NICE National Institute for Health and Care Excellence

NICE guidance

Memokath 051 Ureter stent for ureteric obstruction

HealthTech guidance
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www.nice.org.uk/guidance/htg651

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 MTG35 and MTG75.

1 Recommendations

1.1 Memokath 051 Ureter stent is recommended as an option to manage ureteric obstruction in adults with:

- malignant ureteric obstruction and anticipated medium- or long-term survival after adjunctive therapy
- benign ureteric obstruction who cannot have or do not want reconstructive surgery
- any type of ureteric obstruction, and they cannot have or do not want a double-J stent, or when repeat procedures are particularly high risk.

1.2 Data should be collected prospectively on ureteric stent procedures, including details of patient selection, choice of stent placement procedure and stent used, and adverse events such as stent migration and encrustation rates.

Why the committee made these recommendations

NICE originally recommended Memokath 051 for ureteric obstruction for selected people.

New clinical evidence from retrospective studies suggests that Memokath 051 relieves ureteric obstruction as well as other stents.

For people with malignant ureteric obstruction, Memokath 051 may have advantages over some other treatments because it is a less invasive procedure than nephrostomy, with no need for hospital stay, and fewer stent replacements needed compared with other stents.

Clinical experts also felt that it was important to have Memokath 051 as an option for other people, for example people who cannot have or do not want reconstructive surgery or a double-J stent, or when repeat procedures are particularly high risk.

The cost modelling suggests Memokath 051 is likely to be cost saving compared with

other stents. This is because it may not need to be replaced as often as other stents. But the cost savings are not certain because there's not enough good quality evidence.

There is enough clinical evidence to continue recommending Memokath 051 for selected adults with ureteric obstruction. But prospective data is still needed to be certain about the cost savings of using it, compared with other stents.

2 The technology

Technology

2.1 Memokath 051 Ureter stent is a biocompatible, thermo-expandable, nickel-titanium alloy ureteric stent. It is intended as an alternative to conventional ureteric stents for people with benign or malignant ureteric obstruction. The nickel-titanium alloy has a shape memory effect, which is designed to allow the stent to be more easily inserted and anchored into position. A spiral coil design aims to prevent endothelial ingrowth of the tumour or stricture into the stent so that it can be easily removed. Four different versions of the Memokath 051 stent are available (single or double cone, for either antegrade or retrograde insertion), each in several different lengths. Memokath 051 can be used to treat obstructions elsewhere in the urinary tract, but this is outside the scope of this evaluation.

Care pathway

2.2 Ureteric obstruction can be treated by stenting the ureter, creating a nephrostomy or through reconstructive surgery. It must be treated quickly to avoid obstructive renal failure. Nephrostomy or stenting should be done as soon as possible (within 12 hours of diagnosis). For malignant obstruction, the NICE guideline on prostate cancer recommends decompression of the upper urinary tract by nephrostomy or inserting a double-J stent. The NICE guideline on bladder cancer recommends nephrostomy or retrograde stenting (if technically feasible) for people with locally advanced or metastatic bladder cancer. The NICE guideline on acute kidney injury says that all people with upper urinary tract obstruction should be referred to a urologist.

Innovative aspects

2.3 Memokath 051 can adapt to the natural curves of the urinary tract because of its

tight spiral structure, which also makes it less likely that tissue grows between the coils. According to the company, compared with other stents, it is better tolerated, with fewer stent-related symptoms and complications. It reduces the need for stent replacement and the risk of tissue ingrowth.

Intended use

2.4 Memokath 051 is intended for treating ureteric obstruction in adults with benign or malignant strictures. It is contraindicated for children. People with bleeding disorders or using anticoagulant medication are advised to check coagulation parameters, and the stent should not be implanted if their coagulation parameters are not within the range that would be suitable for surgical intervention. For a full list of contraindications and details on using Memokath 051, see the instructions for use.

Costs

2.5 The cost of Memokath 051 used in the company's submission for the original guidance was £1,690 (excluding VAT). This included the Memokath 051 stent, a guidewire and a dilator-insertion sheath. The company confirmed that there is no change to the cost of Memokath 051 stents.

For more details about the technology, see the website for Memokath 051 Ureter.

3 Evidence

NICE commissioned an external assessment group (EAG) to review the evidence submitted by the company. This section summarises that review. Full details of all the evidence are in the project documents on the NICE website.

Clinical evidence from the original guidance

Evidence came from 6 comparative studies and 10 single-arm studies

3.1 The EAG identified 16 studies (6 comparative studies and 10 single-arm studies) including 6 publications of 5 studies submitted by the company at guidance review. The comparative studies all had a retrospective design, with a small sample size of up to 27 people (Akbarov et al. 2017) in each treatment arm. The single-arm studies were observational case series, with sample sizes ranging from 4 people (Boyvat et al. 2005) to 73 people (Papatsoris and Buchholz 2010). For full details of the clinical evidence, see section 3 of the original assessment report in the supporting documentation (Newcastle upon Tyne Hospitals and York Health Economics Consortium External Assessment Centre, 2017).

Clinical success varied and its definition was not consistent

3.2 Memokath 051 Ureter stent's clinical success rates ranged from 43% (Kim et al. 2014) to 100% (Granberg et al. 2010, Zaman et al. 2011). Results of the comparative studies suggested that the clinical success rate of Memokath 051 was comparable to double-J stents (100% success rate in both arms; Granberg et al. 2010) and Resonance stents (82% and 86% respectively; Nam et al. 2015) but was lower than Allium stents (81% compared with 100%; Bolton et al. 2015), and UVENTA (43% compared with 82%; Kim et al. 2014). The definition of clinical success and how it was measured were not consistently reported in the studies.

Evidence on the length of time that stents remain in place was

limited

3.3 Evidence from 2 comparative studies showed that Memokath 051 remained in place longer than double-J stents (17 months compared with 4 months; NCT00166361, 2014) and UVENTA (14 months compared with 12 months; Kim et al. 2014). The average length of time in place using Memokath 051 was 11 months (Papatsoris and Buchholz 2010).

Memokath 051 had higher stent migration and encrustation rates than other stents

3.4 The evidence from the comparative studies suggested that stent migrations were higher with Memokath 051 than double-J stents (11% against 0%; Maan et al. 2010) and UVENTA (43% against 6%; Kim et al. 2014). Encrustation rates were also higher with Memokath 051 than with double-J stents (29% against 0%; NCT00166361, 2014) and Allium (19% against 0%; Bolton et al. 2015). The other most common adverse events included urinary tract infection (Akbarov et al. 2017, Klarskov et al. 2005, Papatsoris and Buchholz 2010, Zaman et al. 2011) and blockage or obstruction (Akbarov et al. 2017; Kim et al. 2014; Klarskov et al. 2005; NCT00166361 2014; Zaman et al. 2011).

3.5 The EAG did a pooled analysis, the results of which suggested that the stent migration rate for Memokath 051 was 17.7% (13 studies) compared with 5.9% using UVENTA (1 study) and 0% using double-J stents (2 studies) and Allium (1 study).

3.6 The evidence was reviewed in 2021 and long-term retrospective data suggested higher complication rates with Memokath 051 than were previously reported, so NICE decided to update the guidance.

New clinical evidence

New evidence comes from 7 studies including 1 systematic review and 2 comparative studies

3.7 For the guidance update, the EAG considered 7 new studies including 2 abstracts:

- 1 systematic review and meta-analysis (Khoo et al. 2018)
- 2 retrospective non-randomised single-centre comparative studies (Choi et al. 2019, Khoo et al. 2021)
- 4 retrospective single-arm single-centre studies (Bier et al. 2017, Diaz Romero et al. 2018, Elbaroni et al. 2020, Forster et al. 2021).

For full details of the clinical evidence, see section 4 of the assessment report update in the supporting documentation (King's Technology Evaluation Centre [KiTEC], 2022).

Evidence suggests clinical success is similar for Memokath 051 and mesh stent (UVENTA) in people with benign ureteral strictures

3.8 Evidence from a comparative retrospective study of people with chronic benign ureteral strictures reported that primary success rates (maintaining patency without additional procedures) were 28.6% for Memokath 051 and 12.0% for UVENTA during the observation period (Choi et al. 2019). The overall success rates (success defined as maintaining patency after further salvage procedures) were 57.1% for Memokath 051 and 40.0% for UVENTA. The differences between the 2 stents were not statistically significant. This result is consistent with the original guidance, which showed Memokath 051 had similar clinical success rates to UVENTA in the population with benign ureteral strictures.

Length of time the stent remains in place varies in the studies

3.9 The new evidence suggested that the median duration of actual functional stent follow up (censored by stent failure, death or end of study) was 5.5 months for Memokath 051, 11.4 months for Allium and 11.7 months for Resonance. This is shorter than the 2 studies included in the previous guidance, which reported 14 months and 17 months of indwelling time (Kim et al. 2014; NCT00166361 2014). Results of single-arm studies reported a median indwelling time of 11.8 months (range 1 week to 70.8 months; Bier et al. 2017) and a median stent lifespan of 14.5 months and 13.4 months in people with malignant ureter obstruction and benign ureter obstruction respectively.

Long-term data from a non-comparative study suggests high complication rates with Memokath 051

3.10 Forster et al. (2021) reported long-term outcomes using Memokath 051 in an NHS centre. Only 25 out of 100 people included did not have any complications during a 5-year follow up. The common complications were stent migration (36%) and failed ipsilateral upper tract drainage (27%), which included blockage (14%), encrustation (11%) and lost renal function (2%). The study included a subgroup analysis of benign and malignant ureteric obstruction, and the overall complication rate was significantly higher in people with a benign obstruction (85.4%) than those with a malignant obstruction (62.7%). Stent migration was the most common complication in people with a benign obstruction (53.7%) and failed renal drainage was common in people with a malignant obstruction (30.5%). A comparative study with a 5.5-month follow-up period for Memokath 051 suggested that it had higher migration, obstruction and infection rates than Resonance, regardless of whether it was a benign or malignant obstruction (Khoo et al. 2021). Duration of follow-up was censored by stent failure, patient death or end-of-study period. The study did not have long-term comparative data on the complication rates of different stents.

Cost evidence

No new published economic studies were identified by the

company or the EAG

3.11 The original guidance included 3 economic studies, all of which compared the cost associated with using Memokath 051 with double-J stents (Aintree University Hospital 2012; Gonzalez et al. 2011; Zaman et al. 2012). The results indicated that Memokath 051 was likely to be cost saving compared with double-J stents, although the studies were poorly reported and included a heterogeneous group of people with varying types of obstruction and life expectancy.

3.12 The company and EAG search did not identify any new published economic studies since the original guidance. The EAG considered the evidence from 4 new clinical studies including 2 UK studies (Forster et al. 2021, Khoo et al. 2021), 1 German study (Bier et al. 2017) and 1 Korean study (Choi et al. 2019) to be relevant for updating the risk of unplanned stent replacement in the economic model.

Some changes were made to the company's model in the original guidance

3.13 The company developed a simple cost model in the original guidance. The EAG thought that the company's cost model captured the key aspects of treatment, but that the way it dealt with certain structural issues was too simplistic, such as only including double-J stents as a comparator. The EAG adapted the company's model and made the following main changes to the original guidance:

- extending the time horizon from 2.5 years to 5 years
- including reconstructive surgery and other metallic stents as comparators
- adding the ability to report a break-even time point between Memokath 051 and the comparators
- including the risk of urinary tract infections.

Scenario analyses were also added to model the risk of unplanned Memokath 051 replacement. More details of the cost model are in

sections 4.2.2 and 4.2.3 of the original assessment report in the supporting documentation (Newcastle upon Tyne Hospitals and York Health Economics Consortium External Assessment Centre, 2017).

The EAG updated the cost parameters using new evidence

3.14 The EAG considered that the original model structure and assumptions remained valid. It updated the model's parameters because of new evidence available:

- An increase in the monthly risk of unplanned stent replacement for Memokath 051 from 1.40% to 1.80% compared with double-J, Allium, Resonance and reconstructive surgery. A decrease in the monthly risk of unplanned stent replacement for Memokath 051 from 4.40% to 3.57% compared with UVENTA for chronic benign ureteral strictures.
- The monthly risk of unplanned stent replacement remained unchanged for double-J stents (0%). But the monthly risks of unplanned stent replacement were updated from:
- 0.49% to 5.54% for Allium
- 1.40% to 1.78% for Resonance
- 0.49% to 4.99% for UVENTA.

The model assumed that if someone needed an unplanned stent replacement it automatically delayed the planned replacement by the length of time in situ (thus removing any double counting). For full details of the clinical parameters, see economic model parameters in section 9.2 of the assessment report update in the supporting documentation (KiTEC 2022).

The EAG updated the costs for double-J stents, UVENTA and Resonance

3.15 The cost of Memokath 051 and related consumables did not change. The EAG updated the cost of double-J stents, UVENTA and Resonance according to the

NHS Supply Chain reported unit prices. The cost of Allium was the same as the original guidance. The EAG also updated other costs such as staffing and follow-up visits using the most up-to-date data sources available. For full details of the cost sources, see economic model parameters in section 9.2 of the assessment report update in the supporting documentation (KiTEC, 2022). In the original guidance, a passport balloon dilator was needed when inserting Memokath 051, and the assumption was that a dilator was also needed when inserting UVENTA and Resonance stents. At consultation, the EAG ran a scenario analysis and found that removing the cost of a balloon dilator for Resonance had a minimal effect on overall costings and did not change the cost saving conclusion for Memokath 051.

Updated EAG base-case results show Memokath 051 is cost saving compared with other stents but cost incurring compared with reconstructive surgery

3.16 The EAG's updated base-case results showed that using Memokath 051 is cost saving per person over 5 years by:

- £1,926 compared with double-J stents
- £6,260 compared with Resonance
- £8,813 compared with UVENTA
- £9,365 compared with Allium.

But using Memokath 051 incurred an additional £1,321 per person over 5 years compared with reconstructive surgery. Memokath 051 was also cost incurring compared with reconstructive surgery in the original guidance (£467) but the size of the additional cost has increased. Base-case results were modelled over a 5-year period, reflecting the indwelling duration for Memokath 051 after which planned replacement is needed. Risks of unplanned replacement were also applied for the full-time horizon of the model.

Change in risk of stent replacement is the key cost driver

3.17 The EAG's scenario analyses showed that, compared with UVENTA, Allium and Resonance, Memokath 051 was cost saving in all scenarios. Compared with double-J stents, Memokath 051 was cost saving in all scenarios, except when the replacement cost of double-J stents dropped to £717. Memokath 051 would be cost neutral if the replacement cost of a double-J stent was £1,008. In addition, Memokath 051 would be cost incurring compared with double-J stents if the monthly unplanned replacement risk was 2.81% over a 2-year time horizon. Scenario analyses were done to investigate the impact of unplanned replacement of Memokath 051 at various timepoints in the stent lifespan, but it was found to still be cost saving compared with UVENTA, Allium and Resonance. For full details of the scenario analyses, see economic model parameters in section 9.3 and 9.4 of the assessment report update and appendix D of the addendum to the assessment report update in the supporting documentation (KiTEC, 2022).

3.18 Compared with reconstructive surgery, Memokath 051 was cost incurring in all the scenarios, except when the reconstructive surgery cost was £12,656 and the Memokath 051 monthly follow-up cost was £21 (1 visit per year). The threshold at which Memokath 051 could be cost neutral was if the cost of reconstructive surgery was £9,287. Memokath 051 would be cost saving if its risk of replacement in the first 2 years was 1.8%, and it was not replaced in the remaining 3 years of a 5-year time horizon, or it had a 1.8% monthly unplanned replacement risk over a 2-year time horizon.

4 Committee discussion

Clinical effectiveness overview

Memokath 051 is effective at relieving ureteric obstruction but comparative evidence remains limited

4.1 The committee agreed that the new evidence supports the original guidance, suggesting that Memokath 051 Ureter stent had similar clinical success to other stents. But only 2 studies compared Memokath 051 with other stents. The clinical experts thought that, although there was new evidence, the evidence base has not improved substantially and the quality remained low. The committee concluded that, although there was new evidence reporting comparable clinical success rates with Memokath 051 and other stents, the comparative evidence remains limited.

Memokath 051 could be less likely to cause bladder irritation symptoms and is well tolerated compared with double-J stents

4.2 The patient expert explained that people living with ureteric stents commonly reported pain, discomfort and urinary tract infections, and that the impact of stenting on people's quality of life is important. The clinical experts explained that Memokath 051 is a metal stent and usually well tolerated. They added that people tend to have fewer of the bladder irritation symptoms that are commonly associated with double-J stents, so have a better quality of life. However, there is no new evidence on patient-reported outcomes or quality of life. The committee concluded that Memokath 051 could be a treatment option with improved patient experience, but more data on patient-reported outcomes and quality of life is needed.

Side effects and adverse events

Stent migration is common after Memokath 051 but the rate may be reduced by careful patient selection

4.3 The new evidence suggested that stent migration is the most common complication with Memokath 051 (as was the case in the original guidance). The committee was aware that the latest evidence suggests that Memokath 051 is more likely to move than other types of stents. But clinical experts explained that this may have been a result of differences in patient selection, and they also explained that stent migration does not necessarily lead to complications because the migration may be caused by changes in the ureteric obstruction itself. Other possible reasons for stent migration include stents placed too close to the pelvi-ureteric junction, using a stent that is too long, or using a single cone Memokath 051 stent, which is more likely to migrate than a double cone stent. The committee heard from the clinical experts that migration rates may be reduced with Memokath 051 by selecting patients carefully (see section 4.7), and possibly by a move to using the double cone stent instead of single cone.

Other patient benefits or issues

Equality considerations

4.4 No new equality issues were identified during the guidance update development. Some ureteric obstructions are caused by tumours, and everyone with cancer is protected under the Equality Act 2010 from the point of diagnosis. People with ureteric strictures caused by tumours may benefit from having Memokath 051 available as an alternative to double-J stents. This is because it may be associated with fewer replacement procedures and reduced adverse events, which would reduce their overall number of appointments and improve their quality of life as they undergo cancer treatments, or make them more comfortable and have more time out of hospital if they have a limited life expectancy. Memokath 051 may also provide an alternative treatment for people with ureteric strictures who cannot tolerate conventional stents or for whom they

have failed, who would otherwise be nephrostomy-dependent and may be disabled under the Equality Act 2010.

More information about treatment should be provided to people with ureteric obstruction

4.5 Clinical and patient experts explained that most people who had stent procedures knew little about what kind of stent they were having. The clinical experts explained that stent choice often relies on the assessment of urethral obstruction during a stent procedure in the surgical suite. They agreed that a best-case scenario would be explaining treatment options and associated risks to a person before placement, then giving them information about the treatment afterwards, including what stent was used and possible adverse events. The committee concluded that more information should be given to people to explain their care.

Relevance to the NHS

There is new evidence from UK studies but generalisability to the NHS may be limited

4.6 The clinical experts explained that Memokath 051 is currently used in some NHS trusts. The committee noted that some new published evidence for Memokath 051 is from studies that were done in the UK. One of the clinical experts involved in 1 of the UK studies (Forster et al. 2021) explained that a wide range of people with benign and malignant ureteric obstruction was included in the study, and its inclusion criteria for Memokath 051 were more relaxed than clinical practice. Therefore, people included in the retrospective analysis may be different from those who would be selected for Memokath 051 in clinical practice. The committee concluded that the new evidence is limited in the generalisability to clinical practice across sites in the UK because of the variability in patient selection.

NHS considerations overview

Resource savings are possible with Memokath 051 but patient selection is important to avoid adverse events

4.7 The clinical experts said that different treatment options, including Memokath 051, are available in the NHS for people with ureteric obstruction. They considered that treatments need to be offered to people on an individual basis, guided by clinical assessment of individual circumstances. Important factors to consider include the cause of the obstruction and its length and location. Clinicians should also take into account the person's preference. For people with malignant ureteric obstruction, quality of life is often the most important factor in determining what treatment will be needed. Memokath 051's advantages over some other treatments available for ureteric obstruction in the NHS are that it is a less invasive procedure with no need for hospital stay, and fewer stent replacements are needed. For people with benign ureteric obstruction, Memokath 051 is an option if they cannot have, or prefer not to have, open surgical procedures such as reconstructive surgery. The clinical experts said that Memokath 051 should not be used in people with bladder cancer or bladder stones, or in people with pelvi-ureteric junction obstruction because of an increased risk of stent migration. It concluded that careful patient selection for Memokath 051 is important when treating ureteric obstruction.

Regular follow-ups are needed after Memokath 051 is inserted

4.8 The clinical experts said that people are monitored after stent insertion, but the way they are monitored varies. For instance, changes in the ureteric obstruction or stent position can be detected using different imaging examinations such as ultrasound or X-ray. Using an X-ray and an ultrasound scan together is considered the best way to detect stent migration. The committee concluded that regular follow-up visits are needed after Memokath 051 is inserted to monitor stent positioning.

Cost modelling overview

Memokath 051 is cost saving compared with other stents but cost incurring compared with reconstructive surgery

4.9 The committee understood that the original cost model was relevant to the decision problem because its model structure and key assumptions remained valid. The external assessment group (EAG) updated the clinical parameters, including the cost of Memokath 051 and comparators to reflect changes in the risk of stent replacement and adverse events. Its updated base case showed that Memokath 051 remained cost saving compared with Allium, double-J stents, Resonance and UVENTA over 5 years (see section 3.16). But using Memokath 051 is likely to incur an additional cost of £1,321 per person over 5 years compared with reconstructive surgery.

The cost case for Memokath 051 remains uncertain because of the limited evidence base

4.10 The committee considered that the cost case remains uncertain because of the lack of good quality evidence. The risk of stent replacement was 1 of the key drivers of the estimated cost savings with Memokath 051 compared with other stents. The analysis was based on an assumption that the same stent would be used for replacement. The clinical experts advised that, in clinical practice, people would not necessarily have the same brand of stent for replacement because people's conditions may change and Memokath 051 may no longer be suitable for them. There was limited data on stent replacement, and this introduced some uncertainty in the cost case between Memokath 051 and other stents.

4.11 The EAG's sensitivity analyses also identified other cost drivers including the length of time the stent is in place, replacement cost and follow-up costs. Memokath 051 remained cost saving in most of the scenarios compared with double-J, UVENTA, Allium and Resonance but would be cost incurring compared with reconstructive surgery. The committee noted these were one-way sensitivity analyses, which may not fully address uncertainties in the cost model. It

concluded that the cost case for Memokath 051 remained uncertain because of the limited evidence base.

Further research

Prospective data on Memokath 051 and other ureteric stents is needed

4.12 Given the limited evidence available, the original guidance committee noted that it would be beneficial to routinely collect data on all ureteric stent placement procedures. This was ideally in collaboration with a national professional society such as the British Association of Urological Surgeons. Clinical experts confirmed that an NHS registry for stent procedures has not been set up since the original guidance, and the evidence base remains limited with no prospective data available. The committee for this guidance update considered it important to further emphasise the need for collecting data using a national database or clinical registry on ureteric stent procedures. The prospective data collection should cover information about patient selection, choice of stent placement procedure and stent used, and adverse events such as stent migration and encrustation rates. It concluded that this should form part of its recommendations in section 1 of the guidance, and agreed that such data collection should be used to help inform the most appropriate patient population for Memokath 051.

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 of each committee meeting, 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 technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

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Update information

Minor changes since publication

December 2025: Medical technologies guidance 75 has been migrated to HealthTech guidance 651. The recommendations and accompanying content remain unchanged.

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