

HERC Coverage Guidance – Hip Resurfacing Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition																																				
<i>Orthopedic Surgeon</i> Salem, OR	1	<p>This procedure is the prosthetic of choice for the very young, 20-50 year old. The traditional total hip has a high failure rate. I can give you 7 references on this problem of early failure, dislocation, revision, and fracture.</p> <p>I have done 35 OHP patients in 2000-2002 with resurfacing and all of them are highly functioning. Several of them had drug and mental issues with good results. Hip resurfacing in my group of 123 patients 10-12 years postop, 98.4% which is better than total hips at 92-98% over ten years. I am part of a FDA study since 2000, so Salem has a high level of expertise.</p>	Thank you for this information.																																				
<i>Smith & Nephew, Inc.</i> Andover, MA	2	<p>Smith & Nephew, Inc. is a global medical technology business specializing in Endoscopy, Orthopedics and Wound Management. We comment on the draft coverage guidance for hip resurfacing based on Washington State’s 2009 Health Technology Assessment.¹ We offer updated clinical evidence to distinguish the clinical performance of our BIRMINGHAM HIP™ Resurfacing System (BHR).</p> <p>We support the recommendations stated in the guidance. Concerns raised subsequent to Washington’s Assessment led to ongoing reconsideration of the risk-benefit ratio of all metal-on-metal hip prostheses. Evaluation of hip resurfacing implants is most appropriately conducted by individual product rather than by categorical review because risks and evidence are not equal among products.²⁻⁶ Published evidence documenting clinical experiences over time varies among hip resurfacing products, both to each other and to standard hip arthroplasty.</p>	Thank you for your comment. The HTAS does not believe it is necessary at this time to evaluate hip resurfacing implants by individual product.																																				
	3	<p>Table 1 lists eight peer-reviewed publications reporting mid- to long-term survivorship data for BHR covering between 6 to 13 years of follow-up. Each shows an annual rate of revision below the maximum 1% per annum benchmark established by the UK’s National Institute for Health and Clinical Excellence (NICE)⁷, a recognized standard for hip prostheses.</p> <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>Table 1: Mid- to Long-term Survival of BHR Reference</th> <th>N</th> <th>Survival</th> <th>Years</th> </tr> </thead> <tbody> <tr> <td>Coulter⁸ (2012)</td> <td>230</td> <td>94.5%</td> <td>10</td> </tr> <tr> <td>McMinn⁹ (2011)</td> <td>3,095</td> <td>96.4%</td> <td>13</td> </tr> <tr> <td>Treacy¹⁰ (2011)</td> <td>144</td> <td>93.5%</td> <td>10.9</td> </tr> <tr> <td>Carrothers¹¹ (2010)</td> <td>5,000</td> <td>95.3%</td> <td>10</td> </tr> <tr> <td>Reito¹² (2011)</td> <td>144</td> <td>96.7%</td> <td>6</td> </tr> <tr> <td>Rahman¹³ (2011)</td> <td>329</td> <td>96.5%</td> <td>7</td> </tr> <tr> <td>Khan¹⁴ (2009)</td> <td>679</td> <td>95.7%</td> <td>8</td> </tr> <tr> <td>Holland¹⁵ (2012)</td> <td>100</td> <td>92%</td> <td>10</td> </tr> </tbody> </table>	Table 1: Mid- to Long-term Survival of BHR Reference	N	Survival	Years	Coulter ⁸ (2012)	230	94.5%	10	McMinn ⁹ (2011)	3,095	96.4%	13	Treacy ¹⁰ (2011)	144	93.5%	10.9	Carrothers ¹¹ (2010)	5,000	95.3%	10	Reito ¹² (2011)	144	96.7%	6	Rahman ¹³ (2011)	329	96.5%	7	Khan ¹⁴ (2009)	679	95.7%	8	Holland ¹⁵ (2012)	100	92%	10	<p>None of these were included in the van der Weegen 2011 SR.</p> <p>Only Treacy 2011 was included in the CTAF review. Figures in Table confirmed.</p> <p>Thank you for this information.</p>
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	4	Revision data for BHR are reported in the national joint registries of Australia ² , Sweden ³ , and England and Wales (UK). ⁴ BHR has an unadjusted rate of 0.72 revisions per 100 observed years in the Australian registry, compared to 1.7 and 1.23 revisions per 100 observed years for all other resurfacing devices and for MoM total hip arthroplasty (THA), respectively. ²	Unable to find these figures in the reference cited.
	5	The Swedish registry analysis adjusted for age, gender and diagnosis reported that BHR performs as well as a control group of THA devices, better than all MoM resurfacing devices and better than all MOM THA devices.	Unable to retrieve the Swedish registry from link provided. In the 2010 <i>Annual Report</i> , BHR performs as well as THA, and better than other resurfacing devices. Conclusion of this section of the report is as follows: “In summary we find that the risk of revision within five years and irrespective of cause is more than doubled in the use of resurfacing. The best-functioning design, BHR, involved no definite disadvantage regarding the risk of revision if used in men; but neither are there any clear advantages among these patients, either. Possible continued use of this implant concept should take place under strict control and be offered only to younger men. Several studies have shown that good surgical competence is important for the result. This means that the intervention should be performed only at a limited number of units that can maintain sufficiently large volumes to maintain their competence.”
	6	Following 9,678 BHR procedures, the Australian registry reports a revision rate of 6.3% at 10 years, while the UK registry reports a revision rate of 3.44% for 17,366 procedures at 5 years, both below NICE’s benchmark revision rate. In both registries, BHR demonstrates the lowest cumulative revision risk for reported MoM resurfacing devices.	Unable to find these figures in the reference cited for the Australian registry. Figures confirmed for the UK registry.
	7	Australian registry data also reports favorable performance of BHR compared with primary conventional THA in men under age 64. ²	Unable to find these figures in the reference cited.
	8	Survival data for 920 BHR procedures are reported by the Swedish Hip Arthroplasty Register. ³ At an average follow-up of 9 years, cup and stem revision rates of 2.2% and 4%, respectively, have been observed.	Figures confirmed in the 2010 Swedish Registry Annual Report.
	9	A broad evidence base documents the long-term clinical performance of the BHR system supporting its safety and effectiveness when implanted in accordance with the approved operative technique and in indicated patients. We applaud your decision to make hip resurfacing available to appropriate patients and appreciate the opportunity to comment.	Thank you for your comment.