NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Medical technology guidance

SCOPE

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

1 Technology

1.1 *Description of the technology*

The PleurX peritoneal catheter drainage system allows the repeated drainage of ascitic fluid in the community setting. It is intended for use in the palliative management of treatment-resistant, recurrent malignant ascites.

The PleurX peritoneal catheter is made of silicone and is 71cm in length and 5.12mm (15.5 Fr) in diameter. The distal end of the catheter has several side-holes and is placed within the peritoneal cavity. There is a polyester cuff midway along the catheter which is sited 1-2cm within the subcutaneous tunnel and helps to secure the catheter in place by encouraging tissue ingrowth. The initial subcutaneous course of the catheter reduces the risk of subsequent infection and the leakage of peritoneal fluid.

The proximal end of the PleurX 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 accumulating. The drainage system comprises a one litre vacuum bottle with a drainage line that connects to the PleurX 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 dressing over the catheter.

The initial catheter placement procedure can be performed under local anaesthesia in an outpatient setting using ultrasound guidance and follows the same principles as placing a catheter for abdominal paracentesis.

The PleurX peritoneal catheter can remain in place indefinitely and patients and carers are trained to perform fluid drainage themselves as and when required. When drainage is undertaken, the vacuum bottle is attached to the catheter and a fresh valve cap and dressing are re-applied once the fluid drainage is completed. For the majority of the time, the catheter is coiled up and covered with a gauze pad and waterproof dressing.

1.2 *Regulatory status*

CE certification (directive 93/42/EEC on medical devices) for PleurX catheter was obtained in July 2010.

PleurX catheter was approved by the Food and Drug Administration (FDA), USA (510k, number K051711) in November 2005 for the intermittent drainage of symptomatic, recurrent, malignant ascites that does not respond to medical management of the underlying disease in order to provide palliation of symptoms related to recurrent malignant ascites.

1.3 *Claimed benefits*

The claimed patient benefits of using the PleurX peritoneal catheter drainage system as compared to large volume paracentesis (LVP) for the palliative management of recurrent malignant ascites resistant to medical management are:

- Greater patient convenience and independence. The PleurX catheter drainage system enables the repeated drainage of ascitic fluid in community settings. This allows for greater

patient independence and control of their symptoms as well as the flexibility to fit the drainage procedure into their daily lives.

- Reduced procedures and infection risk. Insertion of the PleurX catheter is a one-off procedure and once in place, it can remain indefinitely. This reduces the need for repeated needle punctures which are required when LVP is undertaken. This, combined with the presence of the polyester cuff reduces the risk of peritoneal infection as well as the risk of organ injury from repeated punctures.

- Improved symptom control. The PleurX catheter drainage system allows the frequent drainage of smaller quantities of ascitic fluid. This may result in better control of symptoms associated with the accumulation of large amounts of ascites, i.e. breathlessness, nausea, bloating, acid reflux, abdominal pain, early satiety, reduced mobility and psychological distress related to body image. An improvement in appetite may improve dietary intake, with potential physical and psychological advantages for patients whose cancer is at an advanced stage.

The health system benefits claimed by the manufacturer as compared to LVP are:

- Resource savings to the NHS through a reduced need for hospital nurse and physician time, outpatient visits, and hospital bed days.

1.4 *Relevant diseases and conditions*

The PleurX peritoneal catheter drainage system is intended for use in patients with recurrent malignant ascites that is resistant to medical management.

There are no data available on the prevalence of treatment-resistant, recurrent malignant ascites in the UK. Hospital Episode Statistics (HES) main procedures and interventions data for 2008-9

report approximately 25,000 finished consultant episodes involving abdominal paracentesis for the drainage of ascitic fluid from the peritoneal cavity for both diagnostic and therapeutic indications. Malignant ascites (ascites due to a cancer) accounts for approximately 10% of all cases. In four out of five patients with malignant ascites, the disease is caused by ovarian carcinoma or gastrointestinal tumours. It may also occur in patients with breast, pulmonary, uterine and cervical tumours. Patients with malignant ascites have a mean survival of 1 to 4 months, depending on the nature and extent of the underlying tumour. This may be significantly longer in patients undergoing further palliative treatment.

1.5 *Current Management*

The conventional management of patients with treatment-resistant, recurrent malignant ascites involves multiple large volume paracentesis (LVP) procedures that are undertaken in hospital. Paracentesis (abdominal tap) refers to the insertion of a catheter into the peritoneal cavity for the drainage of ascitic fluid. LVP refers to the removal of more than 5 Litres of ascitic fluid in one go.

2 Reasons for developing guidance on PleurX peritoneal catheter drainage system

The Committee recognised that the PleurX peritoneal catheter kit is one of many catheters that can be used for the drainage of ascitic fluid. It was recognised that this technology may be of particular benefit in the palliation of symptoms in patients with recurrent malignant ascites which has proved resistant to medical management. The committee considered the disadvantages associated with repeated conventional LVP which include:

- repeated procedural risks of intestinal injury, peritonitis, fistulae, hypoalbuminaemia, metabolic disturbance and cachexia,

- the temporary nature of any palliative benefits, necessitating repeated procedures with progressive symptoms developing as ascites re-accumulates,

- the need for repeated hospital visits frequently necessitating overnight stays,

- a negative impact on quality of life for patients who are eager to remain in the community and avoid hospital attendance.

The Committee considered that the PleurX peritoneal catheter drainage system may offer practical advantages to patients including:

- a single catheter insertion procedure with reduced risk,

- better symptom control,

- the avoidance of repeated hospital visits,

- improved quality of life.

The Committee concluded that the published evidence shows that the PleurX peritoneal catheter drainage system is likely to be effective in the drainage of ascitic fluid in the community setting with better symptom control through the frequent withdrawal of small quantities of fluid and higher patient satisfaction ratings as compared with LVP.

The Committee was advised that the PleurX peritoneal catheter is made using silicone which is better tolerated than polyurethane (used in other catheters). Furthermore, the PleurX drainage kit drains fluid using a vacuum bottle which may result in faster drainage as compared with the gravity assisted drainage system that is used in other drainage kits. This may also allow a certain amount of debris to be removed reducing the risk of catheter blockage.

The Committee recognised that the transfer of the financial burden of ascitic fluid drainage to a community setting may prove to be a barrier to the widespread uptake of this device. It was recognised that some patients may have ascites with multiple loculations and that the PleurX peritoneal catheter kit may have limited benefits in such cases, or require additional measures such as fibrinolysis to break down septa between loculations. The Committee noted that patient compliance is needed for the PleurX peritoneal catheter drainage system and that it may not be suitable in cases where this cannot be assured. It was also acknowledged that training would be required for both the community healthcare professionals and patients. Patient education may be needed to prevent complications of excessive fluid drainage and catheter site infections.

3 Statement of the decision problem

	Final scope issued by NICE
Population	Patients with treatment-resistant, recurrent malignant ascites
Intervention	PleurX peritoneal catheter drainage system
Comparator(s)	Inpatient large volume paracentesis Outpatient large volume paracentesis
Outcomes	The outcome measures to consider include: • successful device deployment • successful drainage of the ascitic fluid • resolution of symptoms (i.e. bloating, nausea, acid reflux, reduced appetite, perception of body image, psychological well-being and quality of life outcomes) • frequency of drainage • resource use outcomes for example re-admission rates, re-interventions and duration of hospital stay (i.e. total number of hospital bed days related to paracentesis after initial drainage) • catheter site infections • peritonitis • catheter occlusion, • other device related adverse events, e.g. haemorrhage, bowel perforation
Cost analysis	Population: Patients with treatment-resistant, recurrent, malignant ascites Intervention: PleurX peritoneal catheter drainage system Comparator: Inpatient LVP and outpatient LVP Costs will be considered from an NHS and Personal Social Services perspective. The analysis should take into account any resource use associated with hospital and community care and management of the malignant ascites, and training required to use the device. Adverse events and complications relating to the use of the device and treatment required for these complications should also be considered (for example, the costs associated with care if the patient has a peritoneal infection). The time horizon for the economic evaluation should be based on the appropriate time period over which costs and benefits can reasonably be expected to be experienced given the chronic nature of the condition.
Subgroups to be considered	
Special considerations, including issues related to equality	Patients with cancer are protected under the Equality Act 2010.

4 External organisations

4.1 *Professional organisations*

4.1.1 Specialist societies contacted for expert advice

British Association for the Study of the Liver

British Society of Interventional Radiology

Royal College of Nursing

Royal College of Physicians

4.1.2 Specialist Societies to comment on the scope

Association for Palliative Medicine of Great Britain

British Association for the Study of the Liver

British Society of Interventional Radiology

National Forum of Gynaecological Nurses

Royal College of Nursing

Royal College of Physicians

United Kingdom Oncology Nursing Society (UKONS)

4.2 *Patient organisations*

NICE's Patient and Public Involvement Programme contacted the following organisations for patient commentary:

Beating Bowel Cancer
Bowel Cancer UK
Breakthrough Breast Cancer
Breast Cancer Campaign
Breast Cancer Care
Breast Cancer Haven
Breast Cancer Research Trust (BCRT)

Breast Cancer UK
Cancer Black Care
Cancer52
CANCER active
GIST Support UK
Gynae C
Helen Rollason Heal Cancer Charity
Jo's Trust
Lymphoma Association
Lynn's Bowel Cancer Campaign
Macmillan Cancer Support
Maggie’s Centres
National Council for Palliative Care
National Hereditary Breast Cancer Helpline
Orchid Cancer Appeal
Ovarian & Prostate Cancer Research Trust
Ovarian Cancer Action
Prostate Action
Prostate Cancer Charity
Prostate Cancer Network
Prostate Help Association
Rarer Cancers Foundation
Sarcoma UK
Stomach Cancer Awareness Network
Target Ovarian Cancer
Tenovus
The Eve Appeal
The Genesis Appeal
WellBeing of Women
Women's Health Concern