NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Review Decision

Review of MTG9: The PleurX peritoneal catheter drainage system for vacuum-assisted drainage of treatment-resistant, recurrent malignant ascites

This guidance was issued in March 2012.

NICE proposes an amendment of published guidance if there are no changes to the technology, clinical environment or evidence base which are likely to result in a change to the recommendations. However the recommendations may need revision to correct any inaccuracies, usually in relation to providing a more accurate estimate of the results of the cost modelling. The decision to consult on an amendment of published guidance depends on the impact of the proposed amendments and on NICE's perception of their likely acceptance with stakeholders. NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

1. Review decision

Amend the guidance to update the estimated cost savings and minor factual changes and do not consult on the proposed amendments

Publish a summary of the updated cost model.

Consider producing a medtech innovation briefing on the use of PleurX for pleural effusions.

A list of the options for consideration, and the consequences of each option is provided in Appendix 1.

2. Original objective of guidance

To assess the case for adoption of the PleurX peritoneal catheter drainage system for vacuum-assisted drainage of treatment-resistant, recurrent malignant ascites.

3. Current guidance

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.

4. Rationale

Although new studies on using PleurX in peritoneal ascites drainage in a number of diseases, patient groups and settings, there was no new high quality evidence which would be likely to change the recommendations. The only change in the care pathway, technology, mode of action or regulatory status is in some relevant NHS resource costs which increases the estimated per-patient saving. It is therefore proposed that this guidance should be amended (proposed amendments shown in Appendix 3) without consultation on the review proposal.

5. New evidence

The search strategy from the original assessment report was re-run. References from 2011 to October 2017 were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathway. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

5.1 Technology availability and changes

The PleurX system remains available to the NHS and the components are unchanged from the version evaluation in MTG9. The costs are also unchanged but the product is marketed in the UK by BD following the acquisition of UK Medical Ltd.

5.2 Clinical practice

Expert advice confirmed that standard treatment for patients with treatment-resistant, recurrent, malignant ascites is paracentesis done in secondary care. There

remains no clear standard practice for paracentesis which is offered as inpatient, outpatient and day case across the NHS. One expert adviser, who also advised on MTG9, mentioned that there are a number of other peritoneal catheter devices available for drainage of recurrent malignant ascites. Another expert commented that PleurX is more robust and reliable than competitor products.

5.3 NICE facilitated research

Not applicable.

5.4 New studies

The evidence base supporting the use of PleurX has expanded but remains of a similar relatively low quality to that presented in the guidance development. One study which was available to the EAC and committee as academic in confidence has been published and is consistent with the submitted manuscript (Day et al. 2013). Results from two ongoing clinical trials noted in section 3.16 of MTG9 have not been published because of recruitment difficulties.

Three particularly relevant studies published since MTG9 were identified. All are non-comparative, observational studies which confirm the clinical utility of PleurX in managing malignant ascites, mostly from settings in the US.

- Narayanan et al. (2014) included 38 patients managing their ascites drainage in the community using PleurX in the US. It reported a 100% successful catheter insertion rate and a mean survival rate of 40.7 days (4-434).
- Lungren et al. (2013) studied 188 patients with refractory ascites and also reported a 100% successful catheter insertion rate and a mean catheter survival time of 60 days (0-796).
- Qu et al. (2016) studied 84 patients and recorded their pre- and post-treatment use of resources, including hospital admissions, bed day cost whilst receiving paracentesis treatment or PleurX. This analysis showed significantly lower hospital admissions (-1.4/month) and hospital stays (-4.2/month) for patients using PleurX, resulting in an estimated cost saving of $9,535/month (mean $21,952/patient).

The evidence base used for MTG9 guidance development included a total of 192 patients and the selected new studies include 310 patients using PleurX. A number of smaller non-comparative studies on PleurX and a large number (>20) case reports on ascites drainage using PleurX have been published all of which support the clinical use of PleurX. There are 2 systematic reviews of catheter drainage of

recurrent malignant ascites but these are unclear in their reporting of the specific catheter used and the setting (Christensen et al. 2016, Stukan 2017).

5.5 Updates to the cost model

The KiTEC external assessment centre reviewed the cost modelling for MTG9. It concluded that the cost case for PleurX remains valid and that the updated model supports the conclusions in the current recommendations although some NHS resource costs have changed.

The cost of the device and consumables remains the same. The largest changes in other inputs were increases in the cost of hospital bed days (+14%) and decreases in the cost of a typical nurse visit (-47%). Other smaller uplifts and adjustments to other costs included uplifting the comparator and consumables costs from 2011 prices and using the latest HRG codes from NHS reference costs 2015-16. This results in an updated cost saving estimate of £1051 per patient for Pleurx compared with inpatient paracentesis, increased from the £679 per patient saving in MTG9. The differential cost between PleurX and paracentesis as an outpatient procedure is reduced but still results in additional costs of £871 per patient (compared with £1010 in MTG9).

6. Adoption

The company could not supply any UK sales or adoption data and NICE Adoption and Impact uptake team had no further data on usage. An expert adviser stated that PleurX is used in both malignant and non-malignant cardiac and liver disease for both pleural effusions and ascites as palliative treatment where high volumes are troublesome in the absence of alternative treatment options. Another expert adviser commented that due to the very high acceptance by patients and increased familiarity of clinicians, use of PleurX has increased and insertions are performed earlier (possibly as day-cases) with increased cost savings.

7. Summary of new information and implications for review

The new clinical evidence on PleurX supports the original recommendations of MTG 9. The updated cost model shows the technology is still cost-saving compared with in-patient paracentesis. Nothing has been identified which suggests the recommendations should be changed so the proposal is to amend the guidance to reflect the updated cost modelling results. The proposed amendments to the guidance are presented in appendix 3.

The suggested amendments include correcting the company name in 2.1 and a brief description of the revised cost modelling. Since these amendments do not materially change the recommendations and advice from the experts and the company are that the recommendations are still valid, we do not consider a consultation is required.

8. Equality issues

No new equality issues have been identified.

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	Consequences	Selected – 'Yes/No'
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	Yes
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	

Appendix 2 – supporting information

Registered and unpublished trials

Trial name and registration number	Details
NCT01188746: Impact of Palliative Catheter Placement on the Quality of Life of Patients With Refractory Ascites Status: This study is ongoing, but not recruiting participants	This is a non-comparative observational study of patient quality of life using catheters of various designs (including, but not limited to, a Tenckhoff catheter, a PleurX catheter, or a Denver Shunt). It was included in the original MTG9 as ongoing and has had recruitment problems so is still listed as ongoing with an extended end date. Expected enrolment: 50 Estimated primary completion date: August 2018 Location: New York, USA

Appendix 3 – Proposed amendments to original guidance

Table 2: proposed amendments to original guidance

Section of MTG	Original MTG	Proposed amendment
Recommendations, 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.	The PleurX peritoneal catheter drainage system is associated with an estimated cost saving of £1051 per patient when compared with inpatient large-volume paracentesis [2017 – see 5.15].
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.	The PleurX peritoneal catheter drainage system (BD) 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. [2017]
Cost considerations 5.15	New section added summarizing the updates to the model used to calculate the revised basecase values	**Revised basecase inputs** For the guidance review, the external assessment centre revised the model to reflect 2017 costs (original guidance values given in brackets). The largest changes were increases in the cost of hospital bed days (£312 to £355) and decreases in the cost of a typical nurse visit (£27 to £14.33). Base case results for the 2017 revised model shows a cost saving of £1051 (£679) per patient. The differential cost between PleurX and paracentesis as an outpatient procedure is reduced to an additional cost of £871 (£1010) per patient. Further details of the 2017 revised model are in the revised model summary [2017]

Appendix 4 – major revised costs in the economic model

Cost Parameter	Cost parameters		Source for updated cost parameters
	Value used in the original model	Updated value	
Inpatient stay for PleurX catheter			
Cost per hospital bed day	£ 312.00	£ 355.00	NHS reference cost 2015-16, HRG code used: FZ12Q (Major General Abdominal Procedures, 19 years and over, with CC Score 0)
Follow-on costs of ascites management			
Cost per home visit per hour	£78.00	£67.89	Uplifted from PSSRU 2015

Cost per typical nurse visit (20 minutes)	£27.00	£14.33	PSSRU 2016

References

Christensen, L., et al., 2016. Permanent catheters for recurrent ascites—a critical and systematic review of study methodology. *Supportive Care in Cancer*, *24*(6), 2767-2779.

Lungren, M.P., et al., 2013. Tunneled peritoneal drainage catheter placement for refractory ascites: single-center experience in 188 patients. *Journal of Vascular and Interventional Radiology*, *24*(9), 1303-1308.

Narayanan, G., et al., 2014. Safety and efficacy of the PleurX catheter for the treatment of malignant ascites. *Journal of palliative medicine*, *17*(8), 906-912.

Qu, C., et al., 2016. The Impact of Tunneled Catheters for Ascites and Peritoneal Carcinomatosis on Patient Rehospitalizations. *Cardiovascular and interventional radiology*, *39*(5), 711-716

Stukan, M., 2017. Drainage of malignant ascites: patient selection and perspectives. *Cancer management and research*, *9*, 115.