

National Institute for Health and Clinical Excellence

Medical Technologies Evaluation Programme

EP 131 The PleurX peritoneal catheter drainage system for vacuum-assisted drainage of treatment-resistant, recurrent malignant ascites

Consultation Comments table

MTAC date: 19 January 2012

There were 12 consultation comments from four consultees (two NHS professionals, one manufacturer and one patient representative). The comments are reproduced in full.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
1	Consultee 3, Target Ovarian Cancer	1	Provisional recommendations: Overall we agree with the provisional recommendations. Section 1.2 - we feel there is the potential for confusion over the term treatment-resistant and that the recommendations would benefit from greater clarity around this. Is the recommendation that the PlureX device is considered when there are no more treatment options available. For example, women with ovarian cancer commonly develop resistance to platinum chemotherapy once this point is reached other chemotherapy agents will be used. Treatment-resistant could be interpreted as platinum resistant or all treatment options exhausted.	Thank you for your comment. Clinical advice indicates that the term 'treatment-resistant' applies when there is a low likelihood of further intervention preventing re-accumulation of ascites. The Committee considered this comment and decided to add an explanation to section 3.14 of the guidance.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
2	Consultee 3, Target Ovarian Cancer	2	The Technology: We agree that the PlureX peritoneal drainage system will help manage the often distressing side-effects of malignant ascites. There is enormous value to the patient and NHS in reducing the number of outpatient visits and bed days.	Thank you for your comment.
3	Consultee 3, Target Ovarian Cancer	3	Clinical Evidence: We agree that the decision of when to initiate use of the PlureX catheter system should be one that is made between the patient and their clinical team. Guidance on how to make that decision needs to be clearer, particularly around the use of the phrase treatment-resistant and what this actually means clinically confusion around this could lead to necessary delays.	Thank you for your comment. See response to comment 1. The Committee considered this comment carefully and decided to add additional information regarding the meaning of the term 'treatment-resistant' in section 3.14 of the guidance.
4	Consultee 3, Target Ovarian Cancer	4	NHS considerations: No comment	
5	Consultee 3, Target Ovarian Cancer	5	Cost considerations: No comment	
6	Consultee 3, Target Ovarian Cancer	6	Conclusions: Target Ovarian Cancer agrees with and supports the conclusions presented in this document.	Thank you for your comment.
7	Consultee 3, Target Ovarian Cancer	7	Implementation: No comment	
8	Consultee 3, Target Ovarian Cancer	8	Related NICE Guidance: No comment	

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
9	Consultee 1, NICE Sponsor Team, Department of Health	General	Thank you for the opportunity to comment on the evaluation of the above medical technology. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment.
10	Consultee 2, Royal College of Nursing	General	Unsure why a vacuum bottle is being used for this system? Unlike the pleural equivalent, it is not clear why a drainage bag cannot be used instead, This would cut costs considerably.	<p>Thank you for your comment.</p> <p>PleurX is licensed for home management vacuum drainage. According to the sponsor and advice from clinical experts, vacuum bottles do not rely on gravity therefore facilitating faster drainage. Vacuum bottles may be more reliable than drainage bags for use in the home and may also lower the risk of infection.</p> <p>The Medical Technologies Evaluation Programme (MTEP) evaluates technologies as notified and the PleurX system is indicated for vacuum-assisted drainage. The clinical evidence on which the Committee developed its recommendations is based on the use of the PleurX system for vacuum-assisted drainage.</p>
11	Consultee 2, Royal College of Nursing	General	Aware that Rocket Medical also produces an almost identical drainage system for pleural and peritoneal. They seem cheaper than Pleurx. Would the procedure be going through a similar appraisal process?	<p>Thank you for your comment.</p> <p>Medical technologies guidance evaluates the claimed benefits of single, notified, technologies compared with the current standard of care. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.</p>

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
12	Consultee 4, Product Development Manager	General	UK Medical Ltd supports the findings listed in the consultation document including the suggested provisional recommendations. UK Medical Ltd would like to be eligible to make a resolution request once the final guidance document has been produced. Please accept this response to the draft guidelines in line with section 6.2 of your process guide 'Eligibility to make a resolution request'.	Thank you for your comment. All consultees are eligible to receive the pre-publication guidance for resolution.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or Advisory committees."