time to fusion is still of benefit in preventing adjacent segment disease remains to be seen. | |