National Institute for Health and Clinical Excellence

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

Issued: March 2012

NICE medical technology guidance 9

guidance.nice.org.uk/mtg9

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NICE medical technologies guidance addresses specific technologies notified to NICE by manufacturers. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

1.1 The case for adopting the PleurX peritoneal catheter drainage system in the NHS is supported by the evidence. The available clinical evidence suggests that the PleurX peritoneal catheter drainage system is clinically effective, has a low complication rate and has the potential to improve quality of life: it enables early and frequent treatment of symptoms of ascites, in the community, rather than waiting for inpatient treatment.

1.2 The PleurX peritoneal catheter drainage system should be considered for use in patients with treatment-resistant, recurrent malignant ascites.

1.3 The PleurX peritoneal catheter drainage system is associated with an estimated cost saving of £679 per patient when compared with inpatient large-volume paracentesis.

2 The technology

Description of the technology

2.1 The PleurX peritoneal catheter drainage system (UK Medical Ltd) is intended for use in the palliative management of treatment-resistant, recurrent malignant ascites (accumulation of fluid in the peritoneal cavity) in the community setting.

2.2 The PleurX peritoneal catheter is made of silicone and is 71 cm in length and 5.12 mm (15.5 Fr) in diameter. The distal end of the catheter has several side holes and is placed in the peritoneal cavity. There is a polyester cuff midway along the catheter, which is sited 1–2 cm within a subcutaneous tunnel and helps to secure the catheter in place by encouraging tissue growth into the polyester. The external end of the PleurX peritoneal catheter has a safety valve that prevents air entering or fluid leaking out of the catheter. A cap protects the valve and prevents debris from building up.

2.3 The drainage system comprises a 1 litre vacuum bottle with a drainage line that connects to the PleurX peritoneal catheter for fluid removal. It also includes a procedure pack that contains the supplies needed to perform the drainage procedure and to replace the cap and the gauze pad dressing over the catheter.

2.4 The PleurX peritoneal catheter is designed to remain in place indefinitely and patients and carers are trained to perform fluid drainage when needed by attaching the vacuum bottle to the catheter. A fresh valve cap and dressing are applied once the drainage is completed. For the majority of the time, the catheter is coiled up and covered with a gauze pad and a waterproof dressing.

2.5 The list prices stated in the sponsor's submission for the PleurX peritoneal catheter and the PleurX drainage kit with a 1 litre vacuum bottle are £245 and £64 per unit respectively.

2.6 The claimed benefits of the PleurX peritoneal catheter drainage system in the case for adoption presented by the sponsor are:

- Repeated drainage of ascitic fluid in community settings may allow greater patient independence, and the flexibility to fit the drainage procedure into their daily lives.
- Better symptom control by frequent drainage of smaller quantities of ascitic fluid. Symptoms associated with the accumulation of large amounts of ascites include breathlessness, nausea, bloating, acid reflux, abdominal pain, early satiety, reduced mobility and psychological distress related to negative body image.
- Reduced need for repeated large-volume paracentesis procedures and the associated risk of infection from repeated catheter insertion.
- Resource savings through a reduced need for hospital physician and nurse time, outpatient visits and hospital bed days.

Current management

2.7 The conventional management of treatment-resistant, recurrent malignant ascites involves repeated large-volume paracentesis (needle drainage of fluid) procedures that are carried out in hospital. Most commonly this is done as an inpatient procedure, although some centres are able to offer paracentesis as a day-case procedure. Inpatient paracentesis is carried out when patients have developed troublesome symptoms from recurrent ascites. This can entail some delay while waiting for admission, during which the patient continues to experience symptoms.

2.8 Paracentesis involves inserting a catheter, often under local anaesthetic, into the peritoneal cavity to drain ascitic fluid. During large-volume paracentesis the catheter stays in place until most of the ascites has been drained, which often exceeds 5 litres of fluid. This may be done in one go, but some patients cannot tolerate rapid drainage and may need to stay in hospital for one or more nights for repeated drainage procedures.

3 Clinical evidence

Summary of clinical evidence

3.1 The key clinical outcomes for the PleurX peritoneal catheter drainage system presented in the decision problem were:

- technical success of catheter insertion and drainage procedure
- resolution of symptoms (bloating, nausea, acid reflux, reduced appetite, negative perception of body image and resulting psychological distress)
- quality of life outcomes
- adverse events (catheter site infections, peritonitis, catheter occlusion, and haemorrhage or bowel perforation when the device is inserted)
- drainage frequency
- resource use outcomes, for example re-admission rates, re-interventions and duration of hospital stay.

3.2 The clinical evidence for the PleurX peritoneal catheter drainage system was based on nine observational studies (ten manuscripts), two of which were conducted in the UK. Six studies were case series with ten or more patients, one study was a qualitative case series (four patients), and there were three case reports (four or fewer patients). The External Assessment Centre considered all the studies identified by the sponsor to be relevant and did not identify any further studies.

3.3 Rosenberg et al. (2004) conducted a single-centre, retrospective, comparative case series. It evaluated treatment complication rates in patients whose malignant ascites was managed using the PleurX peritoneal catheter drainage system (n = 40 patients and catheters) compared with inpatient large-volume paracentesis (n = 67 patients, 392 procedures). Overall complication rates (using number of patients rather than number of procedures) were the same for both procedures: 7.5% (3 of 40; 95% CI 1.6% to 20%) for the PleurX peritoneal catheter drainage system and 7.5% (5 of 67; 95% CI 2.2% to 15%)

for large-volume paracentesis. In patients whose ascites was managed with PleurX, complications were infection (n = 1), leakage (n = 1) and loculations (n = 1), and all catheters were subsequently removed. Large-volume paracentesis complications were peritonitis (n = 3) and loculations (n = 2). The PleurX peritoneal catheter patency rate (defined as the number of catheters known to be functioning at death, study end or resolution of ascites) was 67.5% (n = 27); however 11 (27.5%) patients were lost to follow-up.

3.4 Courtney et al. (2008) carried out a multi-centre, single-arm, prospective case series evaluating treatment outcomes in 34 patients with malignant ascites treated with the PleurX peritoneal catheter drainage system over a 12 week follow-up period (or until death in some patients). It reported 100% technical success during the placement procedure (defined as intraperitoneal positioning of the device and the ability to withdraw ascitic fluid from the device at the completion of the procedure), with one minor procedural complication. Twenty patients experienced complications during the follow-up period including minor complications that resolved spontaneously. Two catheters needed to be removed, and other complications were infection (n = 2), occlusion/loculations (n = 4), leakage of ascitic fluid (n = 7), dizziness (n = 5), shortness of breath (n = 1) and severe anaemia (n = 1). Available records from 19 patients showed that the mean number of drainage sessions after placement of the PleurX peritoneal catheter was 23.3 per patient (range 5–56), and that of the total 433 sessions, 13% were performed by a nurse, and the remainder were carried out by the patient alone (28%) or a carer (58%). The catheter patency rate was 85% (n = 29); the remaining five patients were lost to follow-up. Changes in symptom severity between baseline and at 2, 8 and 12 weeks were assessed using a validated tool. There was a reduction in the severity of abdominal discomfort, bloating, diarrhoea and nausea at 2 and 8 weeks. An overall improvement in quality of life at 12 weeks was reported in 28% of respondents.

3.5 In a single-arm retrospective case series study, Mullan et al. (2011b) evaluated the procedural safety, mean survival, long-term efficacy, long-term complication profile and cost benefit of the PleurX peritoneal catheter drainage system in the management of recurrent malignant ascites (n = 50 patients, 52 catheters; two patients had their catheters re-inserted). On average, 5.3 inpatient large-volume paracentesis drainage procedures were performed before PleurX

peritoneal catheter insertion. A 100% procedural success rate was reported. A mean patient survival of 59.4 days (range 4–216 days) and 165 days (range 29–1036 days) was reported after the PleurX peritoneal catheter insertion and after the first inpatient large-volume paracentesis procedure respectively. The average hospital stay for patients having inpatient large-volume paracentesis was 2.8 days (range 1–6 days; n = 23) and the average ascitic fluid drainage per episode of paracentesis was 9.2 litres. Eight patients experienced complications after insertion of the PleurX peritoneal catheter, which were peritonitis (n = 1), lymphangitis (n = 1), occlusion/loculations (n = 3), ascitic leakage (n = 1), displacement (n = 1) and pain (n = 1); one catheter needed to be removed. Primary or secondary catheter patency at death was 100%, with management of complications augmented by multi-modality imaging and fibrinolysis of malfunctioning catheters.

3.6 In a single-arm retrospective case series study (n = 10 patients and catheters), Richard et al. (2001) evaluated the clinical outcomes after PleurX peritoneal catheter insertion in patients with treatment-resistant, recurrent malignant ascites. They reported 100% procedural success. Two patients experienced complications, which were occlusion/loculations (n = 1) and displacement (n = 1). The average time catheters remained in place was 70 days (range 1–100 days).

3.7 In a single-arm retrospective case, Tapping et al. (2011) evaluated the clinical outcomes after PleurX peritoneal catheter insertion in 28 patients (32 catheters) with treatment-resistant, recurrent malignant ascites. A technical success rate of 100% was reported. There were 12 complications, which comprised minor catheter site infections (n = 5), ascitic leakage (n = 1), displacement (n = 4), hernia (n = 1) and one further complication that was not described. No catheters needed to be removed other than those that were inadvertently dislodged. The catheters remained in place for an average of 113 days (range 5–365 days) and catheter patency was 86% (24 of 28).

3.8 Saiz-Mendiguren et al. (2010) conducted an observational descriptive case series study of patients (n = 10) who had the PleurX peritoneal catheter inserted. They analysed the duration of the procedure, pain reported by the patient during the procedure (using a visual analogue scale score), short- and

long-term complications, median patency of the catheter, and the volume of ascitic fluid drained at home (reported by telephone or during consultation). The technical success rate of the insertion procedure was 100%. Two patients reported discomfort during the procedure (visual analogue scale scores 2 and 3 out of 10). No complications were reported during or after the procedure. In one patient with generalised sepsis thought to be caused by a venous cannula, the PleurX peritoneal catheter was removed 58 days after placement as a precaution. Nine patients died; their catheters remained patent for a median of 52 days (range 13–113 days). At the end of the study, one patient remained alive with a patent catheter 124 days after placement. The mean ascitic fluid drainage reported by patients or their carers was approximately 1 litre (one vacuum bottle) every 2–10 days.

3.9 Day et al. (2011) conducted a small qualitative case study, which is currently available in abstract form, and from which the Committee considered detailed findings presented as academic-in-confidence data. Patients who had inpatient large-volume paracentesis were also included in the study, but no comparisons were drawn between the two treatment groups. Patient opinions and experiences were described in a narrative form and categorised into emergent themes following semi-structured interviews. The results revealed a positive trend of opinion towards PleurX, particularly relating to symptom improvement and increased convenience. All patients were reported to be glad that they had had the PleurX peritoneal catheter inserted. Some negative opinions were expressed including the fact that some patients did not like seeing the ascitic fluid, and others felt that the PleurX peritoneal catheter drainage system made them feel 'more of a patient'.

3.10 Three case reports relevant to the decision problem were also identified. Brooks et al. (2006) described one patient who had had a PleurX peritoneal catheter in place for 18 months and had developed three complications: drain blockage (immediately relieved by flushing), hernia around the catheter site, and the presence of gram-negative bacilli in urine and ascites (treated successfully with ciprofloxacin). Iyengar et al. (2002) described three patients who had catheters in place for 6, 7 and 12 weeks. One patient experienced dehydration, and one catheter was removed as a precaution in a patient with sepsis. Mullan et al. (2011a) reported experiences of four patients taken from a

larger study (Mullan et al. 2011b) in whom streptokinase fibrinolytic therapy was successfully used to treat loculations.

Committee considerations

3.11 The Committee concluded from the available clinical evidence that the PleurX peritoneal catheter drainage system is effective in the palliative management of treatment-resistant, recurrent malignant ascites. It has a high procedural success rate, a low complication rate and the potential to improve patient quality of life.

3.12 Patients with malignant ascites have a disability as defined by the Equality Act 2010. The Committee recognised that treatment-resistant, recurrent malignant ascites often has an adverse impact on patients' activities of daily living, which may be improved with the PleurX peritoneal catheter drainage system. The Committee was advised by the patient and clinical experts that improvement in quality of life is mainly a result of avoiding regular hospital visits and inpatient stays associated with large-volume paracentesis, and alleviation of symptoms associated with massive ascites through the frequent drainage of small volumes of ascitic fluid.

3.13 The Committee recognised the uncertainty about the point in the care pathway at which it would be clinically appropriate to treat patients with treatment-resistant, recurrent malignant ascites with the PleurX peritoneal catheter drainage system. Tapping et al. (2011) considered that patients who had had at least three previous large-volume paracentesis procedures would be suitable for treatment with the PleurX peritoneal catheter drainage system, whereas Courtney et al. (2008) inserted the PleurX peritoneal catheter in patients who had had at least two large-volume paracentesis procedures in the previous 30 days. The Committee considered that the decision to start treatment with the PleurX peritoneal catheter drainage system should be shared between clinicians and patients.

3.14 The Committee was advised that the term 'treatment-resistant' is normally understood by clinicians to mean that there is a low likelihood of further

medical or oncological interventions (particularly chemotherapy) being successful in preventing or reducing re-accumulation of ascites.

3.15 The Committee acknowledged that the current evidence is based on observational studies, with very limited data available comparing the PleurX peritoneal catheter drainage system with other treatments.

3.16 The Committee noted that there are two ongoing clinical trials using the PleurX peritoneal catheter drainage system. One is investigating the impact on quality of life and the other is comparing early stage PleurX peritoneal catheter insertion with standard large-volume paracentesis. Both trials are expected to be completed in 2012.

4 NHS considerations

System impact

4.1 The evidence suggests that the PleurX peritoneal catheter drainage system is a safe and effective alternative to inpatient large-volume paracentesis, is cost saving and reduces hospital bed use.

Committee considerations

4.2 The clinical experts advised the Committee that the PleurX peritoneal catheter insertion procedure is unlikely to be more costly to the NHS than the large-volume paracentesis procedure.

4.3 The main resource consideration with PleurX is the relative need for community nursing support for the ongoing drainage procedures. However, the Committee was advised that the PleurX peritoneal catheter drainage system is unlikely to increase overall community nursing input as was assumed in the cost model (see section 5). This is because most patients in the terminal stages of cancer need community nursing support regardless of the PleurX peritoneal catheter drainage system, and large-volume paracentesis is associated with a greater need for nursing for overall wound management. Indeed, the Committee was advised that it is possible that using the PleurX peritoneal catheter drainage system could lead to an overall reduction in community nursing costs, which would further enhance the resource savings associated with its use.

4.4 The Committee recognised that training is needed for community nurses, patients or carers to perform drainage procedures in a community setting.

5 Cost considerations

Cost evidence

5.1 The sponsor submitted a new cost analysis based on a decision tree model with an embedded Markov model. This model evaluated the costs per patient and system impact of the PleurX peritoneal catheter drainage system for the drainage of treatment-resistant, recurrent malignant ascites in the community setting when compared with inpatient and outpatient large-volume paracentesis.

5.2 The time horizon of the model was 26 weeks (6 months) from the time of the initial PleurX peritoneal catheter insertion. The Markov model was run over 26 weekly cycles to account for the short duration of survival in patients with malignant ascites. The cycles used transition probabilities based on 100% survival at week 0 to 4% survival at week 26. The cost of treatment was multiplied by the transition probability at each cycle; half-cycle corrections were used to incorporate changes in survival within a cycle.

5.3 The key assumptions used in the model were:

- no change in the survival rate in both arms of the model
- the need for two nurse visits to train patients to self-manage the drainage at home using the PleurX peritoneal catheter drainage system
- similar levels of treatment monitoring needs in both arms of the model
- a nurse visit length of 15 minutes for the PleurX peritoneal catheter drainage system to help with drainage at home
- drainage volume of 9.2 litres per procedure in patients who have repeated large-volume paracentesis
- average drainage volume of 3.5 litres per week using the PleurX peritoneal catheter drainage system

- one nurse visit per litre of ascitic fluid drained using the PleurX peritoneal catheter drainage system
- the cost of re-intervention being equivalent to a first-time catheter insertion procedure.

5.4 The model calculated the costs per patient of the PleurX peritoneal catheter drainage system and large-volume paracentesis as well as the incremental costs of the PleurX peritoneal catheter drainage system. The costs of the system included: inpatient stay (1 day), procedure consumables and other costs (including staff time), PleurX drainage kits, home nurse visits and treatment of complications (infection, catheter failure and re-intervention). The cost of large-volume paracentesis included: inpatient stay (2.8 days) or outpatient (1 day), procedure consumables and treatment of complications. In addition, the system impact was presented in terms of number of paracentesis sessions, number of litres of ascitic fluid drained, number of bed days, and number of nurse visits for both interventions.

5.5 The cost per patient for the management of malignant ascites using the PleurX peritoneal catheter drainage system was estimated to be £2466, whereas for inpatient and outpatient large-volume paracentesis it was estimated to be £3146 and £1457 respectively.

5.6 The base-case analysis showed that managing treatment-resistant, recurrent malignant ascites with the PleurX peritoneal catheter drainage system may result in cost saving of £679 per patient when compared with inpatient large-volume paracentesis. In this scenario, 7.4 hospital bed days were saved per patient, but 23.5 more community nurse visits to the patient's home were needed. When the PleurX peritoneal catheter drainage system was compared with outpatient large-volume paracentesis, an additional cost of £1010 per patient was incurred, including 23.5 extra nurse visits but 1.9 fewer hospital bed days used per patient.

5.7 The key drivers of the new cost analysis were: cost of a hospital bed day, number of bed days per large-volume paracentesis session, number of large-volume paracentesis procedures per month, number of bed days for PleurX peritoneal catheter placement, cost per drainage kit box (10 units), and number

of drainage kits used per week per patient. The analysis showed that cost savings associated with the PleurX peritoneal catheter drainage system, when compared with inpatient large-volume paracentesis, were heavily dependent on a reduction in hospital stay. The cost of a bed day was estimated at £312.

5.8 The sponsor carried out one-way deterministic sensitivity analysis. All variables (except for population size) were tested, and were analysed using a variance of 20% regardless of the level of confidence in an input or the parameter-specific circumstances. Six key drivers were selected and subjected to further deterministic threshold analysis by the External Assessment Centre across a wide range of values, to identify the point at which the PleurX peritoneal catheter drainage system became more costly or cost saving compared with inpatient and outpatient large-volume paracentesis respectively.

5.9 The findings of the threshold sensitivity analysis showed that using the PleurX peritoneal catheter drainage system may incur additional costs when compared with inpatient large-volume paracentesis in the following scenarios: the cost of an excess bed day is reduced to less than £220 per day; the frequency of an inpatient large-volume paracentesis procedure is reduced to fewer than one per month; the average length of inpatient stay after the large-volume paracentesis procedure is decreased to 2.1 days; the number of inpatient bed days following the PleurX peritoneal catheter insertion procedure is increased to more than 3.1 days; the cost of the PleurX drainage kit is increased to more than £915 (per 10 units); more than 5.1 drainage kit units are needed per week. The PleurX peritoneal catheter drainage system may become cost saving when compared with outpatient large-volume paracentesis in the following scenarios: the cost of an excess bed day is increased to more than £825 per day; the frequency of an outpatient large-volume paracentesis procedure is increased to more than 2.5 per month; the average length of hospital stay after the outpatient large-volume paracentesis procedure is increased to more than 2.1 days; the cost of the PleurX drainage kit is decreased to less than £225 (per 10 units); fewer than 1.14 drainage kit units are needed per week.

5.10 The sensitivity analysis demonstrated that the PleurX peritoneal catheter drainage system is likely to remain cost saving when compared with inpatient

large-volume paracentesis and is likely to incur extra costs when compared with outpatient large-volume paracentesis.

Committee considerations

5.11 The new cost analysis showed that the PleurX peritoneal catheter drainage system was cost saving when compared with inpatient large-volume paracentesis, but incurred additional costs when compared with outpatient large-volume paracentesis. The additional costs, compared with outpatient treatment, were incurred mainly from an increased number of home nurse visits, with only a small offset saving in hospital bed days. However, the Committee was advised that the additional cost burden imposed on community nursing staff as a result of the PleurX peritoneal catheter drainage system may have been overestimated, given that most patients will receive healthcare in the community regardless of whether or not they have a PleurX peritoneal catheter in place. The Committee was advised that many patients may not prefer outpatient to inpatient large-volume paracentesis because it does not necessarily alleviate the intolerable symptoms associated with ascitic fluid build-up any better than inpatient large-volume paracentesis and yet still creates the need for repeated outpatient visits.

5.12 The Committee recognised that large-volume paracentesis is currently offered as an inpatient, outpatient or day-case procedure and that practice varies across the UK. Moreover, the resource costs for outpatient and day-case large-volume paracentesis differ, with the day-case procedure being more costly (although this was not reflected in the cost model). The Committee was advised that the PleurX peritoneal catheter drainage system is likely to be cost saving when compared with day-case large-volume paracentesis.

5.13 The clinical experts advised the Committee that the mean hospital stay of 2.8 days following inpatient large-volume paracentesis that was used in the base-case analysis is a realistic estimate and reflects current practice in many NHS centres.

5.14 The Committee recognised that the NHS tariff used for the calculation of excess bed days underestimated the cost of an inpatient stay and that

correcting this may further increase the cost savings attributable to the PleurX peritoneal catheter drainage system.

6 Conclusions

6.1 The Committee concluded that the PleurX peritoneal catheter drainage system is a clinically safe and effective palliative therapy for the management of treatment-resistant, recurrent malignant ascites, which has the potential to improve quality of life and is cost saving when compared with inpatient large-volume paracentesis.

7 Implementation

7.1 NICE are developing tools to help organisations put this guidance into practice.

- Slides highlighting key messages for local discussion.
- Costing template and report to estimate the national and local savings and costs associated with implementation.
- Audit support for monitoring local practice.
- Clinical case scenarios.

8 Related NICE guidance

There is no related guidance for this technology.

Andrew Dillon
Chief Executive
March 2012

Appendix A. Committee members and NICE lead team

A Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)
Consultant Vascular Surgeon, Exeter

Dr Peter Groves (Vice Chair)
Consultant Cardiologist, Cardiff and Vale NHS Trust

Dr Dilly Anumba
Senior Clinical Lecturer/Honorary Consultant Obstetrician and Gynaecologist, University of Sheffield

Ms Susan Bennett
Lay member

Professor Bipin Bhakta
Charterhouse Professor in Rehabilitation Medicine and NHS Consultant Physician, University of Leeds

Dr Keith Blanshard
Consultant Radiologist, Leicester Royal Infirmary

Dr Martyn Bracewell
Senior Lecturer in Neurology and Neuroscience, Bangor University

Dr Daniel Clark
Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Professor Karl Claxton
Professor of Economics, University of York

Mrs Gail Coster
Radiography Manager, Strategy, Planning and Governance, Yorkshire NHS Trust

Dr Alex Faulkner
Senior Research Fellow, Centre for Biomedicine & Society, King's College London

Professor Tony Freemont
Professor of Osteoarticular Pathology, University of Manchester

Professor Peter Gaines
Consultant Interventional Radiologist, Sheffield, Vascular Institute and Sheffield Hallam University

Mr Harry Golby
Head of Commissioning, Acute, Access and Diagnostics, Salford NHS

Mr Matthew Hill
Lay member

Dr Paul Knox
Reader in Vision Science, University of Liverpool

Ms Catherine Leonard
Reimbursement Manager, Medtronic UK

Dr Susanne Ludgate
Clinical Director, Devices Medicines and Healthcare Products Regulatory Agency

Mrs Jacqui Nettleton
Programme Director, Long Term Conditions, West Sussex PCT

Professor Sharon Peacock
Professor of Clinical Microbiology, University of Cambridge

Professor Brian Pollard
Professor of Anaesthesia, University of Manchester

Dr Allan Swift
Director of Quality and Regulatory Affairs, Gen-Probe Life Sciences

Dr Allan Wailoo
Reader in Health Economics, School of Health and Related Research

Professor Stephen Westaby
Consultant Cardiac Surgeon, John Radcliffe Hospital, Oxford

Dr Janelle Yorke
Lecturer and Researcher in Nursing, University of Salford

B NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a technical expert, a patient expert, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

Mukesh Dhariwal
Joanne Higgins
Technical Analysts

Lizzy Latimer
Technical Adviser

Dr Hans-Ulrich Laasch
Mrs Debbie Fitzgerald
Lead Expert Advisers

Mrs Janet Allen
Patient Expert

Dr Alex Faulkner
Non-Expert Committee Member

Dr Judith White
External Assessment Centre Representative

Appendix B: Sources of evidence considered by the Committee

A The External Assessment Centre report for this assessment was prepared by CEDAR:

- White J, Carolan-Rees G, Dale M (2011) External assessment centre report: PleurX indwelling peritoneal catheter for vacuum assisted drainage of recurrent malignant ascites at home (September 2011)

B Submissions from the following sponsor:

- UK Medical Ltd

C The following individuals gave their expert personal view on the PleurX peritoneal catheter drainage system by providing their expert comments on the draft scope and assessment report.

- Dr Hans-Ulrich Laasch, British Society of Interventional Radiology – clinical expert
- Mrs Debbie Fitzgerald, National Forum of Gynaecology Oncology Nurses – clinical expert
- Ms Lisa Peck, National Forum of Gynaecology Oncology Nurses – clinical expert
- Mrs Janet Allen, Target Ovarian Cancer – patient expert

D The following individuals gave their expert personal view on the PleurX peritoneal catheter drainage system in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Dr Robert Jones, British Society of Interventional Radiology – clinical expert
- Dr Hans-Ulrich Laasch, British Society of Interventional Radiology – clinical expert
- Mrs Debbie Fitzgerald, National Forum of Gynaecology Oncology Nurses – clinical expert
- Ms Lisa Peck, National Forum of Gynaecology Oncology Nurses – clinical expert
- Ms Frances Reid, Target Ovarian Cancer – patient expert
- Ms Judith Robinson, Target Ovarian Cancer – patient expert

About this guidance

NICE medical technology guidance addresses specific technologies notified to NICE by manufacturers. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This 'case' is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

This guidance was developed using the NICE medical technologies guidance process.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes after publication
April 2012: minor maintenance

Your responsibility
This guidance represents the views of NICE and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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