National Institute for Health and Care Excellence

IP972/2 Percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure

IPAC date: 9 September 2021

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS professional British Cardiovascular Society	**Section 1.1**	The draft recommendations, while not unreasonable, are rather open-ended for a technology which is not part of established UK practice. It might be sensible to include a recommendation that its use should be restricted to patients who meet the entry criteria into the main randomised controlled trial in his area. It appears from the specialist advice questionnaires that the device costs £10,000-12,000. Furthermore, the main trial was conducted in the US - what is known about the cost-effectiveness of using the device (in the NHS)? Might it be sensible to consider restricting use to patients who are entered into UK-based trials or to consider encouraging entry of patients into trials until data are available from non-US studies, for example, CardioMEMS HF system OUS post market study (NCT02954341; observational, cohort study; Australia, Belgium, Denmark, France and UK; estimated enrollment, n=800; estimated study completion date: December 2023)?	Thank you for your comment. The committee has considered this comment but has decided not to add a recommendation relating to patient selection criteria as this is covered by section 1.2: *"Patient selection, continuing monitoring and management should be done by a multidisciplinary team….."* Cost-effectiveness is not part of the remit of the IP Programme.
2	Consultee 2 Company	**Section 1.1**	We welcome the draft recommendations that support the percutaneous implantation of pulmonary artery	Thank you for your comment.

	Abbott Laboratories		pressure sensors in standard arrangements on the basis of adequate evidence on safety and efficacy data.	
3	Consultee 3 NHS professional British Society for Heart Failure	**Section 1.2**	Any alert from an implanted remote monitor for heart failure is only useful, if there is an action taken as a result. Direct 'Action' in this case involves patient contact to advise of changes to their heart failure management that may prevent worsening. This is usually initiated by physiologists and/or Heart Failure Nurse Specialist, perhaps after a Heart Failure MDT discussion. Most remote monitoring programs fail due to the lack of human resource to make it work effectively. In encouraging new remote technology for heart failure, it is advisable to also recommend that an adequately staffed multidisciplinary team is in place *before* its use. It is insufficient to only provide recommendations for the implanters.	Thank you for your comment. Section 1.2 has been changed to: *"Patient selection**, continuing monitoring and management** should be done by a multidisciplinary team…"* Section 2.5 has been changed to: *"This procedure allows the provision of data to guide **the ongoing monitoring and** management of chronic heart failure, with the aim of reducing hospitalisations caused by heart failure."*

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