


National Institute for Health and Care Excellence
IP843/2 Transaxial interbody lumbosacral fusion for low back pain
IPAC 10 May 2018

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 British Association of Spinal Surgeons (BASS)	General	<p>Having been forwarded your e-mail, it is my pleasure to respond to your invitation on behalf of the British Association of Spinal Surgeons (BASS).</p> <p>We note that having considered the limited evidence available and the specialists' comments, the advice from NICE in 2011 was that the specified procedure could be undertaken for the management of severe and refractory degenerative back pain affecting the lumbosacral junction provided:</p> <ul style="list-style-type: none"> • The Trust's clinical governance department was informed that the procedure was being undertaken • The operating surgeon had undertaken specific training in the procedure • The patient was appropriately consented and audit measures should be in place. <p>We note that little has changed in the proposed updated guidance. The original indications and recommendations remain the same with the additional recommendation that surgeons undertaking this procedure should be '<i>encouraged</i>' to enter the details onto the British Spine registry (BSR).</p> <p>Our considered comments on the proposed updated guidance are set out below:</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The updated draft guidance recommends that the procedure may be used provided that standard arrangements are in place for clinical governance, consent and audit. The main recommendation has changed from the 2011 guidance, which stated that the procedure should only be used with special arrangements for clinical governance, consent and audit or research.</p> <p>The number of procedures done per year in the UK is not included in Interventional Procedures Guidance. These</p>

		<p>1) We believe the specific indications for the use of this technique are very limited.</p> <p>2) We recommend that, if the data is available, the current number of procedures/year carried out in the UK is included in the guidance.</p> <p>3) We question how the proposed recommendations can be consistent with NG59, which states that fusion for low back pain should only be undertaken as part of a randomised controlled trial, when this recommendation is not contained within the proposed procedural guidance.</p> <p>4) We suggest that the wording of the recommendation for use of BSR should be strengthened.</p> <p>I will be grateful for acknowledgement of this e-mail.</p> <p>Kind regards</p> <p> Policy and Guidelines, BASS.</p>	<p>can be obtained using the relevant OPCS codes.</p> <p>NICE guideline 59 Low back pain and sciatica in over 16s: assessment and management was published in November 2016. It did not include this procedure because it had a 'special arrangements' recommendation. Because guidelines focus on placing established treatments in the care pathway, they will generally only include IP guidance that recommends 'standard' arrangements.</p> <p>Future revision of NG59 will take into consideration new recommendations for IPG387.</p> <p>IP guidance differs from other NICE guidance in that it addresses the safety and efficacy of interventions, not their role in routine clinical practice.</p> <p>Section 1.3 of the guidance will be changed to "Clinicians should enter data onto the British Spine Registry".</p>
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2	Company TranS1	General	<p>TranS1, the American manufacturer of the AxialIF procedure for spinal fusion utilizing the Transaxial Interbody Lumbosacral Fusion technique, responds as follows to the Committee's Draft Recommendations:</p> <p>TranS1 appreciates the diligence and thoroughness of the Committee in its substantive review of the medical literature and real world evidence related to Transaxial Interbody Lumbosacral Fusion, as well as the opportunity for TranS1 personnel to answer questions from Committee Members related to this procedure at the Committee Meeting in February, 2018.</p> <p>TranS1 applauds and fully endorses the Committee's recommendation to designate Transaxial Interbody Lumbosacral Fusion as a Standard Procedure. The benefits offered to patients and surgeons by the Transaxial approach include smaller incision size, less blood loss, shorter operating time, faster recovery time, and, importantly, the Transaxial procedure eliminates the need to incise the patient's core muscles in the stomach and/or back required by more traditional fusion methods for L5-S1; these are core muscles which aid the patient in her or his recovery and return to daily life. These advantages are gained while creating a stable, safe, and effective spinal fusion.</p> <p>TranS1 offers its sincere thanks and expresses gratitude for the diligent review performed by the Committee, and remains at all times willing and able to answer questions from NICE regarding Transaxial Interbody Lumbosacral Fusion.</p> <p>Submitted by [REDACTED] TranS1 Executive Vice President</p>	<p>Thank you for your comment.</p> <p>Consultee agrees with main recommendation.</p>
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