NICE National Institute for Health and Care Excellence

NICE guidance

Thopaz+ portable digital system for managing chest drains

HealthTech guidance
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www.nice.org.uk/guidance/htg465

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. 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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces MTG37.

1 Recommendations

1.1 The case for adopting Thopaz+ for managing chest drains is supported by the evidence. Thopaz+ can reduce drainage time and length of stay in hospital, and improves safety for people with chest drains. Its use may also improve clinical decision-making through continuous, objective monitoring of air leaks and fluid loss.

1.2 Thopaz+ should be considered for people who need chest drainage after pulmonary resection or because of a pneumothorax. The system can increase patient mobility because it is portable. Staff find it more convenient and easier to use than conventional chest drains.

1.3 Cost modelling indicates that Thopaz+ is cost saving compared with conventional chest drains in people after pulmonary resection. The estimated saving is £108 per patient per hospital stay, with savings mainly achieved through reduced length of stay **[2022]**. The resource impact assessment for this guidance shows that, at a national level, adopting Thopaz+ is expected to save around £8.5 million per year in England.

2 The technology

Description of the technology

2.1 Thopaz+ (Medela UK) is a portable digital chest drain system that provides regulated negative pressure close to the patient's chest and continuously monitors and records air leak and fluid drainage. The system comprises an in-built, regulated suction pump with a digital display, rechargeable battery, tubing that connects to any standard chest drain catheter and a Thopaz+ disposable fluid collection canister. Sensors in the system turn the pump on and off to ensure the pressure level set by the healthcare professional is precisely maintained.

2.2 The rental cost of each Thopaz+ unit, as stated in the company's submission, is £115 per month. It can also be purchased for £3,570 **[2022]**.

2.3 The claimed benefits of Thopaz+ in the case for adoption presented by the company are:

- reduced chest tube duration
- shorter length of hospital stay
- reduced rates of patient complications
- higher patient satisfaction
- reduced hospital costs
- increased convenience for doctors and nursing staff
- improved chest drain management
- better prediction of patient outcomes
- less plastic consumable waste.

Current management

2.4 Conventional chest drains use an underwater seal to help drain air and fluid from the pleural space, allowing the lung to re-inflate. This can be done with or without additional wall suction. NICE's guideline on major trauma recommends chest drains for managing chest trauma in pre-hospital and hospital settings, but chest drain management is not specifically covered by NICE guidance.

2.5 The British Thoracic Society guidelines on pleural disease state that chest drains should include a valve mechanism to prevent fluid or air entering the pleural cavity. This may be an underwater seal, flutter valve or other recognised mechanism. Chest drains with underwater seals appear to be standard care in the NHS and consist of a water seal, optional suction control and drainage collection bottle. These drains collect fluid and prevent backflow into the pleural cavity, while at the same time allowing a subjective assessment of air leaks and fluid loss. The drainage bottle must be placed below chest level and kept upright. Suction may sometimes be needed, depending on the patient's condition, and can usually be provided using a wall suction unit.

3 Clinical evidence

Summary of clinical evidence

3.1 The evidence for Thopaz+ assessed by the external assessment centre (EAC) comprises 13 studies (n=1,632), including 9 comparative studies. Six of the studies were randomised controlled trials (n=826), although no blinding was possible because the devices used look very different. There was 1 non-comparative study in children (Costa et al. 2016) and the remaining studies were in adults. Only 1 study centre in 1 multicentre trial (Pompili et al. 2014) was in the UK: the 12 other studies were done in Europe, Asia and North America. For full details of the clinical evidence, see section 3 of the assessment report.

Main points from the EAC's analysis of the clinical evidence

3.2 The EAC considered that of the 6 randomised controlled trials:

- Pompili et al. (2014) was well designed and reported, and of excellent quality
- 4 were of good quality with clear protocols and results (Gilbert et al. 2015, Lijkendijk et al. 2015, Jablonski et al. 2013 and Marjanski et al. 2013)
- Mier et al. (2010) was of lower quality with no clear hypothesis but had well-matched comparative groups of patients.

The EAC also noted that 3 observational comparative studies (Pompili et al. 2011, Miller et al. 2016 and Shoji et al. 2016) were of high quality using propensity-matched control cohorts.

3.3 The EAC considered that all of the sites in the studies were likely to have different local protocols for inserting and removing chest drains, which may make the results more reflective of the likely variation in chest tube drainage protocols across the NHS.

3.4 All but 1 of the comparative studies (Jablonski et al. 2013) were on the use of Thopaz+ after pulmonary resection. All of the comparators were conventional analogue drainage units using wall suction. The results showed that Thopaz+ was associated with shorter drainage times (7 of 8 studies) and a shorter length of stay (4 of 6 studies) compared with conventional chest drainage.

3.5 Two studies that included patients with pneumothorax (air in the pleural space around the lung) were identified, 1 of which was comparative (n=60; Jablonski et al. 2013). Results from the comparative study showed that both drainage time and length of hospital stay are statistically significantly shorter with Thopaz+.

3.6 Chest drains needed to be reinserted in 4 of the comparative trials. Rates of reinsertion were lower for Thopaz+ than for conventional chest drainage, but the difference was not statistically significant.

3.7 The EAC found no published quantitative, comparative evidence for staff time spent on chest drainage when using Thopaz+ or for fluid loss measurement.

Summary of economic evidence

3.8 The company's economic submission was a simple decision tree with 1 decision node for the use of Thopaz+ or conventional chest drainage with wall suction, based on inputs from Pompili et al. (2011). The time horizon was the length of hospital stay. For full details of the economic evidence, see section 3 of the assessment report.

EAC's analysis of the economic evidence

3.9 The EAC agreed that the company's simple model structure was appropriate, but it made some changes to better reflect the evidence and current NHS practice. These changes comprised:

- adding costs for consumables and training associated with standard drainage

- using a length of hospital stay of 5.4 days for Thopaz+ (based on a weighted average from 6 studies) and 5.8 days for conventional chest drainage (based on 3 studies)
- using a drainage time of 3.5 days for Thopaz+ (based on 8 studies)
- adding the cost of chest drain reinsertion and complications (reinsertion prevalence was calculated as 0.017 from 4 studies)
- revising the consumer and training costs for Thopaz+.

For full details of these changes, see section 4.4 of the assessment report.

3.10 The company's base case resulted in a cost saving per patient of £35.56 for Thopaz+ compared with conventional chest drainage over the length of hospital stay. After the EAC's changes, this cost saving increased to £107.99 per patient **[2022]**.

3.11 The main driver of the cost savings for Thopaz+ is shorter length of hospital stay. The device remained cost saving throughout all realistic one-way sensitivity analyses.

4 Committee discussion

Clinical effectiveness

4.1 The committee noted that the evidence presented for Thopaz+ was mainly for its use in patients after pulmonary resection. The clinical experts confirmed that this reflected their experience in the NHS. The committee considered that Thopaz+ has clear clinical advantages compared with conventional chest drainage using wall suction in patients after pulmonary resection, including a shorter drainage time and a shorter length of stay in hospital.

4.2 The committee recognised that the evidence to support the use of Thopaz+ for chest drains inserted after a pneumothorax was relatively limited. Nonetheless, the committee noted that the studies available appeared to demonstrate clinical benefits that were comparable with those observed after pulmonary resection. One clinical expert noted that audit data from their NHS hospital had indicated that Thopaz+ showed similar clinical advantages in both patient populations. The committee therefore concluded that the clinical benefits of the technology are likely to be generalisable to patients with pneumothorax.

4.3 The committee considered the use of Thopaz+ in other patients who need chest drainage. None of the experts had experience of using the technology in children, but they did report the use of Thopaz+ in other patients needing chest drainage (such as after cardiac surgery and trauma). The clinical experts explained that if devices are available on wards they may be used safely for a broad range of patients who need chest drainage, but evidence to support clinical or system benefits in these circumstances is currently lacking.

4.4 The clinical experts stated that there are other potential benefits that may not be reflected in the published evidence. They described improved decision-making because Thopaz+ can objectively measure the rate of air leakage and total fluid drainage. The clinical experts also advised that Thopaz+ is portable and easy to manage, allowing increased mobility which aids recovery and patient satisfaction. The committee concluded that there may be additional advantages for patients not captured in the published studies.

NHS and system impact considerations

4.5 The clinical experts explained that using Thopaz+ allows treatment across wards to be standardised, because it provides objective measurements of air leakage and fluid loss. These data make it easier to assess and record patients' progress. This, in turn, may help clinicians determine when is best to remove the chest drain. One clinical expert explained how the use of Thopaz+ had helped them redesign the logging system for chest drain management.

4.6 The committee heard that managing chest drains with Thopaz+ is easier than with conventional chest drainage and this may release nurse time. Patients may also need fewer chest X-rays with the use of Thopaz+.

4.7 The clinical experts explained that using Thopaz+ improves patient safety. The system has in-built alarms that warn users of potential problems such as a blocked tube, full canister or low battery. When visiting the X-ray department, people may be safely accompanied by non-nursing staff because of the alarm. If the device is accidentally switched off, it changes to a normal, single-way valve chest drain. The committee concluded that the safety features of the technology increase staff confidence in managing chest drains.

Cost savings

4.8 The committee noted that the estimated cost savings with Thopaz+ of £107.99 per patient in people after pulmonary resection was largely attributable to a reduced length in hospital of up to 1.5 days (average 0.4 days) per patient compared with conventional chest drainage **[2022]**. The committee considered the implications of this reduced length of stay and whether it was realisable in practice. The clinical experts explained that the continuous, objective monitoring possible with Thopaz+ helps reliable decision-making and encourages earlier chest drain removal and discharge. The committee noted that Thopaz+ remained cost saving even with a difference in length of stay of only 0.071 days.

4.9 The EAC explored device utilisation in a sensitivity analysis. In its base case, the company assumed 50% device utilisation. The committee heard from 2 clinical experts who use Thopaz+ that device utilisation in their own units was closer to

100%, and that once introduced Thopaz+ rapidly became the standard of care for patients with chest drains. The committee concluded, therefore, that the device utilisation in the company's base case was conservative.

4.10 The committee considered the different options through which Thopaz+ is available (that is, purchase or rental). It noted that the EAC scenario analysis based on a £3,570 purchase price resulted in increased savings of £120.74 per patient. However, including the purchase of 5-year warranties reduced the cost savings by £1.96 per patient **[2022]**. The company stated that leasing arrangements are available and that volume purchasing discounts are available; for example, buying over 25 devices would reduce the individual purchase price to £3,000 **[2022]**.

4.11 The committee concluded that cost savings are also likely in people with pneumothorax. It noted that the EAC's scenario analysis, which produced a cost saving of £653.82 per patient, was based on a single comparative study **[2022]**. This reported a larger difference in length of hospital stay between Thopaz+ and conventional chest drain use in people with pneumothorax compared with people after pulmonary resection (1.9 days compared with 0.4 days). The clinical experts clarified that shorter drainage times and lengths of stay were plausible in this patient group. The committee concluded that Thopaz+ is likely to be cost saving in people with pneumothorax, but that the evidence is more uncertain than in people after pulmonary resection.

4.12 The committee concluded that cost savings are also likely in people with pneumothorax. It noted that the EAC's scenario analysis, which produced a cost saving of £550.90 per patient, was based on a single comparative study. This reported a larger difference in length of hospital stay between Thopaz+ and conventional chest drain use in people with pneumothorax compared with people after pulmonary resection (1.9 days compared with 0.4 days). The clinical experts clarified that shorter drainage times and lengths of stay were plausible in this patient group. The committee concluded that Thopaz+ is likely to be cost saving in people with pneumothorax, but that the evidence is more uncertain than in people after pulmonary resection.

4.13 The committee concluded that using Thopaz+ is likely to lead to significant clinical and system benefits compared with conventional chest drainage in people

who need chest drainage after pulmonary resection or pneumothorax.

4.14 For the guidance review, the EAC revised the model to reflect 2021 costs (original guidance values given in brackets). The main parameter change was the cost of Thopaz+ at £3,570 (£3,400). Other parameter changes were associated with staff costs, bed days and complications. Further details of the 2021 revised model are in the revised model summary **[2022]**.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

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

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal) and a technical adviser.

Paul Dimmock
Technical analyst

Bernice Dillon
Technical adviser

Jae Long
Project manager

Update information

June 2022: We updated this guidance to reflect 2022 costs and revise cost-saving estimates. These are marked **[2022]**. Details of the changes are explained in the review decision.

Minor changes since publication

December 2025: Medical technologies guidance 37 has been migrated to HealthTech guidance 465. The recommendations and accompanying content remain unchanged.

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